

# Protocol

This trial protocol has been provided by the authors to give readers additional information about their work.

Protocol for: Schoen RE, Pinsky PF, Weissfeld JL, et al. Colorectal-cancer incidence and mortality with screening flexible sigmoidoscopy. *N Engl J Med* 2012;366:2345-57. DOI: 10.1056/NEJMoa1114635.

**PLCO** VERSION  
**MOOP 13**



**MARCH 1, 2006**



# TABLE OF CONTENTS

## **PART I: INTRODUCTION**

### **1.0 Introduction**

- 1.1 Background of the PLCO Screening Trial**
- 1.2 Objectives of the PLCO Screening Trial**
- 1.3 Organizational Structure**
  - 1.3.1 National Cancer Institute
  - 1.3.2 PLCO Monitoring and Advisory Panel
  - 1.3.3 PLCO Steering Committee
  - 1.3.4 Coordinating Center
  - 1.3.5 Screening Centers
  - 1.3.6 Laboratory (Screening Test)
  - 1.3.7 Biorepository
  - 1.3.8 Processing Laboratory (Etiologic)
  - 1.3.9 Analytic Laboratories (Etiologic)
- 1.4 Overview of Data Collection Activities**
- 1.5 Time Schedule of the PLCO Screening Trial**
- 1.6 Studies of Cancer Etiology and Early Markers of Disease (The Biorepository)**
- 1.7 Study Policy Guidelines**
  - 1.7.1 Guidelines for Describing Study Sponsorship and Using the PLCO Logo
  - 1.7.2 Publication Policy
  - 1.7.3 Ancillary Study Policy
- 1.8 Purpose and Organization of the Manual of Operations and Procedures**
  - 1.8.1 Purpose of the Manual
  - 1.8.2 Organization of the Chapters of the Manual
  - 1.8.3 Appendices of the Manual

## **PART II: RANDOMIZATION**

### **2.0 Recruitment and Eligibility Determination**

- 2.1 Overview**
- 2.2 Recruitment Materials**
- 2.3 Eligibility Determination**
- 2.4 Tracking Potential Participants**
- 2.5 Summarizing and Reporting Recruitment Efforts**
- 2.6 Monitoring Recruitment Efforts**
- 2.7 Reporting Recruitment Summary Data**

### **3.0 Obtaining Informed Consent**

- 3.1 General Procedures for Obtaining Participant Consent**
- 3.2 Main Study Consent**
  - 3.2.1 Documenting the Results of Obtaining Informed Consent – Main Study
- 3.3 Protocol Changes Consent (PCC)**
  - 3.3.1 Administration of the PCC
  - 3.3.2 Documenting the Results of Obtaining Informed Consent – PCC

- 3.4 Etiologic Studies Consent**
  - 3.4.1 Administration of the ESC
  - 3.4.2 ESC Non Response – Intervention
  - 3.4.3 Documenting the Results of Obtaining Informed Consent – ESC
- 3.5 Monitoring the Results of Obtaining Informed Consent – Main Study, PCC and ESC**
- 3.6 Reporting the Results of Obtaining Informed Consent**

## **4.0 Randomization/Enrollment Procedures**

- 4.1 Overview**
- 4.2 Verification of Eligibility**
- 4.3 Randomizing and Enrolling the Participant**
  - 4.3.1 Randomization in the Event of Computer Failure
  - 4.3.2 Randomization From a File of Eligibles (Batch Randomization)
- 4.4 Post-Randomization Procedures**
  - 4.4.1 Special Procedures for Women Without Ovaries
  - 4.4.2 Notifying Participants of Their Group Assignments
- 4.5 The Participant ID**
- 4.6 Randomization Errors**
  - 4.6.1 Documenting Duplicate Randomization
  - 4.6.2 Documenting Randomized Ineligibles
- 4.7 Monitoring Participant Accrual**
- 4.8 Reporting Participant Accrual to the Coordinating Center**

## **5.0 Administering the Baseline Questionnaire and Baseline Locator Form**

- 5.1 Overview**
- 5.2 Administration of the Baseline Questionnaire and Baseline Locator Form**
- 5.3 Preparing Mailings of the Baseline Questionnaire and Baseline Locator Form**
- 5.4 Receipt, Edit and Data Entry of Baseline Questionnaire and Baseline Locator Form Data**
- 5.5 Follow-up of Non-Respondents and Data Retrieval**
- 5.6 Monitoring Completion of the Baseline Questionnaire and Baseline Locator Form**
- 5.7 Transmitting Data to the Coordinating Center**

## **6.0 Scheduling, Conducting And Reporting Baseline Screening Tests and Administering the Dietary Questionnaires**

- 6.1 Overview**
- 6.2 Scheduling the Baseline Screening Visit**
- 6.3 Documenting Non-Participation**
  - 6.3.1 The Missing Data Form
  - 6.3.2 The Nonresponse Form
- 6.4 Preparing for the Baseline Screening Visit**
- 6.5 Conducting the Baseline Screening Tests**
- 6.6 Documenting the Baseline Screening Visit**
  - 6.6.1 The Participant Control Record
  - 6.6.2 Documenting a Duplicate Screening Visit
- 6.7 Monitoring the Baseline Screening Tests**
- 6.8 Reporting Results of the Baseline Screening Tests**
  - 6.8.1 Reporting Results Immediately After the Screening Exam
  - 6.8.2 Generating the Screening Test Results Report (STRR)
  - 6.8.3 Reporting Results Using an SC-Designed Report
  - 6.8.4 Reporting Detailed Findings of the Examinations
  - 6.8.5 Reporting Results of the Screening Tests to Participants and Physicians
  - 6.8.6 Correcting an Erroneous Results Report
  - 6.8.7 Making Referrals for Abnormal Examinations
  - 6.8.8 Internal Referrals

- [6.8.9 Monitoring the Reporting of Results](#)
- [6.8.10 Transmitting Results of the Screening Tests to the Coordinating Center](#)

## **6.9 Dietary Questionnaires**

- [6.9.1 Administration of the Dietary Questionnaire \(DQX\)](#)
- [6.9.2 Administration of the Diet History Questionnaire \(DHQ\)](#)
- [6.9.3 Receipt and Editing the Dietary Questionnaires](#)
- [6.9.4 Monitoring Dietary Questionnaire Completion](#)
- [6.9.5 Follow-up of Non-Respondents](#)
- [6.9.6 Shipping Completed Dietary Questionnaires to NCS](#)
- [6.9.7 NCS and Westat Processing and Data Retrieval](#)

## **PART III: FOLLOW-UP OPERATIONS**

### **7.0 Annual Participant Follow-up Activities**

- [7.1 Overview](#)
- [7.2 Completing the Annual Study Update and Follow-up Locator Form](#)
- [7.3 Receipting the Annual Study Update and Follow-up Locator Form](#)
- [7.4 Scheduling Annual Follow-up Screening Visits](#)
- [7.5 Preparing for the Annual Follow-up Visit](#)
- [7.6 Conducting Annual Follow-up Screening Tests](#)
- [7.7 Documenting the Annual Follow-up Screening Visit](#)
- [7.8 Documenting A Duplicate Screening Visit](#)
- [7.9 Documenting Non-Participation](#)
  - [7.9.1 Non-Participation Due to Refusal](#)
  - [7.9.2 Non-Participation Due to PLCO Organ Removal](#)
  - [7.9.3 Non-Participation Due to PLCO Cancer Reported](#)
  - [7.9.4 Non-Participation Due to Mental or Physical Illness](#)
- [7.10 Reporting Results of Annual Follow-up Screening Tests](#)
- [7.11 Transmitting Results of the Screening Tests to the Coordinating Center](#)
- [7.12 Tracing Lost Participants](#)
  - [7.12.1 Post Office Address Correction Request](#)
  - [7.12.2 Termination of Tracing](#)
- [7.13 Monitoring Follow-up Activities](#)
- [7.14 Procedures for Contamination Assessment](#)
  - [7.14.1 Overview](#)
  - [7.14.2 Administration of the Health Status Questionnaire](#)
  - [7.14.3 Mailing the Health Status Questionnaire](#)
  - [7.14.4 Receipt, Follow-up, and Data Retrieval of the Health Status Questionnaire](#)
  - [7.14.5 Shipping the Health Status Questionnaire to the CC](#)
  - [7.14.6 Monitoring the Completion of the Health Status Questionnaire](#)

### **8.0 Ascertainment of Cancer Status**

- [8.1 Overview](#)
- [8.2 Methods to Ascertain Cancer Status](#)
  - [8.2.1 Reports for Tracking Cancer Suspicions](#)
  - [8.2.2 Updating Cancer Status to "Suspected" in the SMS](#)
- [8.3 Collection of Medical Records](#)
  - [8.3.1 Collection of Medical Records for Confirmation of PLCO Cancers](#)
  - [8.3.2 Collection of Medical Records for Confirmation of Non-PLCO Cancers](#)
  - [8.3.3 Tracking the Medical Records Collection Process \(Epi-Info\)](#)
  - [8.3.4 Acquisition of the Histopathology/Cytopathology Report](#)
- [8.4 Abstraction of the Medical Record](#)
  - [8.4.1 Abstracting Diagnostic Evaluation Information](#)

- [8.4.2 Abstracting Treatment Information](#)
- [8.4.3 Abstracting Non-PLCO Cancer Information](#)
- [\*\*8.5 Receipt and Processing of the Medical Record Abstract Forms\*\*](#)
- [\*\*8.6 Updating Cancer Status in the SMS\*\*](#)
- [\*\*8.7 Documenting Non-Response for Cancer Confirmation\*\*](#)
- [\*\*8.8 Monitoring Cancer Ascertainment Activities\*\*](#)
- [\*\*8.9 Reporting Cancer Status to the Coordinating Center\*\*](#)
- [\*\*8.10 Quality Assurance for Cancer Confirmation\*\*](#)

## **9.0 Vital Status Ascertainment and the Death Review Process**

- [\*\*9.1 Introduction\*\*](#)
  - [9.1.1 Background](#)
  - [9.1.2 Overview of the Death Review Process](#)
- [\*\*9.2 Death Ascertainment Activities\*\*](#)
  - [9.2.1 Introduction](#)
  - [9.2.2 Vital Status Ascertainment](#)
  - [9.2.3 Updating Vital Status in the Study Management System](#)
- [\*\*9.3 Death Certificate Acquisition\*\*](#)
- [\*\*9.4 Shipment of Death Certificates\*\*](#)
- [\*\*9.5 Monitoring Vital Status Ascertainment and Death Certificate Processing Activities\*\*](#)
- [\*\*9.6 Folder Preparation and the Death Documentation Sheet \(DDS\)\*\*](#)
- [\*\*9.7 Cancer Status Determination and Confirmation\*\*](#)
  - [9.7.1 Cancer Reports from ASU and Other Sources](#)
  - [9.7.2 Cancer Reports from the Death Certificate](#)
  - [9.7.3 Death Certificates Causes of Death – ‘Natural Causes’](#)
  - [9.7.4 Completion of DE and OCF Forms for Suspected Cancers](#)
- [\*\*9.8 Determining Eligibility for DRC Review\*\*](#)
  - [9.8.1 CC Review of Deaths](#)
  - [9.8.2 The Algorithm Report](#)
  - [9.8.3 Death Review Selection Criteria](#)
- [\*\*9.9 Collection and Preparation of Documents for the DRC\*\*](#)
  - [9.9.1 Document Collection](#)
  - [9.9.2 Document Review](#)
  - [9.9.3 Document Editing](#)
- [\*\*9.10 DRP Material Shipment\*\*](#)
- [\*\*9.11 CC Preparation of Materials for the DRC\*\*](#)
- [\*\*9.12 Requests for Additional Documentation from the SC\*\*](#)
- [\*\*9.13 DRC Review\*\*](#)

## **PART IV: SCREENING TESTS, DIAGNOSTIC PATHOLOGY, LABORATORY AND ENDPOINT ASSESSMENT PROTOCOLS**

### **10.0 Blood Sample Protocol**

- [\*\*10.1 Overview\*\*](#)
- [\*\*10.2 Scheduling Blood Draws\*\*](#)
- [\*\*10.3 Situations in Which the SC Should Not Draw Blood\*\*](#)
- [\*\*10.4 Blood Sample ID Labels\*\*](#)
- [\*\*10.5 The Blood Collection Forms\*\*](#)
- [\*\*10.6 Phlebotomy Protocol\*\*](#)
  - [10.6.1 Recommended and Required Supplies](#)
  - [10.6.2 Participant Preparation](#)
  - [10.6.3 Examination Steps](#)

## **10.7 Blood Processing and Storage Protocol for the PSA/CA-125II**

[10.7.1 Processing Procedures Immediately After the Blood Draw for the PSA/CA-125II](#)

[10.7.2 Processing Procedures for Serum Separation for the PSA/CA-125II](#)

[10.7.3 Storage of PSA/CA-125II Samples](#)

## **10.8 The Blood Processing and Storage Protocol for the Biorepository**

[10.8.1 Processing Procedures Immediately After the Blood Draw for Biorepository Specimens](#)

[10.8.2 Processing Procedures for Biorepository Samples](#)

[10.8.3 Storage Box Assignment for Biorepository Samples](#)

[10.8.4 Storage of Biorepository Cryovials](#)

## **10.9 UCLA and Biorepository Blood Sample Shipment**

[10.9.1 Scheduling UCLA and Biorepository Shipments](#)

[10.9.2 Tasks to be Completed the Day of UCLA and Biorepository Shipments](#)

[10.9.3 The Blood Sample Transmittal Log for UCLA and Biorepository Shipments](#)

[10.9.4 The Blood Sample Pre-Transmittal Log for UCLA and Biorepository Shipments](#)

[10.9.5 Packing Containers for Frozen Blood Samples](#)

[10.9.6 Labeling Shipping Containers for Frozen Samples](#)

## **10.10 Packaging and Shipment of Yellow-top Tubes**

[10.10.1 Scheduling Processing Laboratory Shipments](#)

[10.10.2 Tasks to be Completed the Day of Processing Laboratory Shipments](#)

[10.10.3 The Processing Laboratory Transmittal Log](#)

[10.10.4 Packaging and Shipping Yellow-top Tubes to the Processing Laboratory](#)

[10.10.5 Labeling Shipping Containers for Yellow-top Tubes](#)

## **10.11 Resolving Problems with Shipments**

[10.11.1 Discrepancies in UCLA Shipments](#)

[10.11.2 Discrepancies in Biorepository Shipments](#)

[10.11.3 Discrepancies in Processing Laboratory Shipments](#)

## **10.12 Reporting Medical Complications of the Blood Draw Procedure**

## **10.13 Documenting Non-Response for Blood Collection**

## **10.14 Editing and Data Entry**

## **10.15 Resolving Blood Collection Form Discrepancies Between DEES and SMS**

## **10.16 Interpreting Results of the PSA and CA-125II**

## **10.17 Reporting Results**

## **10.18 Violations of the Blood Collection Protocol**

## **10.19 Training Requirements for PLCO Shipments**

## **10.20 Examiner Training**

[10.20.1 Minimum Qualifications for Examiners](#)

[10.20.2 Examiner Training Protocol](#)

[10.20.3 Examiner Certification](#)

## **10.21 Equipment Specifications**

## **10.22 Freezer Security**

## **10.23 Specimen Collection Standardization and Quality Assurance**

## **10.24 UCLA Laboratory Quality Control**

# **11.0 Chest X-Ray Procedures**

## **11.1 Overview**

## **11.2 Scheduling Chest X-rays**

## **11.3 Chest X-ray Protocol**

[11.3.1 Equipment Specifications](#)

[11.3.2 Participant Preparation](#)

[11.3.3 Examination Procedures](#)

[11.3.4 Interpretation of Findings](#)

[11.3.5 Referral of Participants for Abnormal Results](#)

## **11.4 Documenting Performance and Results of the Chest X-ray**

[11.4.1 The Chest X-ray Screening Examination Form](#)

- [11.4.2 Editing and Data Entry](#)
- [11.4.3 Reporting Results of the Chest X-ray Examination](#)
- [11.4.4 Storage of PLCO Images](#)

#### **11.5 Examiner Qualifications, Training, and Certification**

- [11.5.1 Minimum Qualifications for Examiners](#)
- [11.5.2 Training Protocol](#)

#### **11.6 Examiner Certification**

#### **11.7 Examination Standardization and Quality Control**

### **12.0 Digital Rectal Examination Procedures**

#### **12.1 Overview**

#### **12.2 Scheduling Digital Rectal Examinations**

#### **12.3 Digital Rectal Examination Protocol**

- [12.3.1 Participant Preparation](#)
- [12.3.2 Examination Procedures](#)
- [12.3.3 Interpretation of Findings](#)
- [12.3.4 Referral of Participants for Abnormal Results](#)
- [12.3.5 Reporting Medical Complications](#)

#### **12.4 Documenting Performance and Results of the Digital Rectal Examination**

- [12.4.1 The Digital Rectal Screening Examination of the Prostate Form](#)
- [12.4.2 Editing and Data Entry](#)
- [12.4.3 Reporting Results of the Digital Rectal Examination](#)

#### **12.5 Examiner Qualifications, Training, and Certification**

- [12.5.1 Minimum Qualifications for Examiners](#)
- [12.5.2 Minimum Qualifications for QA Examiners](#)
- [12.5.3 Minimum Qualifications for Trainers](#)

#### **12.6 Examiner Training and Certification**

#### **12.7 Examination Standardization and Quality Control**

### **13.0 Flexible Sigmoidoscopy Examination Procedures**

#### **13.1 Overview**

#### **13.2 Scheduling Flexible Sigmoidoscopy Examinations**

- [13.2.1 Scheduling T5 Participants with Identified Adenoma](#)
- [13.2.2 Monitoring Reports](#)

#### **13.3 Flexible Sigmoidoscopy Examination Protocol**

- [13.3.1 Equipment Specifications](#)
- [13.3.2 Participant Preparation](#)
- [13.3.3 Examination Procedures](#)
- [13.3.4 Interpretation of Findings](#)
- [13.3.5 Referral of Participants for Abnormal Results](#)
- [13.3.6 Reporting Medical Complications](#)

#### **13.4 Documenting Performance and Results of the Flexible Sigmoidoscopy Examination**

- [13.4.1 The Flexible Sigmoidoscopy Screening Examination Form](#)
- [13.4.2 Data Entry](#)
- [13.4.3 Reporting Results of the Flexible Sigmoidoscopy Examination](#)

#### **13.5 Examiner Qualifications, Training, and Certification**

- [13.5.1 Minimum Qualifications for Examiners](#)
- [13.5.2 Minimum Qualifications for QA Examiners](#)
- [13.5.3 Minimum Qualifications for Trainers](#)

#### **13.6 Examiner Training and Certification**

#### **13.7 Examination Standardization and Quality Control**

### **14.0 Ovarian Palpation Examination Procedures**

#### **14.1 Overview**

## **14.2 Scheduling Ovarian Palpation Examinations**

### **14.3 Ovarian Palpation Protocol**

[14.3.1 Participant Preparation](#)

[14.3.2 Examination Procedures](#)

[14.3.3 Interpretation of Findings](#)

[14.3.4 Reporting Medical Complications](#)

### **14.4 Documenting Performance and Results of the Ovarian Palpation Examination**

[14.4.1 The Ovarian Palpation Examination Form](#)

[14.4.2 Data Entry](#)

[14.4.3 Reporting Results of the Ovarian Palpation Examination](#)

### **14.5 Examiner Qualifications, Training, and Certification**

[14.5.1 Minimum Qualifications for Examiners](#)

[14.5.2 Minimum Qualifications for QA Examiners](#)

[14.5.3 Minimum Qualifications for Trainers](#)

### **14.6 Examiner Training and Certification**

### **14.7 Examination Standardization and Quality Control**

## **15.0 Transvaginal Ultrasound Examination Procedures**

### **15.1 Overview**

### **15.2 Scheduling Transvaginal Ultrasound Examinations**

### **15.3 Transvaginal Ultrasound Protocol**

[15.3.1 Equipment Specifications](#)

[15.3.2 Participant Preparation](#)

[15.3.3 Examination Procedures](#)

[15.3.4 Interpretation of Findings](#)

[15.3.5 Referral of Participants for Abnormal Results](#)

[15.3.6 Reporting Medical Complications](#)

### **15.4 Documenting Performance and Results of the Transvaginal Ultrasound Examination**

[15.4.1 The Transvaginal Ultrasound Screening Examination Form](#)

[15.4.2 Data Entry](#)

[15.4.3 Reporting Results of the Transvaginal Ultrasound Examination](#)

### **15.5 Examiner Qualifications, Training, and Certification**

[15.5.1 Minimum Qualifications for Examiners](#)

[15.5.2 Minimum Qualifications for QA Examiners](#)

[15.5.3 Minimum Qualifications for Trainers](#)

### **15.6 Examiner Training and Certification**

### **15.7 Examination Standardization and Quality Control**

## **16.0 Collection of Pathology Material and Pathology Data Review**

### **16.1 Central Review of Pathology Slides**

### **16.2 Obtaining Pathology Slides from Local Pathologists**

### **16.3 Labeling and Receipting Pathology Slides**

### **16.4 Storing Pathology Slides**

### **16.5 Shipment of Slides to the Central Repository**

[16.5.1 Preparing Pathology Slides for Shipment](#)

[16.5.2 Packing Shipping Containers](#)

[16.5.3 Shipping Address and Contact Information](#)

### **16.6 Receipt of Pathology Slides at the Central Repository**

### **16.7 Monitoring Pathology Slide Procurement Activities**

### **16.8 Reporting the Results of Slide Procurement**

## **17.0 Guidelines for Screening Center Management**

### **17.1 Overview**

### **17.2 Staffing the Screening Center**

[17.2.1 Screening Center Staff Responsibilities](#)

[17.2.2 Training/Certification of SC Staff](#)

[17.2.3 Staff Identification Numbers](#)

### **17.3 Overview of Computer Systems Provided by the Coordinating Center**

#### **17.4 Management of Data Collection Activities**

[17.4.1 Timeframe for Data Collection Activities](#)

[17.4.2 Data Collection Outside the Window](#)

[17.4.3 Requests for Information](#)

[17.4.4 Documenting Missing Data](#)

[17.4.5 Documenting Nonresponse](#)

[17.4.6 Documenting a Participant's Request to Withdraw from the Study](#)

#### **17.5 Organization of Study Data**

[17.5.1 Record Keeping of Hard Copy Data](#)

[17.5.2 Storage of Computer System Reports](#)

[17.5.3 Data Security](#)

[17.5.4 Documenting Loss of Hard Copy Data](#)

#### **17.6 Processing Study Data**

[17.6.1 Manual Editing](#)

[17.6.2 Data Retrieval](#)

[17.6.3 Receipting Forms and Specimens](#)

[17.6.4 Optical Scanning and Data Entry](#)

[17.6.5 Computer Editing](#)

[17.6.6 Assigning the Form Disposition](#)

#### **17.7 Shipping**

[17.7.1 Shipping Blood Samples](#)

[17.7.2 Shipping Pathology Slides](#)

[17.7.3 Shipping Dietary Questionnaires](#)

#### **17.8 Transmission of Data to the Coordinating Center**

#### **17.9 Coordination of Data Collection and Reporting in Satellite Centers**

#### **17.10 Managing Participant Transfers**

#### **17.11 Monitoring Data Collection Activities**

[17.11.1 Monitoring Recruitment Status](#)

[17.11.2 Monitoring Enrollment Status](#)

[17.11.3 Monitoring SC Population Status](#)

[17.11.4 Monitoring Individual Participant Status](#)

[17.11.5 Monitoring Questionnaire Administration, Screening and Followup](#)

[17.11.6 Monitoring Cancer Incidence and Mortality](#)

#### **17.12 SC Operations Support (Management Support Reports)**

#### **17.13 Monitoring Adverse Events**

#### **17.14 Documenting and Resolving Protocol Violations**

[17.14.1 Documenting and Resolving Duplicate Randomization](#)

[17.14.2 Documenting and Resolving Randomized Ineligibles](#)

#### **17.15 Quality Assurance Program**

[17.15.1 Screening Center Monitoring of Data Quality](#)

[17.15.2 Coordinating Center Monitoring of Data Quality](#)

[17.15.3 Reporting to the NCI](#)

[17.15.4 Site Visits](#)

[17.15.5 Monitoring Committees](#)

## **18.0 Buccal Cell Collection Protocol**

### **18.1 Buccal Cell Collection Overview**

### **18.2 ESC Administration for Control Participants**

[18.2.1 ESC Cover Letters, FAQ Sheet and Brochure](#)

[18.2.2 ESC Specific to Control Participants](#)

[18.2.3 Administration of the ESC to Control Participants](#)

### **18.3 Buccal Cell Collection Procedures**

[18.3.1 Buccal Cell Collection Schedule](#)

[18.3.2 Situations in Which a Buccal Cell Sample Should Not Be Collected](#)

[18.3.3 Buccal Cell Collection Kits](#)

[18.3.4 Procedures to Request Kit Mailings](#)

[18.3.5 Procedures to Document Receipt of Samples](#)

[18.3.6 Buccal Cell Sample Non-response](#)

[18.3.7 Requesting a Second Buccal Cell Kit](#)

[18.3.8 Returned Buccal Cell Collection Kits](#)

[18.3.9 Buccal Cell Collection Reports](#)

[18.3.10 Target Response Rates](#)

### **18.4 Reporting Medical Complications of the Buccal Cell Collection**

### **18.5 Specimen Collection Standardization and Quality Assurance**

### **18.6 Buccal Cell Collection Procedures for SCs Assembling and Mailing Kits**

[18.6.1 Buccal Cell Collection Overview Specific to SCs Mailing Kits](#)

[18.6.2 Buccal Cell Collection Kits](#)

[18.6.3 Receipt of Partially Assembled Buccal Cell Collection Kits](#)

[18.6.4 Buccal Cell Expectations](#)

[18.6.5 Buccal Cell Requests \(Directive and Mailing\)](#)

[18.6.6 Generation of Kit Cover Letters, Address Labels and PID Labels](#)

[18.6.7 Final Assembly of Buccal Cell Collection Kits](#)

[18.6.8 Creation of Buccal Cell Shipping Files](#)

[18.6.9 Mailing Buccal Cell Collection Kits to Participants](#)

[18.6.10 Documenting Buccal Cell Sample Receipt at the Biorepository](#)

[18.6.11 Buccal Cell Sample Non-response](#)

[18.6.12 Requesting a Second Buccal Cell Kit](#)

[18.6.13 Buccal Cell Collection Reports](#)

[18.6.14 SC Quality Assurance Procedures for Buccal Cell Collection](#)

## **Appendix A: Data Collection Forms And Specifications**

[A-2-1: Eligibility Screener \(ES\)](#)

[A-4-1 Eligibility Verification Form \(EVF\)](#)

[A-4-2: Administrative Tracking Form \(ATF\)](#)

[A-5-1: Baseline Questionnaire - Male \(BQM3\)](#)

[A-5-2: Baseline Questionnaire - Female \(BQF3\)](#)

[A-5-3: Baseline Locator Form \(BLF\)](#)

[A-6-1: Participant Control Record \(PCR\)](#)

[A-6-2: Dietary Questionnaire \(DQX\)](#)

[A-6-3: Diet History Questionnaire \(DHQ\)](#)

[A-6-4: DHQ/DQX](#)

[A-6-6: NCS Discrepancy Notification Fax](#)

[A-7-1: Annual Study Update \(ASU\)](#)

[A-7-2: Follow-up Locator Form \(FLF\)](#)

[A-8-1: Prostate Cancer Medical Record Abstract Forms \(DEP3, TIP2\)](#)

[A-8-2: Lung Cancer Medical Record Abstract Forms \(DEL3, TIL2\)](#)

[A-8-3: Colorectal Cancer Medical Record Abstract Forms \(DEC3, TIC2\)](#)

[A-8-4: Ovarian Cancer Medical Record Abstract Forms \(DEO3, TIO2\)](#)

[A-8-5: Other Cancer Confirmation Form \(OCF\)](#)

[A-8-6: Diagnostic/Staging Procedures Supplement \(DSS3\)](#)

[A-9-1: Death Documentation Sheet \(DDS\)](#)

[A-9-2: History of Malignancy Form \(HOM\)](#)

[A-9-3: Diagnostic Tests for PLCO Cancers](#)

[A-9-4: DRP Material Transmittal](#)

[A-9-5: Additional Documentation Request Form \(ADR\)](#)  
[A-9-6: Pathology Review Request \(PRR\)](#)  
[A-9-7: Pathology Review Request Transmittal Log](#)  
[A-10-1: Blood Collection Form \(BCF3\)](#)  
[A-10-2: UCLA Discrepancy Notification](#)  
[A-10-3: Biorepository Discrepancy Notification](#)  
[A-10-4: Processing Laboratory Transmittal Log](#)  
[A-10-5: PLCO Shipment Notification for UCLA](#)  
[A-10-6: PLCO Discrepancy Notification from Processing Laboratory](#)  
[A-10-7: T4/T5 Blood Collection Form \(BFF2\)](#)  
[A-10-8: BCF3 Vanguard](#)  
[A-11-1: Chest X-ray Screening Examination Form \(XRY2\)](#)  
[A-11-2: Chest X-ray Screening Examination Form for Quality Assurance \(XRQ2\)](#)  
[A-12-1: Digital Rectal Screening Examination of the Prostate Form \(DRE2\)](#)  
[A-12-2: Digital Rectal Screening Examination of the Prostate Form for Quality Assurance \(DRQ2\)](#)  
[A-13-1: Flexible Sigmoidoscopy Screening Examination Form \(FSG2\)](#)  
[A-13-2: Flexible Sigmoidoscopy Screening Examination Form for Quality Assurance \(FSQ2\)](#)  
[A-14-1: Ovarian Palpation Screening Examination Form \(OVR\)](#)  
[A-14-2: Ovarian Palpation Screening Examination Form for Quality Assurance \(OVQ\)](#)  
[A-15-1: Transvaginal Ultrasound Screening Examination Form \(TVU2\)](#)  
[A-15-2: Transvaginal Ultrasound Screening Examination Form for Quality Assurance \(TVQ2\)](#)  
[A-17-1: Missing Data Form \(MDF\)](#)  
[A-17-2: Nonresponse Form \(NRF\)](#)  
[A-17-4: Adverse Experience Report \(AER\)](#)  
[A-17-5: Record of Experience, Credentials and Training \(ECT\)](#)  
[A-17-6: Comments Continuation Form \(CCF\)](#)  
[A-17-7: Protocol Violation Form](#)  
[A-17-8: Health Status Questionnaire for Male Participants \(HSM\)](#)  
[A-17-9: Health Status Questionnaire for Female Participants \(HSW\)](#)  
[A-17-10: Record of Credentials, Medical Record Abstractor and Nosologist Registration Form \(CAN\)](#)  
[A-17-11: Adverse Events Report \(AER\)](#)  
[A-18-1: Buccal Cell Participant Directions](#)  
[A-18-2: Buccal Cell Frequently Asked Questions](#)  
[A-18-3: Buccal Cell Brochure](#)  
[A-18-4: Shipment Notification for Pittsburgh and Minnesota](#)  
[A-18-5: Buccal Cell Collection Tracking Form](#)

## **Appendix B: System Reports**

[Recruitment Summary Report](#)  
[Recruitment Progress Report - Parts I, II, III](#)  
[Eligibility Screener Review - Parts I and II](#)  
[Session Edit Report \(Production Edits\) for Individual Tracking](#)  
[Possible Duplicates in TASR \(Individual Tracking\)](#)  
[Age Review Report](#)  
[Organization Report](#)  
[Scheduled and Complete Presentations](#)  
[Materials Distribution](#)  
[Summary of Contacts with Organizations](#)  
[TASR/RAND Comparison Report](#)  
[Eligibility Contact Report](#)  
[Number of TASR Eligibles Report](#)  
[PCC Directive/Late Directive](#)  
[Interactive Randomization Report](#)

[Batch Randomization Report](#)  
[Enrollment Status Report](#)  
[Enrollment Summary Report](#)  
[Randomization Assignment Report](#)  
[Study ID Assignment Report](#)  
[Report of BQ/RAND Discrepancies](#)  
[Baseline Directive](#)  
[Duplicate Forms Report](#)  
[Results Pending Report](#)  
[One or More Exam Statuses = Results Pending Three or More Weeks Since Exam Date](#)  
[Referrals for Exam Forms](#)  
[QA Checks Report](#)  
[Examination Summary Report](#)  
[Screening Test Results Report \(STRR\)](#)  
[Screening Test Result Report Not Sent Three or More Weeks Since Exam Date](#)  
[Additional Screening Test Result Report Should Be Sent Reflecting New Exam Results](#)  
[Dietary Questionnaire Transmittal Log](#)  
[DHQ Directive/Late Directive](#)  
[Diet History Questionnaire Transmittal Log](#)  
[ASU Directive - Participant due for New Form](#)  
[ASU Directive - Late Respondents](#)  
[Tracing Log](#)  
[List Of Participants in Tracing](#)  
[PSH/ASU Forms Received](#)  
[ASU Response Rate Report](#)  
[FLF Directive](#)  
[HSQ Directive](#)  
[HSQ Transmittal Log](#)  
[HSQ Status Report](#)  
[HSQ Summary Report](#)  
[Cancer Registries Request List](#)  
[Medical Record Background Report](#)  
[Cancer Confirmation List](#)  
[Abstracting Schedule Report](#)  
[National Death Index List](#)  
[Vital Status Confirmation List](#)  
[Death Certificate Receipt Report](#)  
[Death Certificate Transmittal Log](#)  
[Participants with Cancer on Death Certificate Report](#)  
[Algorithm for Death Review](#)  
[UCLA Transmittal Log](#)  
[Biorepository Transmittal Log](#)  
[UCLA Laboratory Receipt and Discrepancy Reports](#)  
[UCLA Pre-transmittal Log](#)  
[Biorepository Pre-transmittal Log](#)  
[ESC Directive](#)  
[Biorepository Blood Collection](#)  
[T3 Tubes 12/13 Shipped Late Report](#)  
[Screening Examination Report - Chest X-Ray](#)  
[Screening Examination Report - Digital Rectal Examination](#)  
[Screening Examination Report - Flexible Sigmoidoscopy](#)  
[Screening Examination Report - Ovarian Palpation](#)  
[Screening Examination Report - Transvaginal Ultrasound](#)  
[Pathology Slide Transmittal Log](#)

[Staff Report](#)  
[Count/List of MDFs](#)  
[Non-Participation Status Summary](#)  
[Population Profile Report](#)  
[Participant Information Sheet](#)  
[Intervention Activities Report](#)  
[Control Activities Report](#)  
[Open Forms/Specimens Report](#)  
[Production Edit Report](#)  
[Participant Overview Report](#)  
[Summary of Scanned Forms Report](#)  
[Report of DEES Final Disposition](#)  
[Production Edits Report - DEES](#)  
[DEES/SMS Comparison Report](#)  
[Key Field Edits Report](#)  
[SMS/DEES Synchronization Reports](#)  
[Forms Count Report](#)  
[Buccal Cell Directive/Late Directive](#)  
[Buccal Cell Summary Report](#)

## **Appendix C: Sample Materials**

[Sample Recruitment Letter](#)  
[Sample Potential Participant Tracking Log](#)  
[Sample Recruitment Summary Form](#)  
[Prototype Main Consent](#)  
[C-3-2: Prototype Protocol Changes Consent \(PCC\)](#)  
[C-3-3: Prototype Etiologic Studies Consent \(ESC\)](#)  
[Sample Language for Etiologic Studies Consent](#)  
[Prototype Main Consent and Etiologic Studies Consent](#)  
[Sample Participant Results Letter](#)  
[Sample Physician Results Letter](#)  
[Sample Cover Letter for Diet History Questionnaire \(alone\)](#)  
[Sample Cover Letter for Annual Study Update](#)  
[Sample Cover Letter for Health Status Questionnaire](#)  
[Sample Health Status Questionnaire Call Record](#)  
[Sample Cover Letter for Annual Study Update and Diet History Questionnaire \(combined\)](#)  
[Post Office Address Correction Request \(POA\)](#)  
[Sample Medical Authorization Release Form](#)  
[Sample Cover Letter to Request Medical Records](#)  
[Summary of PLCO Protocol](#)  
[Sample Cover Letter for Collection of HOM Information](#)  
[Sample ESC Cover Letter](#)  
[Prototype ESC for Previously Enrolled Controls](#)  
[Sample Buccal Cell Kit Cover Letter](#)

## **Appendix D: PLCO Brochure and Logo**

[PLCO Logo](#)  
[PLCO Recruitment Brochure](#)

## **Appendix E: PLCO Protocol**

## **Appendix F: PI-List**

## **Appendix G: Abbreviations**

[List of Common Abbreviations](#)  
[Staff Positions](#)

## [Appendix H: Answers to Participant Questions](#)

[Cancer Code List](#)  
[Cancer Code List, Included Sites in Alphabetical Order](#)  
[Specifications for the Cancer Code List](#)  
[Location Code List](#)  
[Relationship Code List](#)  
[Translation of ICD-O-2 and ICD-9-CM into 3-Digit PLCO Cancer Codes](#)

## [Appendix J: Screening Examination Protocols](#)

[J-11-1: Protocol for Chest X-Ray Examination](#)  
[Protocol for Digital Rectal Examination of the Prostate](#)  
[J-13-1: Protocol for Flexible Sigmoidoscopy Examination](#)  
[Protocol for Ovarian Palpation Examination](#)  
[J-15-1: Protocol for Transvaginal Ultrasound Examination](#)

## [Appendix K: General Interviewing/Abstracting Techniques](#)

[General Interviewing Techniques](#)  
[General Abstracting Techniques](#)

## [Appendix L: Quality Assurance Plan](#)

[Quality Assurance Plan](#)  
[Central Review of Cancer Diagnosis and Staging Data](#)

## [Appendix M: PLCO Policy](#)

[PLCO Review Policy for Etiologic Studies](#)  
[PLCO Publication Policy](#)

# Part I: Introduction

# 1.0 INTRODUCTION

This chapter presents an overview of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO Screening Trial) and an introduction to this document, the Manual of Operations and Procedures.

## 1.1 Background of the PLCO Screening Trial

Lung and colorectal cancers are among the most commonly occurring cancers in the United States. According to the American Cancer Society's Cancer Facts and Figures – in 2000, there were an estimated 28,500 deaths among women and 27,800 deaths among men from colorectal cancer and, respectively, 67,600 and 89,300 deaths from lung cancer. About 14,000 women died from ovarian cancer and 31,900 men from prostate cancer. Death rates for prostate and colorectal cancers have remained relatively constant for many years, while the death rate for lung cancer has continued to increase in both sexes, more so in women. Successful screening programs for these three cancers could possibly have a major impact on overall cancer mortality in the U.S. The death rate for ovarian cancer continues to rise, though slowly. Since the majority of ovarian cancers present as advanced disease with poor prognosis, while recent reports indicate that early disease may have as much as a 90 percent cure rate, successful screening for ovarian cancer might substantially reduce mortality from this disease.

Uncertainty regarding the value of screening for these cancers has resulted in conflicting positions in the medical community and confusion in the populations at risk. The Division of Cancer Prevention (DCP) of the National Cancer Institute (NCI), in collaboration with 10 Screening Centers (SCs) throughout the United States, is seeking to resolve these uncertainties by conducting a long-term randomized controlled trial. The trial will eventually include nearly 155,000 men and women, aged 55 to 74 at entry. The participants will be equally divided into two study arms; half will receive annual cancer screening and half will continue their normal health care routine. The occurrence of disease-specific morbidity and mortality will be determined and compared between the two groups.

## 1.2 Objectives of the PLCO Screening Trial

The primary objective of this trial is to determine in people, aged 55 to 74 at entry, whether or not the following are true.

- In males and females:
  - ▶ Screening with flexible sigmoidoscopy can reduce mortality from colorectal cancer; and
  - ▶ Screening with chest x-ray can reduce mortality from lung cancer.
- In males:
  - ▶ Screening with digital rectal examination plus serum prostate-specific antigen (PSA) can reduce mortality from prostate cancer.
- In females:
  - ▶ Screening with CA-125II and transvaginal ultrasound can reduce mortality from ovarian cancer.

- ▶ In 1998, NCI dropped the ovarian palpation examination from the screening protocol.

Secondary objectives are:

- To assess screening variables other than mortality for each of the interventions including sensitivity, specificity and positive predictive value.
- To assess incidence, stage and survival experience of cancer cases.
- To investigate the mortality predictive value of biologic and/or prognostic characteristics of tumor tissue as intermediate endpoints.

Additional information regarding the design and objectives of the PLCO Screening Trial is provided in the study protocol (see [APPENDIX E: PLCO PROTOCOL 2001](#)).

### 1.3 Organizational Structure

Exhibit 1-1 shows the structure of the primary organizations and groups involved in designing, conducting and monitoring the PLCO Screening Trial. The roles and responsibilities of each group are described below.

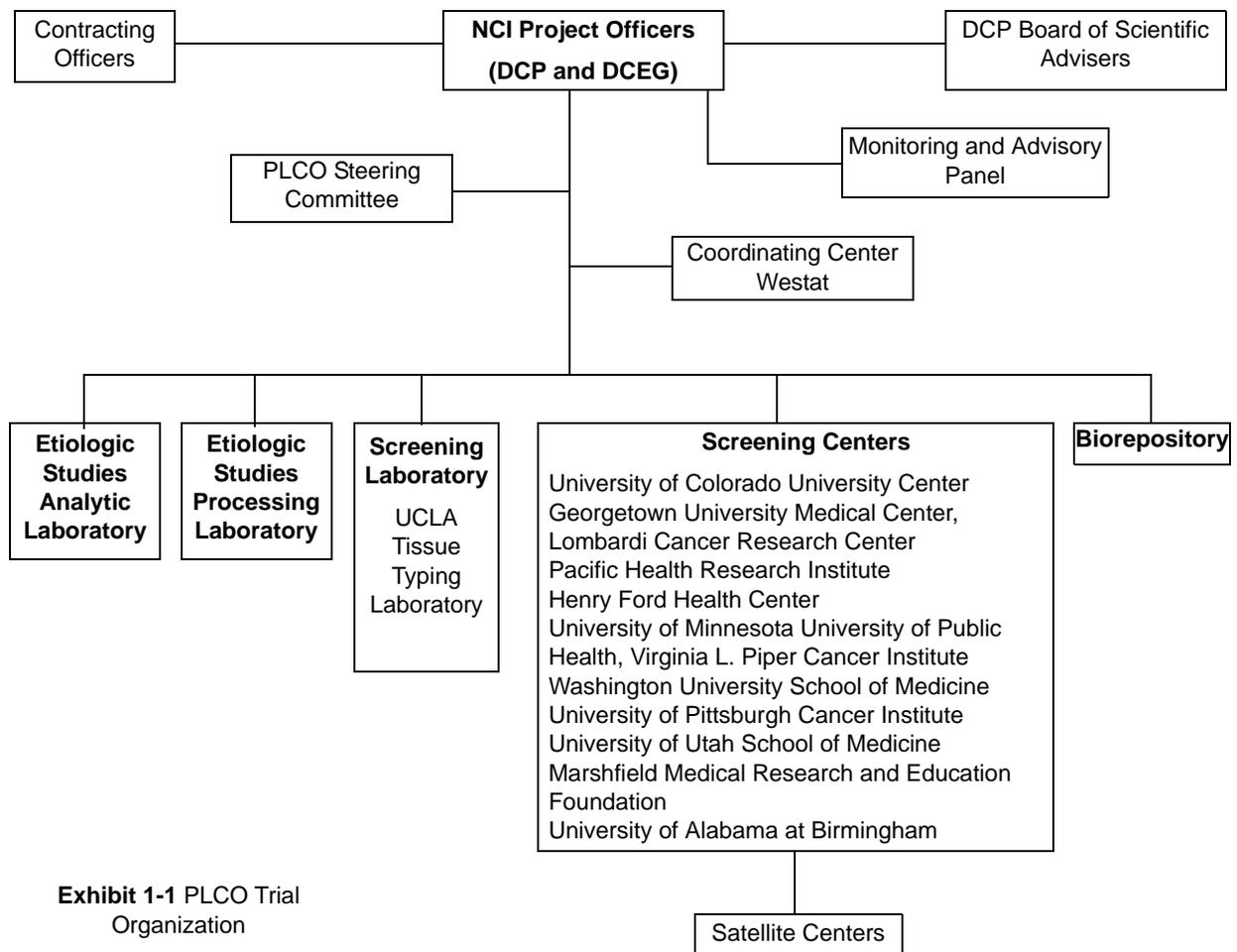


Exhibit 1-1 PLCO Trial Organization

### 1.3.1 National Cancer Institute

The NCI Project Officers, Drs. Christine Berg and Philip Prorok, are responsible for design and oversight of all aspects of the PLCO trial. They will work directly with the Coordinating Center (CC), which will provide support for the development and implementation of the study protocol, and with the Principal Investigators from each of the SCs to ensure that the technical aspects of the trial are carried out under rigorous scientific standards. The NCI Project Officers are also responsible for coordinating the analysis of the data resulting from the PLCO Screening Trial and the dissemination of the results of the trial through the scientific literature. As detailed in various sections of this manual, the SCs are required to submit certain documentation regarding their plans and procedures to the NCI Project Officers for review and approval.

The NCI Contracting Officer is responsible for all contractual matters between the NCI, the CC, the Laboratories and each of the SCs.

### 1.3.2 PLCO Monitoring and Advisory Panel

The PLCO Monitoring and Advisory Panel (MAP) is an oversight committee composed of outside experts in mass screening, clinical trials, appropriate medical specialties, medical ethics, biostatistics and other appropriate disciplines who will meet periodically during the course of the trial and review its progress. They will specifically address issues such as success of participant recruitment and results of other screening trials or medical research which might impinge on the appropriateness of the screening protocols. They will review suggested protocol changes and may also suggest such changes as appropriate. As the trial progresses, their function will include data monitoring to determine whether significant benefit or harm has been demonstrated for any of the screening modalities. They will also provide advice regarding the possible termination of any aspect of the trial should this be deemed necessary.

### 1.3.3 PLCO Steering Committee

The PLCO Steering Committee is composed of the NCI Project Officers and the Principal Investigators of the SCs, the Laboratories and the CC. This committee will provide overall scientific direction for the study and serve as the major decision-making body for the operational aspects of the study. Subcommittees will be created to address specific aspects of the trial. These subcommittees are:

- **Protocol Subcommittee** - The Protocol Subcommittee will address development issues regarding eligibility determination, randomization, central pathology review, central death data review and quality assurance. This subcommittee will also review major protocol changes and monitor operational aspects of the trial.
- **Prostate Subcommittee** - The Prostate Subcommittee will develop the protocols for the screening examinations related to the prostate and monitor these protocols on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the prostate examinations. It will also regularly review data regarding the prostate examination and prostate cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will

initiate ideas for publications, direct supporting data analyses and produce manuscripts.

- **Lung Subcommittee** - The Lung Subcommittee will develop the protocols for the screening examination related to the lung and monitor this protocol on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the lung examination. It will also regularly review data regarding the chest x-ray examination and lung cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses and produce manuscripts.
- **Colon/Colorectum Subcommittee** - The Colon Subcommittee will develop the protocols for the screening examination related to the colon and monitor this protocol on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the colon examination. It will also regularly review data regarding the colon/colorectal examination and colon/colorectal cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses, and produce manuscripts.
- **Ovary Subcommittee** - The Ovary Subcommittee will develop the protocols for the screening examinations related to the ovaries, and monitor these protocols on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the ovary examinations. It will also regularly review data regarding the ovarian examinations and ovarian cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses and produce manuscripts.
- **Ancillary Studies Subcommittee** - The Ancillary Studies Subcommittee will review and approve/disapprove letters of intent for ancillary studies that will use PLCO participants and/or PLCO data.
- **Publications Subcommittee** - The Publications Subcommittee will facilitate preparation of manuscripts and peer reviews of papers prior to publication. This subcommittee will also evaluate publications and presentations about the PLCO Trial.
- **Modeling and Simulation Subcommittee** - The Modeling and Simulation Subcommittee will serve to coordinate mathematical and statistical modeling projects involving PLCO data. This subcommittee will serve as a resource for PLCO investigators interested in utilizing modeling techniques to address questions of scientific or public health interest and act to encourage such utilization where appropriate. The subcommittee will help to disseminate the results of modeling efforts among the investigators.

The members of these subcommittees will include representatives from NCI, the CC, SCs, and outside consultants. All subcommittee recommendations for protocol revisions or additions will be sent in writing to NCI for approval.

### **1.3.4 Coordinating Center**

The CC, Westat, will work closely with NCI and other study investigators to ensure overall success of the PLCO Screening Trial. Westat will coordinate activities related to the development of the study protocol, arrange and document meetings, and produce standardized study materials, including this Manual of Operations and Procedures. Westat will also be responsible for training the SC Coordinators, medical record abstractors and medical technologists on study procedures. Westat will monitor the work completed at the SCs through receipt of reports and data and will establish regular telephone contact with the coordinators at each of the SCs. The CC will also disseminate quarterly reports to NCI on the progress of activities, including the status of recruitment, randomization, screening and follow-up and will conduct site visits as necessary.

The CC will design and manage the implementation of computer systems to support recruitment, randomization, receipt control, study management, and data entry/editing at the SCs. Training on the use of the systems will be conducted by the CC's programming training staff. The CC will also provide written and/or electronic documentation for all systems. All data forms will be stored at the SCs, but computerized data will be sent electronically from each SC and from the Laboratories to the CC. The CC will perform quality assurance checks on all data received and will report results to both NCI and individual SCs.

### **1.3.5 Screening Centers**

Ten SCs from different areas in the country will participate in the trial. They are:

- University of Colorado Health Sciences Center
- Georgetown University Medical Center, Lombardi Cancer Research Center
- Pacific Health Research Institute
- Henry Ford Health System
- University of Minnesota School of Public Health/Virginia L. Piper Cancer Institute
- Washington University School of Medicine
- University of Pittsburgh Cancer Institute
- University of Utah School of Medicine
- Marshfield Medical Research and Education Foundation
- University of Alabama at Birmingham

SCs are responsible for designing procedures necessary to implement the PLCO Screening Trial at their particular institution and for carrying out all data collection, data management and data processing activities as required by the study protocol. A list of the Principal Investigators from the SCs is provided in Appendix F.

### **1.3.6 Laboratory (Screening Test)**

Screening in the PLCO Trial includes the PSA blood test for prostate cancer and the CA-125II blood test for ovarian cancer. One laboratory, the Tissue Typing Laboratory of the University of Southern California at Los Angeles (UCLA), will

carry out the testings for all blood samples in the study. Samples will be sent to the laboratory on a weekly basis from each SC and results will be sent back to the individual SCs within a week of receipt.

### **1.3.7 Biorepository**

The NCI Division of Cancer Etiology and Genetics (DCEG), in collaboration with the DCP, has established a Biorepository in Frederick, Maryland for storage of blood products for future study of cancer etiology and early detection biomarkers and other research. SCs will ship aliquots of serum, plasma, and buffy coat to the Biorepository for storage at -70°C. The Biorepository will maintain a computerized inventory of all samples and track all movements of the samples within or outside the facility.

### **1.3.8 Processing Laboratory (Etiologic)**

The NCI DCEG has designated a laboratory in Frederick, Maryland to process whole blood for cryopreservation of lymphocytes. The Processing Laboratory will receive daily shipments of whole blood samples, aliquot, cryopreserve and ship samples to the Biorepository.

### **1.3.9 Analytic Laboratories (Etiologic)**

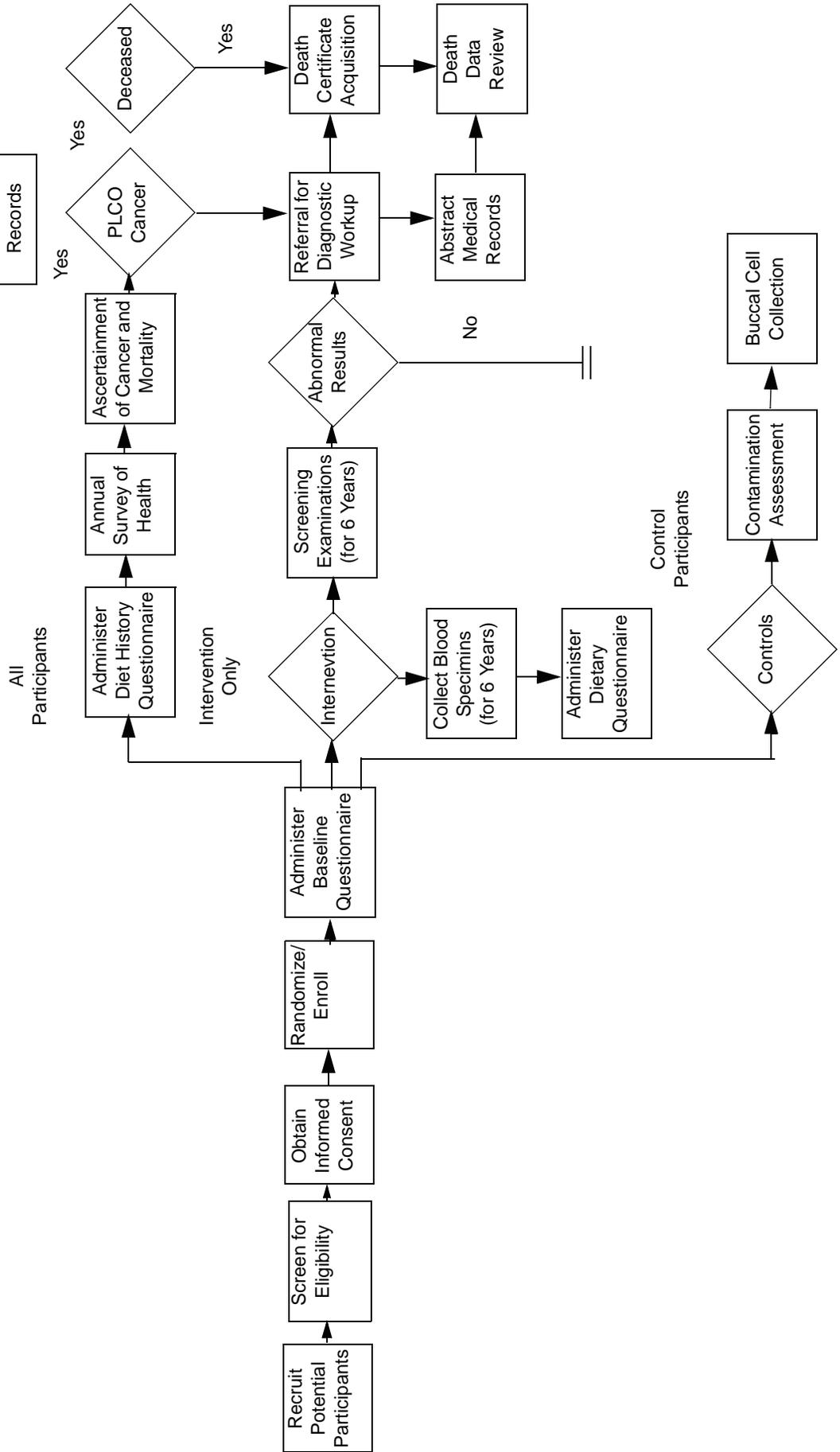
The NCI DCEG will designate laboratories to process and/or analyze selected biospecimens for specific etiologic studies. These laboratories will receive, process and/or analyze samples, provide results of any processing or analyses and, as required, return the residual samples to the Biorepository.

## **1.4 Overview of Data Collection Activities**

Exhibit 1-2 presents a schematic overview of the data collection activities of the PLCO Screening Trial. These activities are briefly outlined below. The remaining chapters of this manual provide detailed information on the standardized forms and procedures involved in each of these activities.

Initially, potential participants (men and women between the ages of 55 and 74) will be identified and screened for eligibility and interest. Those who fulfill the eligibility criteria and are interested will be recruited into the trial and must provide a signed informed consent form. Participants will be randomly assigned into one of two study arms: the intervention group will receive annual screening examinations for six years, the control group will follow their normal routine of health care. Baseline data collection for participants in both arms of the trial includes completion of a questionnaire which collects basic demographic data and risk factor information for the four cancers under study.

Exhibit 1-2  
 PLCO Cancer Screening Trial  
 Flow of data Collection Activities



Participants in the intervention group will receive the screening examinations, which include:

- Flexible Sigmoidoscopy
- Chest X-ray
- Digital Rectal Exam (males only)
- PSA blood test (males only)
- Transvaginal Ultrasound Exam (females only)
- CA-125II blood test (females only)

Participants with positive screening results will be referred to the physician of their choice for further diagnostic evaluation.

Cancer incidence and mortality will be tracked for all participants during the entire course of the trial. For those determined to have prostate, lung, colorectal or ovarian cancer, the medical records will be reviewed and abstracted for diagnostic evaluation and treatment information. A pathology slide will be obtained for confirmation of the cancer through a central review process.

The death certificate will be obtained for all participants reported as deceased, both as confirmation of death and to establish cause of death. A death review process will also be incorporated into the trial. This process will include a thorough review of cause of death information from multiple sources and will involve collection of supporting documentation and review both at the SC, CC, and by an outside committee.

## **1.5 Time Schedule of the PLCO Screening Trial**

The first 24 months of the trial will be considered the pilot phase. Study procedures will be tested during this time and changes may be made as a result. Recruitment will continue through the ninth year. The entire duration of the trial will be approximately 22 years.

For participants randomized into the screening arm of the trial, screening examinations will be conducted for six consecutive years. All screening examinations are performed annually through the third annual screening visit with the exception of the flexible sigmoidoscopy. The sigmoidoscopy is done at the baseline and fifth annual screening visit. During the fourth and fifth screening visits, only PSA or CA-125 are determined.

Morbidity and mortality findings will be analyzed as the trial proceeds and will influence the number of years of follow-up included. At the time of initiation of the pilot phase, it is expected that participants will be followed for at least 13 years after the baseline year. A study time line appears in Exhibit 1-3.



## 1.7 Study Policy Guidelines

### 1.7.1 Guidelines for Describing Study Sponsorship and Using the PLCO Logo

Certain guidelines have been established which apply to materials produced by the SCs for distribution to study participants, physicians, and others who may be contacted regarding the study. These materials include letters, brochures and similar items. Guidelines are as follows:

- The sponsorship of the trial should always be stated in such a way that the National Cancer Institute is primary.
- The authorized PLCO logo ([Appendix D-1-1](#)) must be used on letter-head and promotional materials. The layout, design and typeface may not be altered. The entire logo, however, may be reduced or enlarged as necessary and may be produced in black or any color. Materials carrying the PLCO logo must go through regular NCI clearance procedures. SCs may also develop their own logo which, with NCI approval, may be used in conjunction with the NCI PLCO logo.

### 1.7.2 Publication Policy

All data and specimens collected and stored according to the statements of work contained in contracts with the NCI for the PLCO Screening Trial are the property of the National Cancer Institute. All PLCO Screening Trial publications must be approved by the PLCO Steering Committee, NCI Project Officers and the NCI Contracting Officer. The publication policy for the PLCO Screening Trial is presented in [Appendix M-2](#).

The PLCO Steering Committee will take responsibility for writing primary PLCO publications. Authors will be listed as members of the PLCO Investigators Group, which will include at least one investigator from each of the participating SCs and appropriate NCI Project Officers and staff.

### 1.7.3 Ancillary Study Policy

An ancillary study is defined as any research that requires either (1) supplemental observations or procedures to be performed on all or a subgroup of PLCO participants according to a set protocol; or (2) additional work to be completed by or information obtained from the CC.

Generally, ancillary studies are encouraged. However, to protect the integrity of the trial, such ancillary studies must be reviewed and approved by the Ancillary Studies Subcommittee to the PLCO Steering Committee, the NCI Project Officers and the NCI Contracting Officer before they can be initiated.

Ancillary studies must:

- Not interfere with the implementation/operation of the main PLCO Trial;
- Not adversely affect cooperation or compliance of PLCO Trial participants;
- Not divert PLCO Trial funds;
- Not jeopardize the public reputation of the PLCO Trial;
- Not lead to premature publication of any PLCO Trial results;

- Not complicate the interpretation of any PLCO Trial results;
- Not violate the rights of PLCO Trial participants;
- Obtain IRB approval from their institution;
- Protect confidentiality of all PLCO Trial data;
- Allow review of manuscripts by the PLCO Publication Subcommittee prior to submission in order to ensure accuracy of statements and data related to the PLCO Trial;
- Include the relevant PLCO SC principal investigator as a co-investigator;
- Ensure that all PLCO Trial data remain under the direct management of the PLCO Trial principal investigator;
- Not present methodological or ethical problems; and,
- Not jeopardize the PLCO Trial in any way.

The request for approval of an ancillary study should contain a brief description of the objectives, methods, and significance of the study. Some ancillary studies may require approval from the OMB, if they add significantly to the participant burden. Full details should be provided concerning any procedures to be carried out on participants.

The relevant PLCO principal investigator should send his/her letter of intent to the PLCO Project Officers, who will review the proposed work for acceptability. Questions and objections raised by the Project Officers will be summarized and referred back to the PLCO principal investigator, who can then amplify, clarify, or withdraw the proposal. Approved letters of intent will be followed by a detailed ancillary study proposal which will be sent to the Ancillary Studies Subcommittee of the PLCO Steering Committee for review. The subcommittee will prepare a statement of the subcommittee consensus, including any reservation or objections. This statement will then be sent to the NCI Project Officers and Contracting Officer for a final decision.

If no additional funds from the NCI are required, the investigator may proceed with the ancillary study as soon as it is approved. Because funds for ancillary studies are not included in the negotiated contracts, they would have to be obtained separately, if needed. Submission of an application to a funding agency should not be made prior to final approval of the proposal by PLCO/NCI officials.

## **1.8 Purpose and Organization of the Manual of Operations and Procedures**

### **1.8.1 Purpose of the Manual**

This Manual of Operations and Procedures has been developed for the PLCO Trial, by Westat, the CC in conjunction with NCI. The purpose of this manual is to document the trial procedures that will be implemented at all 10 SCs. These procedures will enable each SC to carry out the study requirements as outlined in the protocol. It is expected that the Manual of Operations and Procedures will be used as a resource by the Principal Investigator, the SC Coordinator and their staff.

The manual will be updated as necessary throughout the course of the trial. Each page is identified with a version date. Replacement pages will be identified by a new version date. The SC Coordinator is responsible for ensuring that replacement pages are distributed to each individual with a copy (or parts of) this manual at the SC.

The manual has been structured so that sections dealing with procedures for a particular task can be readily identified and can be provided by the SC Coordinator to the individual involved in that particular task, without providing the entire manual. For example, the chapter dealing with the chest X-ray protocol and its related appendices would be provided to the radiologist and radiology technician involved in this particular screening test.

Four other manuals will be used in conjunction with the Manual of Operations and Procedures. Three manuals document computer systems and are titled *Study Management System User's Guide*, *Data Entry and Editing System User's Guide*, and the *PLCO Network User's Guide*. Documentation of computer system upgrades are also resources for information regarding SC procedures and use of computer systems. The fourth document is the *PLCO Decision Log*. This document presents NCI's decisions and resolutions regarding all protocol, procedural, and forms questions; suggestions for changes; and SC or laboratory administrative and management issues. Often the PLCO Subcommittees or working groups are consulted for these resolutions. The final decisions are presented in a numbered and dated list (PLCO Decision Log) and distributed regularly to all study collaborators.

**Note:** In May, 2004, the conversion of the SMS to a newer software platform was completed at all SCs. Some modules of the SMS providing functionality for phases of the PLCO study completed prior to the conversion were not included in the newer revision of the SMS. For completeness, information about those vestigial modules was left in this manual, and notes have been added indicating those modules that are no longer available.

## 1.8.2 Organization of the Chapters of the Manual

Chapters 2 through 6 of this manual cover procedures carried out during the baseline period. Recruitment of study participants is covered in [Chapter 2.0](#) and obtaining participants' consent is covered in [Chapter 3.0](#). Randomization procedures and administration of the Baseline Questionnaire are discussed in [Chapter 4.0](#) and [Chapter 5.0](#), respectively. [Chapter 6.0](#) details the procedures for scheduling, conducting, and reporting on baseline screening tests, and administration of the Diet History Questionnaire.

Chapters 7, 8, and 9 detail the follow-up operations as they should be carried out at individual SCs. Procedures addressed in these three chapters include administration of the Annual Study Update, performance of annual follow-up visits, and assessment of contamination in the control group, discussed in [Chapter 7.0](#), the ascertainment of cancer status, discussed in [Chapter 8.0](#), and the ascertainment of vital status, discussed in [Chapter 9.0](#).

The screening tests and various endpoint assessment protocols are covered in Chapters 10 through 16. Chapters 10 through 13, 15 and 18 contain the protocols for blood samples, the chest X-ray, the digital rectal examination, the flexible sigmoidoscopy, the transvaginal ultrasound, and buccal cell collection, respectively. [Chapter 14.0](#), which contains the procedures for the ovarian palpation examination, has been retained as a reference even though the exam

has been discontinued. [Chapter 16.0](#) details procedures to be used for the pathology review process.

[Chapter 17.0](#) covers guidelines for management of the SCs and includes discussions of center responsibilities as well as coordination, administration, and training activities. Chapter 17 also provides an overview of the data management systems, though each of the data entry, reporting, and transmission systems and procedures will be detailed fully in separate manuals.

### **1.8.3 Appendices of the Manual**

There are thirteen appendices in the Manual of Operations and Procedures. The first three appendices (A-C) are organized into specific categories to help direct the user. In addition, the reference number of each document in Appendix A-C is numbered according to the chapter in which it is primarily discussed.

The appendices of the manual are listed below.

- [APPENDIX A](#) contains the data collection forms of the trial and provides specifications for their use.
- [APPENDIX B](#) contains report and transmittal forms associated with the Study Management System.
- [APPENDIX C](#) contains sample study materials which are provided as prototypes or examples.
- [APPENDIX D](#) contains the study brochure and the PLCO logo.
- [APPENDIX E](#) contains the overall study protocol.
- [APPENDIX F](#) contains a list of the investigators and co-investigators associated with the trial.
- [APPENDIX G](#) contains a list of abbreviations used commonly in this manual and the standard abbreviations used for each data collection form.
- [APPENDIX H](#) contains questions participants and others may ask about the PLCO trial and suggested responses. This information is provided by NCI's Office of Cancer Communications.
- [Appendix I: Cancer Codes](#) contains lists of location codes, relationship codes and cancer codes. These codes will be used in editing the data collection forms.
- [APPENDIX J](#) contains the screening examination protocols.
- [APPENDIX K](#) contains the "General Interviewing Techniques" and the "General Abstracting Techniques."
- [APPENDIX L](#) contains the "PLCO Quality Assurance Plan."
- [APPENDIX M](#) contains the PLCO Publication Policy and the Review Policy for Proposed Etiologic Studies.

# Part II: Randomization

Part II of this manual describes the procedures for conducting the baseline activities. These activities include:

- Recruiting Participants and Determining Eligibility;
- Obtaining Informed Consent;
- Administering the Baseline Questionnaire;
- Randomizing and Enrolling Participants; and
- Scheduling and Conducting Baseline Screening Tests.

In the past, each of the Screening Centers used one of two possible approaches, described below, in conducting these activities. Currently, all Screening Centers follow the Single Consent Approach.

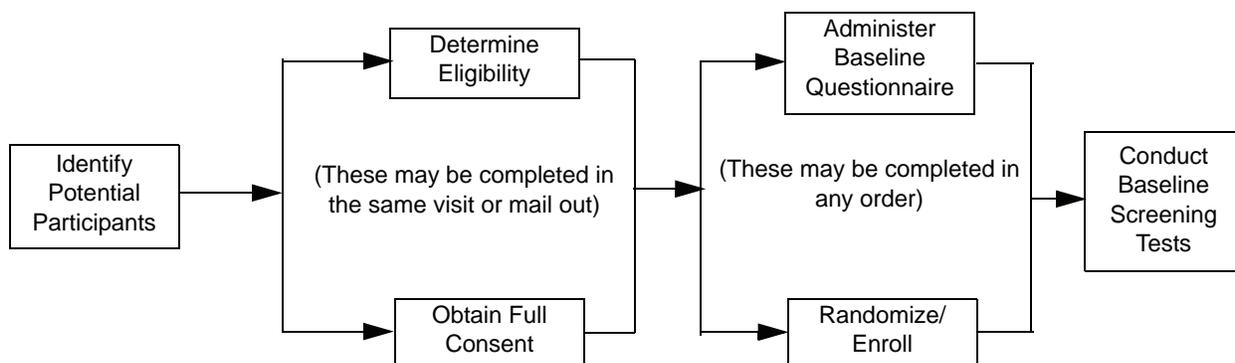
## **Single (Pre-Randomization) Consent Approach**

The Screening Centers using the single consent approach will obtain informed consent, using one consent form, for all trial activities before randomizing each individual to the screening or control arm of the trial. This approach is depicted in Exhibit II-1.

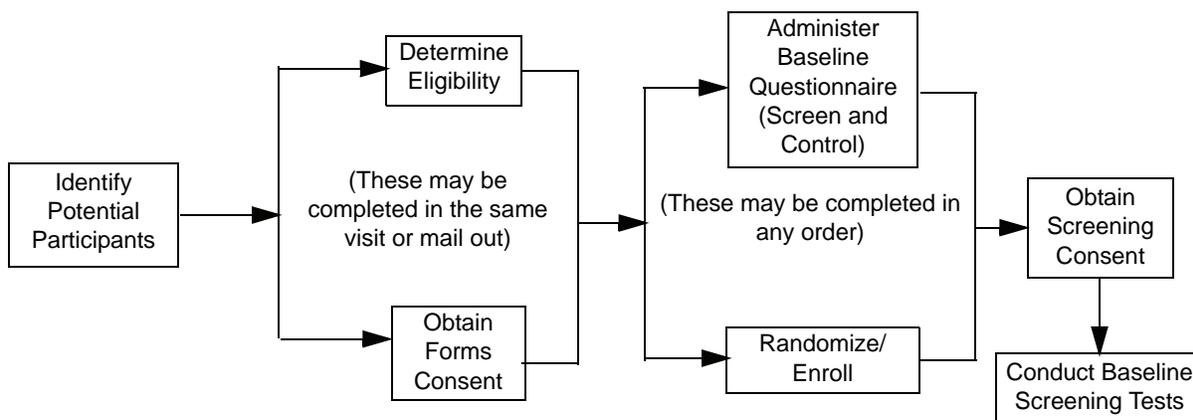
## **Dual Consent Approach**

Several Screening Centers chose to use a dual consent approach for recruitment and enrollment. In this approach, two consent forms were used. The first consent, a "forms" consent, was administered to all potential participants before randomization. The purpose of this document was to obtain consent to access the participant's medical records and to administer questionnaires to the participant throughout the study period. The second consent, a "screening" consent, was obtained only from those participants who were randomized to the screening arm of the trial. The purpose of this document was to obtain consent to conduct the screening tests for the PLCO cancers. This approach is depicted in Exhibit II-2.

**Exhibit II-1: Single (Pre-Randomization) Consent Approach**



**Exhibit II-2: Dual Consent Approach**



Regardless of the consent approach used by a Screening Center, the flow of activities, in general, will be as follows:

1. Identify potential participants;
2. Determine eligibility;
3. Obtain consent;
4. Randomize;
5. Administer Baseline Questionnaire (\*Some Screening Centers may choose to administer the Baseline Questionnaire before randomization.); and
6. Conduct baseline screening tests.

Each of these activities is described in Chapters 2 through 6.

## 2.0 RECRUITMENT AND ELIGIBILITY DETERMINATION

### 2.1 Overview

Each Screening Center (SC) will be responsible for establishing its own procedures for identifying and recruiting participants into the trial. Once potential participants are identified, the SC will collect information about them to make a determination of their eligibility for the trial. Potential participants who are eligible for and interested in the study will be enrolled. The SC will track potential participants from the time they are identified until they are enrolled, or not enrolled, because: (1) they are determined to be ineligible, (2) they are uninterested in the trial, (3) no contact was made, or (4) they will not be participating for some other reason. Each SC will document and report a summary of recruitment progress. These activities are discussed in more detail in the sections below.

### 2.2 Recruitment Materials

To aid in the recruitment process, the Coordinating Center (CC) will provide the SCs with copies of the PLCO Cancer Screening Trial Brochure (included as [Appendix D-2-1](#)). The purpose of this brochure is to provide potential participants with information about the trial that will allow them to determine whether they are eligible for and interested in the study. The CC will provide each SC with enough brochures to meet their requirements. The SC Coordinator should notify the CC at least 8 weeks in advance of needing additional brochures.

Other recruitment materials such as an introductory letter will be developed by individual SCs. The purpose of these materials is to introduce the trial to potential participants and to request their participation. The following must be explained in one or more of the introductory materials (letters, brochures, etc.):

- Legislative authority;
- Purpose of the study;
- Voluntary nature of any response;
- Extent of confidentiality of information;
- Time period for maintenance of records;
- Disposition of records; and
- Consequences of not responding.

A sample introductory letter, which includes the elements listed above, is presented as [Appendix C-2-1](#). All recruitment materials must be approved by the NCI prior to distribution to potential participants.

Appendix H of this manual contains answers to typical questions potential participants or other persons may ask about the PLCO trial. These questions and answers are an additional resource to be utilized in recruitment and the development of recruitment materials.

## 2.3 Eligibility Determination

After potential participants are identified, the SC Coordinator will determine their eligibility for the PLCO trial. A potential participant will be considered eligible for the PLCO trial if he/she does not meet any of the exclusion criteria described below:

- Men and women who at the time of randomization are less than 55 or greater than or equal to 75 years of age.
- Individuals undergoing treatment for cancer at this time, excluding basal-cell and squamous-cell skin cancer.
- Individuals with known prior cancer of the colon, rectum, lung, prostate (men only) or ovary (women only).
  - ▶ This includes primary or metastatic PLCO cancers.
- Individuals with previous surgical removal of the entire colon, one lung, or the entire prostate (men only).
  - ▶ Until October 1996, women with previous surgical removal of both ovaries were excluded from the trial. In order to increase the enrollment of women into the trial, beginning in October 1996, these women were no longer excluded for this reason.
- Individuals who are participating in another cancer screening or cancer primary prevention trial.
- Males who have taken Proscar/Propecia/finasteride in the past 6 months. (Note: Men who are taking Tamoxifen are not excluded from any part of the PLCO Screening Trial.)
  - ▶ Proscar (also known as finasteride – 5-mg dose) is a drug that is used for the treatment of benign prostatic hypertrophy (BPH).
  - ▶ Propecia (also known as finasteride – 1-mg dose) is a drug that is used for the treatment of male pattern baldness.

**NOTE:** Individuals who are already enrolled in the trial when their physician prescribes finasteride are not prevented from taking this medication. As a result, these participants will continue to be screened and followed just as those participants who are not on finasteride.

- ▶ Prior to April 1, 1999 women were excluded from the Trial if they were currently taking or had taken Tamoxifen or Evista\Raloxifene in the past 6 months. As of April 1999 based on a decision from the PLCO Ovary Subcommittee, women who have or are currently taking Tamoxifen or Evista\Raloxifene are not excluded from participation.
- Individuals who are unwilling or unable to sign the informed consent form.
- Males who have had more than one PSA blood test in the past three years.
- Individuals who have had a colonoscopy, sigmoidoscopy, or barium enema in the past three years.

In order to determine whether a potential participant meets any of the exclusion criteria listed above (with exception of the criterion regarding the signing

of the informed consent form), the SCs will be required to collect the following information for each individual:

- Date of Birth;
- Gender; and
- Medical history related to the PLCO organs:
  - ▶ whether the individual is undergoing treatment for cancer at this time (excluding basal-cell and squamous-cell skin cancer);
  - ▶ whether the individual has ever been told by a doctor that he/she has colon, rectal, lung, prostate or ovarian cancer;
  - ▶ whether the individual has had surgery to remove the entire colon, one lung, or the entire prostate;
  - ▶ whether the individual is participating in a cancer screening or cancer primary prevention study;
  - ▶ whether the individual, if male, has taken the medication Proscar, or Propecia in the past 6 months;
  - ▶ whether the individual, if male, has had more than one PSA blood test in the past three years; and
  - ▶ whether the individual has had a colonoscopy, sigmoidoscopy, or barium enema in the past three years.

The determination of eligibility will be made using the **Eligibility Screener** (Appendix [A-2-1](#)) or a combination of the Eligibility Screener and a review of medical records. The Eligibility Screener verifies address information and collects date of birth, gender, race, and medical history related to the PLCO organs. All SCs will use the Eligibility Screener or, if automated, a form containing the same information as the Eligibility Screener, to document the information collected and to make a determination of eligibility. It is not necessary to verify information recorded on the Eligibility Screener with any source other than the potential participant.

The Eligibility Screener will either be completed by the potential participant, or it will be administered by SC personnel by phone or in person. Mailing labels, containing the name and address of potential participants can be generated from the individual tracking component of the Study Management System (SMS), if used by the SC (see [Section 2.4](#)). These labels may be affixed to the front of each screener for name/address verification purposes.

Specifications for the administration of the Eligibility Screener are included as Appendix [A-2-1](#)

When the Eligibility Screener is completed, SC staff will perform the following tasks:

- The date the Eligibility Screener was received at the SC will be recorded as well as selected demographic information in the potential participant's tracking record (See [Section 2.4](#) for information on maintaining tracking records).
- *For SCs using the Eligibility Screener with check boxes to indicate interest in the study:* If the potential participant checked the box on the front of the Eligibility Screener indicating that he/she is not interested in participating, the SC staff will record the potential participant's status as "uninterested" on the tracking record.

- The Eligibility Screener will be reviewed to determine whether the potential participant meets any of the exclusion criteria on the form (i.e., criteria 1-6, 8, and 9, as listed on p. 2-2 and 2-3). If an individual does not know whether or not s/he meets one or more of the exclusion criteria, s/he should be asked to contact his/her physician to obtain the information. If the individual refuses or does not have a physician, or if after contacting the physician, s/he still does not know, s/he is *not* eligible for the trial.
- If the potential participant is determined to be ineligible based on one or more of the exclusion criteria, the SC staff will record the potential participant's status as "ineligible" on the tracking record.
- In some cases the SC will determine that a potential participant should not be enrolled for some other reason such as a language barrier or Principal Investigator disqualification. The status of these potential participants will be recorded as "other reasons for non-participation" on the tracking record.
- If the potential participant is determined to be eligible based on the Eligibility Screener, the informed consent form must be signed and a staff member must complete the Eligibility Verification Form. (See [Chapter 4.0](#) for more information on completing the Eligibility Verification Form.)
- Eligibility Screeners for potential participants with whom the SC has had contact but are not enrolled in the trial, will be kept on file at the SC throughout the study. Eligibility Screeners for participants who are enrolled in the trial will be kept in each participant's study folder. Automated eligibility screeners (i.e., not hardcopy) will be kept on computer disk or tape in a format that allows for retrieval, if necessary.

If a potential participant has not been randomized within one month of eligibility determination, it is advisable to make a second determination of eligibility before randomizing the participant.

## 2.4 Tracking Potential Participants

The SCs will track potential participants from identification through the recruitment and enrollment process to document either their entry into the study or their reason for non-participation. Documentation of tracking efforts is critical for the management of the recruitment process and is useful as a tool for the evaluation of the recruitment effort. Each SC will record recruitment data in a manner that allows for easy retrieval in the future.

Each SC will have a system, manual or automated, for tracking potential participants. This system will include at the minimum, a tracking record for each potential participant with whom the SC has contact. For SCs using mass mailing, summary totals of potential participants listed on mass mailing lists should be maintained. When an individual responds to a mailing, a tracking record should be created for that individual in the SC's active recruitment system. The following information, some of which will be required in reports of recruitment efforts, should be included in the tracking record:

- Full name;
- Date of birth;
- Gender;

- Race;
  - Race will be categorized as follows:
    - White, Not Hispanic
    - White, Hispanic
    - Black, Not Hispanic
    - Black, Hispanic
    - Asian
    - Pacific Islander
    - American Indian or Alaska Native
- Address (including zip code);
- Telephone number;
- Date of initial contact attempt (this is the date that the first mailing or phone call was made to the potential participant);
- Date Eligibility Screener was completed;
- Recruitment status; and
- Reason for ineligibility.

The valid reasons for ineligibility will be the exclusion criteria. For documentation purposes, only one reason for ineligibility need be coded. If the potential participant meets more than one exclusion criterion, then the first reason for ineligibility encountered should be documented.

All potential participants who are recorded in the tracking database are initially classified as "Eligibility Pending." This is denoted in the Individual Tracking version of the Tracking and Summarizing Recruitment (TASR) module by a "blank" eligibility status. As recruitment progresses, each of these pending individuals will be assigned a final recruitment status as follows:

**Eligible:** A potential participant should be classified as "eligible" if s/he does not meet any of the exclusion criteria, including unwillingness or refusal to sign the consent form (exclusion criterion #7). *The SC must have a signed consent form before a potential participant can be classified as "eligible".*

**Ineligible:** A potential participant should be classified as “ineligible” if s/he meets one or more of the exclusion criteria. This includes individuals who refuse or are unable to sign the informed consent.

If a potential participant is not contacted directly, but a relative or household member indicates that the potential participant is ineligible, the SC may classify the individual as “ineligible.”

If a potential participant has been contacted, is determined to meet all of the eligibility requirements except signing the informed consent form, and dies prior to signing the document, the SC may classify the individual as “ineligible.” The reason for ineligibility should be exclusion criterion #7, “Individuals who are unwilling or unable to sign the informed consent form.”

**Uninterested:** A potential participant should be classified as “uninterested” if s/he considers himself/herself unable or unwilling to join the study. This may be for a number of reasons such as:

- ▶ not interested in the study;
- ▶ too ill to participate;
- ▶ too busy to participate;
- ▶ lives too far away and cannot come to the SC, etc.

A potential participant can indicate that s/he is unable or unwilling to participate in the study by checking the box on the front of the Eligibility Screener and returning it to the SC (for SC’s using the screener with check boxes), or by telling a SC staff member that s/he is unable or unwilling to participate.

If a potential participant is not contacted directly, but a relative or household member indicates that the potential participant is unable or unwilling to participate, the SC may classify the individual as “uninterested.”

**No Contact:** A potential participant should be classified as “no contact” if the SC has had no direct contact with him/her, nor has the SC had contact with a relative or household member who could provide information that would allow the SC to classify the individual as “ineligible” or “uninterested.”

This category includes Eligibility Screeners that were never returned (with no subsequent contact), undeliverable letters returned by the post office, disconnected telephone numbers, or numbers that repeatedly have no answer, etc.

Potential participants listed on external mailing lists not transferred to the active recruitment database, should be considered “No Contact” if the SC has no contact with them (e.g. no response to mailings).

The SC Coordinator should establish SC guidelines for classifying potential participants as “no contact.” For example, an SC might determine that after two contact attempts have been made, and 6 months have elapsed, with no contact with the potential participant, and no contact with a relative or household member who could give information that would allow the SC to assign a recruitment status, the potential participant will be classified as “no contact.”

Potential participants who were found to be deceased through a relative, the post office, etc., with no actual contact with the potential participant prior to his/her death, should also be classified as “no contact.”

**Other Reasons for Non-Participation:** A potential participant should be classified as a “non-participant” for reasons other than uninterested, no contact or ineligible, if the SC is unwilling or unable to enroll him/her in the study. (Note that a potential participant’s eligibility need not be determined prior to assigning this status.)

A potential participant may be classified as a “non-participant” for a number of reasons. For example:

- ▶ the Principal Investigator decides the individual is unsuitable for participation in the trial;
- ▶ the potential participant does not speak English and the SC is unable to provide services in the language that is needed;
- ▶ The potential participant completed all of the required forms, including the informed consent form, but died prior to being randomized, etc.

**Note:** the following category should be used for situations in which the SC decides not to enroll a potential participant.

If a potential participant is classified as “non-participant, other reason,” the reason for non-participation must be specified. In order to facilitate the analysis of these reasons, it is desirable for the SCs to use standard language whenever possible. Below is a list of standard phrases which should be used in the

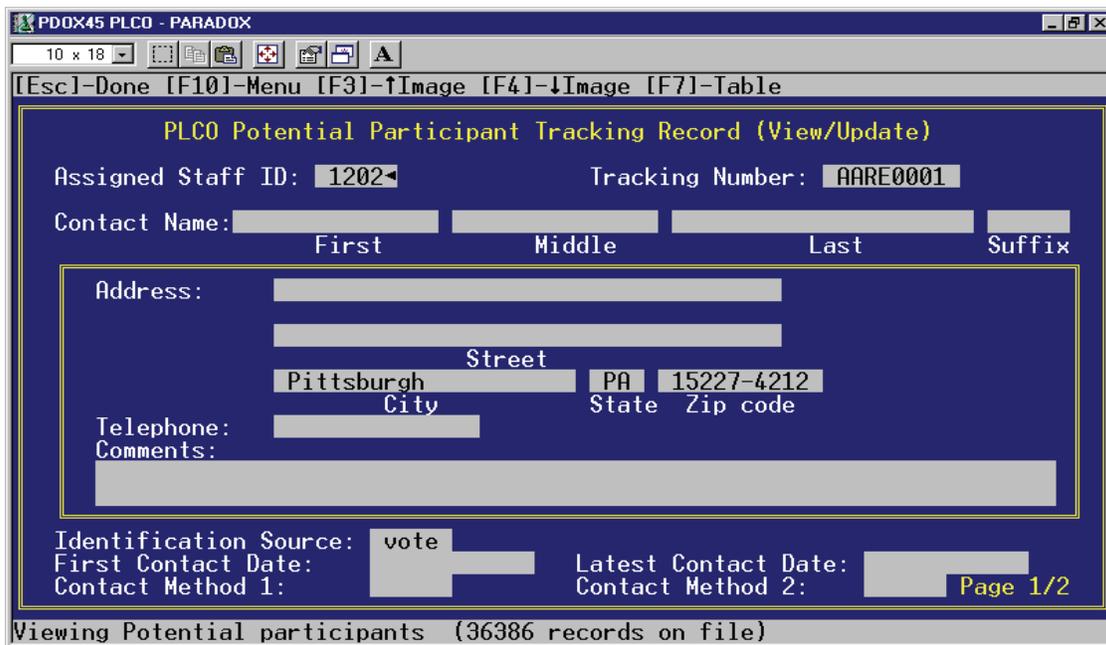
reason field, when appropriate. As the study progresses, additional standard phrases may be added to this list.

Standard Phrase	Situation	Example
"Language-(specify language) "language)" "Medical-(specify condition)"	Language barrier. PI determines that the potential participant is too ill to participate	Language-Arabic Medical-recent myocardial infarction

Tracking records may be maintained individually or as part of a log. A sample potential participant tracking log, containing tracking records for several individuals, is included as [Appendix C-2-2](#). Such a log may be maintained manually or on a computerized tracking system. Summary information regarding potential participants listed on mass mailing lists should also be maintained manually or on a computerized tracking system.

The CC will provide the SCs with an automated tracking system for use during the recruitment phase of the study as a module of the SMS. The Tracking and Summarizing Recruitment (TASR) module will be installed on the PLCO network at the SC. (**Note:** The TASR module of the SMS is no longer available since the recruitment phase is complete.) This module is comprised of two components: the individual tracking component and the recruitment summary component. Use of the individual tracking component is optional, while use of the recruitment summary component is mandatory. The recruitment summary component is described in [Section 2.5](#), Summarizing and Reporting Recruitment Efforts. Additional details can be found in the *SMS User's Guide/SMS Upgrade Documentation*.

The individual tracking component will allow the SC to maintain the required information on each potential participant. The data screen in the system will allow entry of the same data as that on the potential participant tracking log. An example of this screen is provided in Figure 2-1.



**Figure 2-1.** Potential Participant Tracking Log Screen

The individual tracking component has several other features including the production of address labels for SCs employing mailings as one of their recruitment strategies. The SC can load the names, addresses and telephone numbers of potential participants into the system from a file supplied from a recruitment source (such as a hospital, club or other organization) or through interactive data entry. It is not recommended, however, that the individual tracking component be used for large mass mailing efforts. In addition, use of the individual tracking component will facilitate the summarizing and reporting of recruitment data (see [Section 2.5](#)). It will also allow for monitoring of errors and missing values in the recruitment data. For more information on the features of the individual tracking component, refer to the *SMS User's Guide/SMS Upgrade Documentation*.

## 2.5 Summarizing and Reporting Recruitment Efforts

Each SC will summarize and report the status of its recruitment efforts to the CC. As noted earlier, the purpose of reporting summary recruitment data is to enable the NCI to monitor recruitment. Initially, the following recruitment data will be summarized:

- **Total Identified:** This refers to the number of persons identified for possible participation in the trial. This number may not reflect the *total* number of persons identified since many SCs are using outside mailing services and mailing lists for recruitment and the names contained in those lists are only entered into TASR when the SC establishes contact with the individual.
- **Total Not Contacted:** This is the number of potential participants who did not respond to any contact attempt. See [Section 2.4](#) for guidelines on how to determine which individuals are categorized as "no contact."

- **Total Uninterested:** This is the number of potential participants who indicated that they were not interested in the study. This number does *not* include potential participants who refused to sign the informed consent. See [Section 2.4](#) for guidelines on how to determine which individuals should be categorized as “uninterested.”
- **Total Ineligible by Reason:** This is the number of potential participants who were found to be ineligible by reason for ineligibility. This includes potential participants who refused to sign the informed consent.
- **Total Non-Participants Other Reasons (reasons specified):** This is the number of potential participants who were deemed unsuitable for participation by the Principal Investigator or who will not be participating for an SC-determined reason. Reasons for non-participation must be specified.
- **Total Eligible:** This is the total number of eligible participants, including those already enrolled. This number should be greater than or equal to the “Total Enrolled.”
- **Total Participants Enrolled:** This is the number of participants who were randomized and enrolled in the study. This number should be less than or equal to the “Total Eligible.”
- **Total with Eligibility Pending:** This is the remaining group of potential participants who are “in process,” that is, their final eligibility is not determined. This number is calculated as follows:
  - ▶ Identified - (No Contact + Uninterested + Ineligible + Non-Participants, Other Reasons + Eligible) = Eligibility Pending
  - ▶ The total with eligibility pending reflects only those individuals whose data have been entered into TASR. There may be additional potential participants with eligibility pending on lists maintained outside of TASR.

On a monthly basis, the SC Coordinator will summarize recruitment data into the categories described above and transmit these data to the CC. For SCs which are using the individual tracking component to track participant recruitment, this may be accomplished by generating the **Recruitment Summary Report** ([Appendix B-2-1: Recruitment Summary Report](#)). Refer to the *SMS User's Guide/SMS Upgrade Documentation* to find instructions for generating the Recruitment Summary Report. When the SC Coordinator accesses the Recruitment Summary Report Option, the required data will automatically be calculated from the individual tracking component and the randomization and enrollment module. (See [Chapter 4.0](#) for more information about the randomization and enrollment module).

SCs that are not using the tracking module will summarize recruitment data according to the categories outlined above and will keep a record of this summary data. The sample recruitment summary form ([Appendix C-2-3](#)) is one suggested method for recording recruitment summary data. The SCs will not be required to use this form, however, they will be required to maintain a record of recruitment summary data and to enter these data, both for the current period and the totals to date, into the SMS on a monthly basis. For example, some SCs are using an automated “bridge” to transfer data from their own recruitment system to the TASR module of the SMS.

It is the SC's responsibility to track the total number of individuals identified and to reduce duplication as much as possible. The SC should also track response rate to mailings. The SC should track zip codes and be able to summarize the total number of letters mailed to various zip codes. To the extent that additional information is available for individuals on mailing lists (such as gender, race, etc.), the SC should be able to summarize and report such characteristics to the NCI on request.

## 2.6 Monitoring Recruitment Efforts

The SC Coordinator will monitor recruitment against the SC's contract commitments to the NCI. This monitoring activity will enable the SC Coordinator to identify any problems with recruitment and to redirect recruitment resources, if necessary. The following SMS reports will be used for monitoring recruitment. (**Note:** These reports are no longer available from SMS since the recruitment phase is complete.)

- **Recruitment Summary Report** ([Appendix B-2-1: Recruitment Summary Report](#)): This report will show the following summary totals for the current reporting period and for the project to date:
  - ▶ Total Identified;
  - ▶ Total No Contact;
  - ▶ Total Uninterested;
  - ▶ Total Ineligible (by reason);
  - ▶ Total Non-Participants Other Reasons (reasons specified);
  - ▶ Total Eligible;
  - ▶ Total Participants Enrolled; and
  - ▶ Total with Eligibility Pending.

The Recruitment Summary Report will enable the SC Coordinator to monitor the number of potential participants whose eligibility is pending. This number represents "work in process" for the SC recruiting staff. Also, by subtracting the number of potential participants with no contact from the number identified, the SC Coordinator can monitor the number of initial contacts made during the reporting period.

- **Recruitment Progress Report** ([Appendix B-2-2: Recruitment Progress Report](#)): This report shows eligibility status by gender (Part I), race (Part II) and age groups (Part III). It allows the SC Coordinator to identify recruitment issues or concerns for particular demographic groups.
- **Eligibility Screener Review** ([Appendix B-2-3: Eligibility Screener Review](#)): The Eligibility Screener Review Report provides information on participants with incomplete screeners and those whose eligibility has not yet been determined (pending). It is divided into two parts.
  - ▶ **Part 1** shows the total number of participants who were contacted and sent Eligibility Screeners but did not complete them. The names and telephone numbers of the potential participants with incomplete screeners are listed. This report facilitates follow-up contacts to these individuals to ascertain their interest in the trial.

- ▶ **Part 2** shows the total number of potential participants who have completed screeners and the total number of potential participants whose eligibility is pending. The names and telephone numbers of the potential participants whose eligibility is pending are listed so that they may be contacted to verify the information on the screener or to sign an informed consent form.
- **Production Edits Report for Individual Tracking** ([Appendix B-2-4: Session Edit Report for Individual Tracking](#)): While entering data into TASR, several types of errors can be introduced, many of which will appear on the Session Edit Report, automatically generated from the SMS at the end of a data entry session (see *SMS User's Guide/SMS Upgrade Documentation*). In addition to the Session Edit Report, the Production Edits Report can be run. It lists errors and inconsistencies for all records in the TASR database.
- **Possible Duplicates on Individual Tracking** ([Appendix B-2-5: Possible Duplicates in TASR](#)): This report will allow the SC Coordinator to identify possible duplicates among potential participants in the TASR database. Possible duplicates may be identified based on exact name, date of birth, similar name, or some combination of name and date of birth.
- **Age Review Report** ([Appendix B-2-6: Age Review Report](#)): This report checks the date of birth for potential participants who have not been assigned a final eligibility status. It presents those who are currently age ineligible in three parts: those who are too old (age  $\geq$  75); those who are too young (< 55) at the time of the report and will not be old enough by the time recruitment ends; and those who are too young (< 55) at the time of the report, but will be old enough by the end of recruitment. This report will allow the SC Coordinator to quickly identify and categorize age ineligible.
- **TASR/RAND Comparison Report** ([Appendix B-2-11: TASR/RAND Comparison Report](#)): This report compares the data for potential participants in TASR with enrolled participants to highlight data inconsistencies as well as pending randomizations.

The following reports are designed to assist SCs to monitor their contacts with outside organizations for recruitment.

- **Organization Report** ([Appendix B-2-7: Organization Report](#)): This report lists information on organizations the SC has contacted for recruitment using data entered into TASR from the Contact Information screens. The user may print either complete organization information or simply the name, city, state and ID of the organization.
- **Scheduled and Completed Presentations** ([Appendix B-2-8: Scheduled and Complete Presentations](#)): This report summarizes information on presentations entered into TASR using the Presentations to Organization screen. The list includes the organization ID, the date of the presentation, the program name, the ID of presenting staff and the number of attendees.
- **Materials Distribution Report** ([Appendix B-2-9: Materials Distribution](#)): This report shows the distribution cycle for distribution of PLCO materials to organizations. It may be used to monitor the success of recruitment materials (such as brochures) in recruitment through orga-

nizations, and to ensure the availability of such materials throughout the recruitment period.

- **Contact Summary Report** ([Appendix B-2-10: Summary of Contacts with Organizations](#)): This report summarizes contacts with organizations. It shows the number of organizations in the database, the number for whom at least one presentation was done, the total number of presentations to date, and the total number of attendees over all presentations.

The following PLCO system functions support the development of customized reports for management of SC recruitment activities. (**Note:** These functions are no longer available from SMS since the recruitment phase is complete.)

- **Ad-Hoc Query:** This function will allow the SC Coordinator to query the TASR database and produce customized reports.
- **Data Export:** This function will allow the SC to export data from the TASR data tables to files that may be used to produce customized reports. Appendix E of the *SMS User's Guide* contains information regarding use of the data export option.

SCs that are using their own tracking system should use their system to support the monitoring activities outlined above.

## 2.7 Reporting Recruitment Summary Data

On a monthly basis, the SC will transmit the data via an electronic transmission to the CC using the transmission option(s) available in the Data Transmission application of the PLCO computer system. Information on how to transmit data electronically to the CC is presented in the *SMS User's Guide/SMS Upgrade Documentation*.

## 3.0 OBTAINING INFORMED CONSENT

### 3.1 General Procedures for Obtaining Participant Consent

Human research subjects are protected by informed consent procedures. The signing of an informed consent form is a criterion for eligibility to participate in the PLCO trial. Each Screening Center (SC) will determine the preliminary eligibility of the potential participants and will obtain their consent before enrolling them in the study.

The informed consent form addresses four major protections:

- Each participant must be fully informed of all study procedures and requirements in order to be considered a “knowing” participant;
- The study design must minimize risks to the participants and maximize the benefits;
- The study participants must be selected in a non-discriminatory way so that no class of individuals will benefit more than any other based on the selection procedures; and
- Participation is voluntary and all information provided by participants will be kept confidential.

The SC Coordinator will be formally responsible for ensuring that informed written consent to take part in the study is obtained from each participant. In addition, the informed consent form(s) and procedures must be approved by the Institutional Review Board (IRB) at each SC. SCs recruiting non English-speaking individuals (or individuals who have very little knowledge of the English language) must submit to NCI documentation of IRB approval to administer an English language PLCO consent form to non English-speaking individuals.

The prototype consent form, presented in [Appendix C-3-1](#), will be used as a guide by each SC in the development of its own informed consent form(s). The individual SC form(s), once developed, will be reviewed and approved by the NCI before being sent to the SC IRB, and any changes made by the IRB will be submitted to the NCI for review. In general, all information and assurances contained in the prototype form will be included in the consent form(s) that the SCs develop. Additional information may be added based on individual IRB requirements, but required information may not be excluded from the form(s). The consent form must indicate that women who enter the trial with prior surgical removal of their ovaries will not be given the, transvaginal ultrasound or CA125II screenings.

The method of administration of the consent form will vary by SC. In some instances, the form will be mailed to the subject, in others it may be administered in-person. Regardless, administration of the form should occur after the subject has been provided with background information about the study and its requirements. This information will likely include an introductory letter ([Appendix C-2-1](#)) and the PLCO Study Brochure ([Appendix D-2-1](#)) and, in some instances, a conversation with the SC Coordinator in a manner conducive to two-way conversation.

When the consent form is administered, the participant must be offered sufficient time to carefully read the document and must be given sufficient oppor-

tunity to have all questions regarding the study answered before s/he is asked to make a decision on enrollment.

IRB requirements regarding the need for a witness to sign the consent, in addition to the participant, will vary. The participant will be given a copy of the consent form after it is signed. The original will be kept in the participant's file at the SC.

## 3.2 Main Study Consent

Currently all SCs must use a pre-randomization informed consent procedure in which eligible and interested potential participants will sign a Main Study Consent form prior to randomization. The Main Study Consent form will cover all activities of the trial. The prototype consent form, presented in [Appendix C-3-1](#), is an example of a Main Study Consent form. The approach for obtaining consent is illustrated in Figure 3-1.

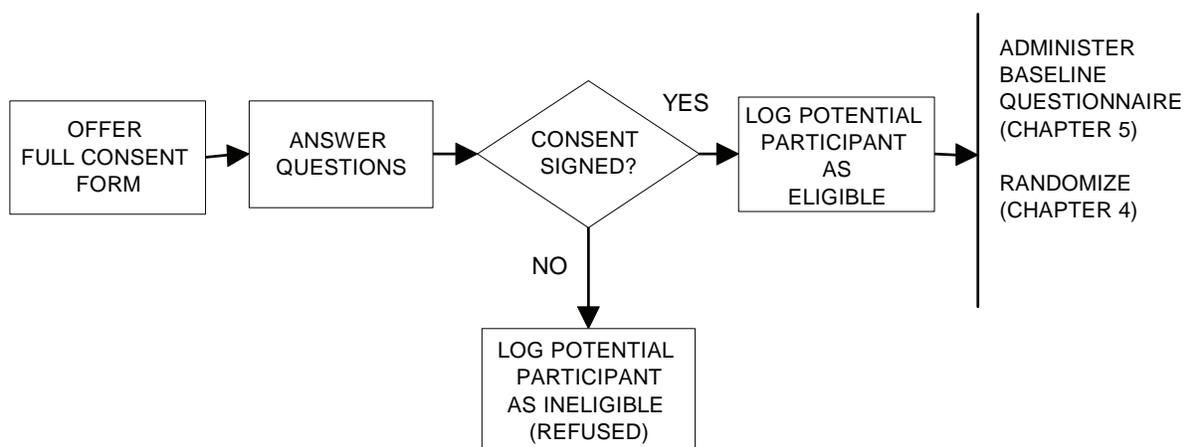


Figure 3-1. Main Study Consent Approach

In the past several SCs used a dual consent approach. As of April 1998, this method of consenting participants is no longer used by any SC.

### 3.2.1 Documenting the Results of Obtaining Informed Consent – Main Study

The SC Coordinator will record the signing or the refusal of the Main Study Consent form in the SC's recruitment tracking system. If the Main Study Consent form is signed, the SC Coordinator will log the individual as "eligible" in the tracking system. If the Main Study Consent form is refused, the SC Coordinator will log the individual as "ineligible" and will record the reason for ineligibility as refusal to sign the consent form. This information will be summarized in the weekly report to the Coordinating Center (CC). Refer to [Chapter 2.0](#) for information on tracking potential participants and reporting recruitment summary data.

### **3.3 Protocol Changes Consent (PCC)**

In December 1998, NCI Project Officers and the PLCO Steering Committee approved MAP recommended changes to the current PLCO protocol. Two more years of screening will be added while simultaneously lengthening the interval between FSG exams. At these last two visits, T4 and T5, PSA and CA-125 tests will be performed. Participants who have not yet had their T3 FSG will receive this exam in the last screening year (T5) instead of having it at T3. The TVU and DRE will not be extended beyond T3. The remaining T3 x-ray exams will be offered only to current or former smokers, and all the ovarian palpation exams will be discontinued. Furthermore, follow-up is extended three years so that all participants will be followed at least 13 years from randomization.

SCs are required to inform all intervention participants enrolled in the Trial of the protocol changes and to obtain their written consent. The Protocol Changes Consent (PCC) was designed to obtain consent for these revisions. The design of the PCC is SC specific but must contain all elements of the sample PCC given in [Appendix C-3-2](#). Each SC must obtain SC IRB and NCI approval of all versions of the PCC. In addition, the Main Study Consent was revised to incorporate the 1998 protocol changes ([Appendix C-3-1](#)).

#### **3.3.1 Administration of the PCC**

Administration of the PCC is SC specific and is expected for *all* intervention participants who have enrolled in the trial before July 1, 1999. The Main Study Consent revised to incorporate the 1998 protocol changes is administered to all intervention participants enrolled *after* July 1, 1999. The SCs will not be required to obtain consent for these protocol changes from control participants. For those participants who require mailing of this consent, the SMS Requests (Directive, Rdirective, Idirective, and Ldirective) are programmed to generate mailing labels and merge files for mailing PCCs.

If the participant is in the T1 through T3 study year and refuses to sign the PCC, the SC should perform the screening exams appropriate for that study year and make another attempt to obtain consent at the next annual exam. If the participant is in his/her T4 study year and refuses to sign the PCC, the SC should complete an MDF for the screening exam. Another attempt should be made to obtain consent at T5. If the participant again refuses, the SC should complete an MDF for the T5 exams and for the PCC. To differentiate between those participants who refused to sign the PCC and those who did not return it, different MDF reason codes should be used. If the participant does not return the form, use the reason code 5 = Can't Locate, subcode 501. If the participant refuses to sign the PCC the MDF reason code should be 1 = Refused, with the appropriate refusal subcode.

Annual screening exams should continue and attempts to gain consent should be made at each yearly exam. If the participant adamantly refuses to continue in the trial, then an NRF should be completed. No additional attempts need to be made to obtain consent, but annual follow-up should continue until the end of the trial.

#### **3.3.2 Documenting the Results of Obtaining Informed Consent – PCC**

All intervention participants who have enrolled in the trial before July 1, 1999 will have an expectation for a PCC until it is receipted or an MDF-PCC is

received. Expectations will be turned off for intervention participants who enroll on or after July 1, 1999, by which time an approved revised Main Study Consent should be in use for new participants.

The status of the PCC (outstanding or received) will appear on the Participant Overview Report, the Open Forms Report and the List/Count of received Missing Data Forms.

The signed PCC will be receipted into SMS. Receipt of the PCC will include the following variables:

- PID;
- Acknowledgement of signature and date signed;

The acknowledgement for each signature in the SMS will require a yes or no answer.

**Note:** If a participant dies prior to signing the PCC (and there is an expectation for this form), the SC should complete an MDF-PCC. If later, a PCC is returned for this participant signed by a proxy, it should not be receipted. Instead, the MDF-PCC should remain in the system and the proxy form should be kept in the participant's file.

### 3.4 Etiologic Studies Consent

The Etiologic Studies Consent (ESC) was implemented in March 1998. The ESC obtains permission to use biologic specimens (blood and pathologic tissue) already collected (prior to implementation of the consent) for research involving genetic studies. It also obtains permission for future collection of blood, buccal cells (saliva) and pathologic tissue, and for the use of those samples for research involving genetic studies. The ESC is not related to obtaining permission for collection of blood for PSA or CA-125 analysis or for collection of tissue for the central pathology review process. Permission for those procedures is obtained under the Main Study Consent.

The prototype ESC form, presented in [Appendix C-3-3](#), will be used as a guide by each SC in the development of its own etiologic studies consent form(s). The individual SC form(s), once developed, will be reviewed and approved by the NCI before being sent to the SC IRB, and any changes made by the IRB will be submitted to the NCI for review. In general, all information and assurances contained in the prototype form will be included in the etiologic studies consent form(s) that the SCs develop. Additional information may be added based on individual IRB requirements, but required information may not be excluded from the form(s).

#### 3.4.1 Administration of the ESC

The ESC is to be administered once to all participants in the PLCO Trial. Depending on the participant's study year and study group (intervention versus control) the ESC may be administered at the SC or mailed with an approved cover letter to the participant. For those participants who require mailing of this consent, the SMS Requests (Directive, Rdirective, Idirective, and Ldirective) is programmed to generate mailing labels and merge files for mailing ESCs. Each SC may prepare their own cover letter to accompany the ESC forms but should include the ESC language provided in [Appendix C-3-4](#) (or similar language), as well as including statements of confidentiality. Cover

letters must be submitted to NCI, with a copy to Westat, for review and approval.

The ESC may be administered to new participants as an integrated consent (combined with the main PLCO consent), presented in [Appendix C-3-5](#), or as a separate document. For those participants who, as of May 4, 1998, have already signed the Main Study Consent, the ESC must be administered prior to the collection of any samples for etiologic studies.

Note:

1. The SCs are not required or encouraged to solicit proxy signatures for deceased participants. After August 1999 the SCs should no longer receipt ESC forms signed by proxies for deceased participants. Instead, an MDF-ESC should be completed using the Deceased code and the proxy ESC form should be kept in the participant's file.
2. For transfer participants, the ESC obtained at the original SC is sufficient. There will be no need to re-consent transfer participants. In these instances, the ESC expectations and receipt issues will be updated and transferred to the new SC.

Procedures for addressing intervention participant non-response to the ESC are given in [Section 3.4.2](#). Procedures for addressing control participant non-response are given in [Chapter 18.0](#).

### **3.4.2 ESC Non Response – Intervention**

The SCs are required to mail the ESC to Intervention group non-responders only twice. If after 2 mailing attempts there is no response, the SC is not required to do additional ESC mailings to that participant. The SC is encouraged to administer the ESC on site during the participant's screening visit but if this is not possible and 2 mailing attempts have been made, an MDF-ESC may be completed.

If an intervention participant has not responded to an ESC mailing by the time of a screening visit, SCs are instructed to administer the ESC on-site. If a participant refuses to sign the ESC, s/he should not be asked again and a Missing Data Form should be completed for the ESC. After March 1998, if the participant has not signed an ESC but biorepository blood or other etiologic studies samples are collected, this constitutes a protocol violation and it should be reported to both Westat and NCI (see [Chapter 17.0](#) for more information about documenting protocol violations). If the specimen is collected and then the consent is signed at a later date, this is still considered a protocol violation, since a specimen was collected without a signed ESC.

#### **3.4.2.1 Prioritizing ESC for Prostate Cancer**

As of July 2002, NCI requests that SCs prioritize completion of outstanding ESC forms for intervention participants with prostate cancer. If these participants come to a screening visit within the next 3 months, then the ESC should be administered at the screening visit. If these participants will not be coming in for a screening visit during the next 3 months, then please conduct the following follow-up activities:

- If the SC has mailed the ESC to the participant within the past three months but has not received the signed form, the SC should conduct telephone follow-up to obtain the signed ESC.

- Regardless of earlier mailings, if the SC has not mailed the ESC to the participant within the past three months, then the consent form should be mailed. Mailings to these participants should be spaced out appropriately to ensure the completion of the required telephone follow-up. If the participant does not return the signed ESC within 3 weeks of the mail date, then the SC should conduct phone follow-up.
- If, after the completion of 5 attempted telephone follow-ups, the participant cannot be located or refused to complete and return the ESC, an MDF-ESC should be completed with the appropriate reason code. If, after the completion of the telephone follow-up, the participant agrees to complete an ESC, the SC should continue to track the event until the ESC is complete.

### **3.4.3 Documenting the Results of Obtaining Informed Consent – ESC**

The signed ESC will be receipted into SMS. Receipt of the ESC for intervention and control participants will include the following variables:

- PID;
- Acknowledgement of Signature A (research on cancer) and date signed; and
- Acknowledgement of Signature B (research on diseases and conditions other than cancer) and date signed.

The acknowledgement for each signature in the SMS will require a yes or no answer.

For those SCs that use an ESC with only one signature and date, the receipt screen must be completed as follows:

- If a participant has checked off yes to both types of research, then the acknowledgement of the signature and date should be entered twice, once as signature A and once as signature B.
- If approval has only been given for one type of research, then only the signature that corresponds to that type of research should be receipted. The other signature should be marked no. (For example, a participant only gives permission for his blood to be used for research involving diseases and conditions other than cancer that affect his age group, then only signature B would be acknowledged. Signature A would be marked no.)

For those SCs that use one consent for combining the main study and etiologic components, the two signatures corresponding to the ESC must be receipted.

Blood samples will be expected (see Open Forms in [Appendix B-17-8: Open Forms/Specimens Report](#) and Participant Overview Reports in [Appendix B-17-10: Participant Overview Report](#)) for all intervention participants unless a Missing Data Form for the ESC has been receipted.

If the SC is unable to obtain consent, the specimens will be flagged at the biorepository so that they cannot be used for research involving genetic studies. An ESC data file will be matched to the PLCO specimen inventory at the biorepository. Only matches, indicating that consent was obtained, will release a sample for etiologic studies research. Any samples collected prior to the implementation of the ESC will automatically be flagged at the biorepository.

This flag will be removed once an ESC is signed and receipted for that participant.

### 3.5 Monitoring the Results of Obtaining Informed Consent – Main Study, PCC and ESC

The SC Coordinator will monitor the number of participants who refuse or were unable to sign an informed consent form. SCs will monitor the signing of the Main Study Consent, ESC and PCC. The following SMS reports will be used for monitoring the results of obtaining informed:

- **Recruitment Summary Report** ([Appendix B-2-1: Recruitment Summary Report](#)): This report, described in detail in [Chapter 2.0](#), will show the number of potential participants who are found to be ineligible because they refused or were unable to sign an initial consent form (full or forms consent). (**Note:** This report is no longer available from SMS since the recruitment phase is complete.)
- **PCC Directive/Late Directive** ([Appendix B-3-1: PCC Directive/Late Directive](#)): This report lists the participants who are due to complete the Protocol Changes Consent (PCC) but the form has not been receipted.
- **Biorepository Activity Without ESC Report:** ([Appendix B-10-7: Biorepository Blood Collection](#)) This report will show participants that had biorepository samples drawn without a signed ESC receipted. These will require further investigation and completion of a protocol violation report.
- **List/Count Receipt MDFs** ([Appendix B-17-2: Count/List of MDFs](#)): This report allows you to generate 3 separate listings of MDFs: 1) total number of MDFs receipted by form type; 2) list of MDFs for a specific PID; and 3) MDF for a specific form by PID.
- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report will show all delinquent or outstanding forms, by individual Participant ID. It can be used to identify those participants who have not signed the PCC and ESC.
- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#)): This report gives a summary of the study information for a participant such as PID, Randomization Date, Randomization Group, Participant Name, Gender, Date of Birth and address. Other vital status and cancer information are also presented as well as forms that are outstanding or receipted. This report can be run for selected PIDs or for a block of participants according to their randomization date. The status of the PCC and ESC will be given as “received” or “outstanding”.

### 3.6 Reporting the Results of Obtaining Informed Consent

The SC will transmit the recruitment summary data to the CC as described in [Chapter 2.0](#). This data will include the number of potential participants found to be ineligible because they did not sign a consent form.

## 4.0 RANDOMIZATION/ENROLLMENT PROCEDURES

### 4.1 Overview

In the PLCO trial, half of the study participants will receive screening tests (the intervention group) and half will receive their regular medical care (the control group). Randomization is the process of randomly assigning potential participants to either the intervention or the control group in the trial. Enrollment is signified by assigning a permanent study identification number to a participant. In the PLCO trial, the study sample will be stratified by age and gender within each Screening Center (SC). The goal of each SC will be to enroll 50% men, 50% women such that these participants will fall roughly equally into four age strata: 55-59, 60-64, 65-69 and 70-74.

The Coordinating Center (CC) will provide the SCs with a module within the Study Management System (SMS) for randomizing and enrolling participants. This module will automatically assign potential participants to either the intervention or control group, and will assign Participant IDs.

The SC Coordinator will perform the following activities to complete the randomization and enrollment process:

- Verify the potential participant's eligibility by completing the **Eligibility Verification Form** ([Appendix A-4-1](#)). See [Section 4.2](#).
- Enter the eligibility verification information into the Randomization and Enrollment (RAND) module of the SMS;
- The SMS will randomize the participant into either the intervention or control group and will assign a Participant ID. Complete enrollment by writing the Participant ID, randomization group, and confirmation number on the Eligibility Verification Form and affixing a Participant ID label to the front of the form;
- Receipt the Eligibility Verification Form into the SMS; and
- Notify the participant of his/her randomization group, as appropriate. In the single (pre-randomization) consent approach, intervention and control participants will be advised of their randomization group. In the past, in the dual consent approach, only intervention participants were advised of their randomization group.

The SMS will also provide capabilities for the SC Coordinator to monitor and report the rate of participant accrual to the CC on a monthly basis.

The following sections describe eligibility verification, randomization, enrollment, and monitoring and reporting participant accrual. (Note: The Randomization and Enrollment [RAND] module of the SMS is no longer available since the randomization/enrollment phase is complete.)

### 4.2 Verification of Eligibility

The eligibility of potential participants will be verified using the Eligibility Verification Form. The Eligibility Verification Form collects selected demographic information such as name, date of birth, and gender, and verifies that potential participants do not meet any of the PLCO exclusion criteria. The SC Coordinator will use information from the Eligibility Screener and if available, the medical records, and main consent form to complete the Eligibility Verification

Form. Some SCs may choose to use the Eligibility Verification Form as an eligibility checklist. The form must be completed and retained for all participants randomized into the trial, but need not be completed or may be discarded for individuals who are found to be ineligible for the trial.

The administrative section and Part A of the Eligibility Verification Form will be completed prior to randomization. In the administrative section at the top of the form, the SC Coordinator will record the SC identifiers and the potential participant's name, date of birth, and gender. In Part A, s/he will confirm each exclusion criterion by checking "Yes" or "No" in response to each question. Refer to the Eligibility Verification Form specifications ([Appendix A-4-1](#)) for detailed instructions on completing the Eligibility Verification Form. In order for a participant to be successfully randomized, the answer to each question in Part A of the Eligibility Verification Form must be "No." If any "Yes" boxes are checked, the potential participant is not eligible for the trial and cannot be randomized. The reason for ineligibility will be recorded on the potential participant's tracking record, if not previously recorded. (See [Chapter 2.0](#), for information on maintaining tracking records). As noted above, an Eligibility Verification Form with any "Yes" answer in Part A may be discarded.

### 4.3 Randomizing and Enrolling the Participant

(**Note:** Since the randomization/enrollment phase is complete, the information in this section pertains to the pre-conversion SMS, not the current SMS.) The SC Coordinator will randomize participants by entering the information from the Eligibility Verification Form into the Randomization and Enrollment module of the SMS. The SMS will be installed on the PLCO computer network at a central site at each SC. At SCs which have one or more satellite centers involved in the randomization and enrollment of participants, a SC staff member at the satellite center will complete the Eligibility Verification Form and will call the central site to communicate the information from the Eligibility Verification Form to the Coordinator who will enter it into the computer.

The randomization process will be initiated by entering a valid staff ID number. All SC staff members will be assigned a four-digit identifier and the system will only recognize the ID numbers of staff who are approved to randomize participants. Refer to [Chapter 17.0](#), SC Management, for more information on assigning staff IDs.

Once the randomization has been initiated, the following information will be entered into the system either via batch or interactive data entry:

- **Caller ID:** This is the four-digit identifier of the person who completed the Eligibility Verification Form. This may be a staff member calling from a satellite center for randomization. If the person who completed the Eligibility Verification Form is also performing the randomization at the computer, the caller ID will be the same as the ID entered to initiate the randomization process.
- **Participant Name:** This is the last, first and middle name of the potential participant as it appears on the Eligibility Verification Form.
- **Date of Birth:** This is the potential participant's date of birth from the Eligibility Verification Form.
- **Gender:** This is the potential participant's gender from the Eligibility Verification Form.

The next step in the randomization process is to enter the responses to the questions in Part A of the Eligibility Verification Form into the randomization and enrollment module. The eligibility verification screen in the randomization and enrollment module is identical to Part A of the Eligibility Verification Form. As with the Eligibility Verification Form, the user must enter an "X" in either the "Yes" box or the "No" box in response to each question. Only Eligibility Verification Forms with all "No" answers should be entered. If the user checks "Yes," the system will prompt for the re-entry of the answer. If the user enters a "Yes" answer to a question, after the second "Yes" answer, the randomization process will stop and the participant record will be deleted.

The screens for entering the Eligibility Verification Form data are presented in Figures 4-1 and 4-2.

ELIGIBILITY CRITERIA		CHECK YES OR NO. IF YES CHECKED, STOP. IF NO CHECKED, CONTINUE.	
1. Is this individual younger than 55 years of age or 75 years or older?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	
2. Is this individual undergoing treatment for cancer, other than basal-cell and squamous-cell skin cancer, at this time?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	
3. Has this individual been diagnosed with cancer of the prostate (men only), ovary (women only), colon, rectum, or lung?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	
4. Has this individual had the entire colon, one lung, or the entire prostate (men only), surgically removed?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	

Page 1/2

Enter "x" or "X" to check answer

Figure 4-1. Eligibility Verification Screen 1

ELIGIBILITY CRITERIA		CHECK YES OR NO. IF YES CHECKED, STOP. IF NO CHECKED, CONTINUE.	
5. Is this individual participating in another cancer screening or cancer primary prevention study?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	
6. Has this individual taken Proscar/Propecia/Finasteride in the past 6 months? (men only)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	
7. Is this individual unwilling or unable to sign the trial/consent form?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	
8. Has this individual had more than one PSA blood test in the past three years?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	
9. Has this individual had a colonoscopy, sigmoidoscopy, or barium enema in past 3 years?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	

Page 2/2

Enter "x" or "X" to check answer

Figure 4-2. Eligibility Verification Screen 2

When each of the questions on the eligibility verification screens has been answered "No," the system will randomly assign the individual to the intervention or the control group and will display the following information:

- Date of randomization/enrollment;
- Participant ID;
- Group assignment (intervention or control);
- The ID of the person who completed the Eligibility Verification Form;
- The ID of the person who performed the randomization; and
- Confirmation number.

An **Interactive Randomization Report** ([Appendix B-4-1: Interactive Randomization Report](#)) listing the above information may be printed after each interactive randomization.

During the randomization process, enrollment tables in the SMS are dynamically backed up to the backup tape immediately after each interactive randomization or each batch. (See *Network User's Guide/Network Upgrade Documentation*.)

The SC Coordinator will enroll the participant by recording the information displayed on the screen in Part B of the Eligibility Verification Form, and writing the PID or affixing the PID label to the Eligibility Verification Form immediately after randomization. As an alternative to writing the information from the screen, the SC may attach hard copy documentation of the randomization (screen shot or **Randomization Assignment Report** ([Appendix B-4-5: Randomization Assignment Report](#)) for interactive randomization; **Batch Randomization Report** ([Appendix B-4-2: Batch Randomization Report](#)) for batch randomization) to the Eligibility Verification Form. Refer to the specifications for completing the Eligibility Verification Form ([Appendix A-4-1](#)). After randomization, the Eligibility Verification Form must be receipted into the SMS.

If the participant is being randomized at a satellite center, the staff member who is running the randomization program at the main site will communicate the above information by telephone to the satellite center staff member who will record it in Part B of the Eligibility Verification Form. The Eligibility Verification Form must then be sent to the main site so that it may be receipted into the SMS.

#### **4.3.1 Randomization in the Event of Computer Failure**

If one or more of the PLCO network workstations is down, the SC staff may randomize participants from another workstation. If the entire network is down, no randomizations may take place. Eligibility information for potential participants may be verified in preparation for randomization, but no actual enrollments may take place until the computer network is back on-line. In the event of any type of computer failure the SC should contact the PLCO Network Administrator. (Refer to the *PLCO Network User's Guide/Network Upgrade Documentation* for details).

#### **4.3.2 Randomization From a File of Eligibles (Batch Randomization)**

Some SCs will be tracking recruitment using systems not provided by the CC and will be determining many of the eligibility criteria based on computer searches of hospital/HMO records. In such cases, the SC will extract a file of

eligible candidates for randomization. To avoid entering all the names, dates of birth and genders individually in this type of situation, the SC may load the file of eligible candidates for randomization into the SMS. The SC must ensure that all data in the file are correct, as all of the stratification data cannot be verified by the system and none of the data may be changed once the participants are randomized. The system does check the file for age ineligibles, potential duplicates and incorrect file structure and provides information on such data problems in the Batch Randomization Report ([Appendix B-4-2: Batch Randomization Report](#)). The SC must also verify that each potential participant has signed a consent form. The file of eligible candidates can then be randomized in batch mode. (See *SMS User's Guide/SMS Upgrade Documentation* for more details.)

## 4.4 Post-Randomization Procedures

After randomization and enrollment are completed, a bar-coded label, displaying the assigned Participant ID, will be affixed to the Eligibility Verification Form. Participant ID labels will be generated from the SMS. After the ID label is attached, the form should be receipted into the SMS (see [Chapter 17.0](#) for more information on forms receipt). The SC staff member will create a study folder for the participant and will store the Eligibility Verification Form and the Eligibility Screener in it. These two forms must be kept on file for all randomized participants.

### 4.4.1 Special Procedures for Women Without Ovaries

Women who enter the trial with prior surgical removal of both ovaries will not be given the Transvaginal Ultrasound Screening Examination (TVU) or the CA-125II blood test. Immediately after enrollment of these women into the screening group, the SC staff should complete and receipt one Missing Data Form to indicate that the TVU and CA-125 examinations will not be performed for T0. This will “turn off” system expectations for all 4 years of TVU screening examinations and for all 6 years of CA-125 screening. These exams will not appear on any list of outstanding examinations for these women in any study year.

### 4.4.2 Notifying Participants of Their Group Assignments

After they are enrolled in the trial, *all* study participants will be notified of their group assignment by mail, by telephone or in person.

## 4.5 The Participant ID

The Participant ID is a unique 7-digit number that will be used throughout the study period to link all data associated with an individual. It is part of a common system for reporting to the CC and will be used by all SCs. Participant IDs will be assigned sequentially by the SMS at each SC. The bar-coded ID labels will be generated using the Reports/Labels function of the SMS. (See the *SMS User's Guide/SMS Upgrade Documentation* for further details.) For SCs with satellite centers, a block of Participant IDs will be reserved by the system for each satellite center and Participant IDs will be assigned sequentially within that block. Note that the ID of the person who completed the Eligibility Verification Form must be associated with the satellite in order for the PID to be assigned from the block reserved for that satellite. Each SC will establish pro-

cedures for ensuring that the appropriate labels are distributed to the satellite centers, and that they are correctly assigned and affixed to forms and specimens.

No Participant ID, once assigned, will be changed or reassigned to another participant. In some situations, participant IDs that are not assigned to participants may be deleted from the SC database, but these deletions must be performed by the CC. If the participant is found to be ineligible after the Participant ID has been assigned, the ID will not be reassigned. Similarly, should a participant move to a new SC area during the trial, the Participant ID will not be changed. This policy ensures that data associated with a participant will not be lost or inadvertently attributed to another participant.

## 4.6 Randomization Errors

Although it is critical that the SC is careful in the randomization process, it is inevitable with a population of this size, that some errors may occur. These may include:

- randomizing a participant twice;
- randomizing a participant with the incorrect gender;
- randomizing a participant with an incorrect date of birth; and
- randomizing a participant who is not eligible for the trial.

All of these errors should be documented appropriately either with an SC Report of Protocol Violation (see [Chapter 17.0](#)) and, as necessary, an Administrative Tracking Form (see [Section 4.6.2](#) below). The CC must be contacted in all cases and must make a correction in the SC database for participants who are randomized twice or randomized with the incorrect gender. If a participant is randomized with an incorrect date of birth, this cannot be changed; however, the correct date of birth will be needed for management purposes and should be entered into the "Corrected Date of Birth" field on the Participant Status screen in the SMS (refer to the *SMS User's Guide/SMS Upgrade Documentation*).

### 4.6.1 Documenting Duplicate Randomization

If a participant is randomized twice, the first randomization will be maintained. To document and resolve the error, a Protocol Violation Form should be completed. If the participant was inappropriately screened, the Biorepository and/or UCLA may also need to be notified. In addition, the participant and his/her physician should be informed of the error and any results should be distributed. Exam forms for erroneous screens should not be receipted, instead the results should be entered in the Participant Status Screen. Maintenance of the participant's files is at the discretion of the SC. The charts can be combined or left separate but complete documentation must be kept so that both PIDs are easily identified and the correct records can be traced if necessary. Detailed procedures to be followed for resolving inappropriate screening and follow-up for a duplicate randomization are provided in [Chapter 17.0](#). An exception to this is the case in which a participant is randomized twice at two different screening centers. This situation is not initially considered a Protocol Violation. Such participants may simply be followed as transfer participants. The CC must be notified, and all documentation submitted to the SC Coordinator at Westat before a decision is made.

## 4.6.2 Documenting Randomized Ineligibles

If the SC becomes aware that a randomized participant was ineligible at the time of randomization, the participant should be documented as a “randomized ineligible” on an **Administrative Tracking Form (ATF)** ([Appendix A-4-2](#)). Upon the discovery of a randomized ineligible participant, the SC is not required to complete a Protocol Violation Report. The CC will use ATF reports to determine the number of randomized ineligible protocol violations that have occurred for each SC within a given timeframe. It is therefore important that the SC completes the “Method of Discovery” section of the ATF so it is clear to NCI whether or not the participant provided accurate eligibility information prior to randomization. Detailed instructions for completing the ATF and for followup of randomized ineligibles are presented in [Chapter 17.0](#).

The purpose of the ATF is to differentiate between the following types of situations that may involve randomization of ineligible individuals:

- Intervention and control individuals who were randomized in error (i.e., the participant provided information to the SC indicating his/her ineligibility, but the SC failed to exclude him/her from the trial);
- Intervention and control individuals who were randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization, (e.g., from a review of the baseline questionnaire, during screening or follow-up of screening, through conversations with the participant, etc.) that the information provided had been incorrect.

Refer to Appendix [Appendix A-4-2](#) for specifications for completion of the Administrative Tracking Form. (**Note:** The entry of the ATF form is no longer available from the SMS.)

The **Report of BQ/RAND Discrepancies** ([Appendix B-4-7: Report of BQ/RAND Discrepancies](#)), formerly called the Randomized Ineligible Report, is automatically generated from Baseline Questionnaire data to identify **potential** randomized ineligibles. This report will identify participants whose Eligibility Screener shows that they are eligible but then later their Baseline Questionnaire shows one or more exclusion criteria. If a discrepancy exists between the Eligibility Screener and the BQ in terms of the participant’s history of PLCO cancer, data retrieval should be performed to verify physician-confirmed diagnoses of cancer. The results of this data retrieval should be listed on the ATF. If the Report of BQ/RAND Discrepancies lists a flexible sigmoidoscopy or prostate specific antigen examination (PSA), it is not necessary to perform data retrieval to confirm the timing of the examination. However, an ATF must be completed for these cases.

All individuals discovered to be ineligible at the time of randomization will continue to be followed regardless of the method of discovery. If a randomized ineligible is in the screening arm of the trial, s/he should be offered all screening examinations unless the reason for ineligibility precludes screening. As with all other participants, if a randomized ineligible refuses a screening test, the test should not be performed.

## 4.7 Monitoring Participant Accrual

The SC Coordinator will monitor participant accrual throughout the recruitment period. The following information will be monitored:

- The number of participants who have been enrolled (out of the total number identified); and
- The distribution of enrolled participants by age, gender and race.

Monitoring the number of participants who have been enrolled will allow the SC Coordinator to compare recruitment progress to participant accrual goals. Monitoring the distribution of enrolled participants by age and gender will allow the SC Coordinator to assess whether the SC is enrolling 50% men and 50% women and the distribution of enrolled participants within the four age strata. Monitoring recruitment by race will allow the SC Coordinator to assess the level of enrollment of minority individuals.

To facilitate this monitoring activity, the Randomization and Enrollment module of the SMS will produce the following reports (**Note:** These reports are no longer available from the SMS):

- **Enrollment Status Report** ([Appendix B-4-3: Enrollment Status Report](#)): This report summarizes the number of participants who have been randomized/enrolled during a specified month and year, and cumulatively, and the distribution between intervention and control groups.
- **Enrollment Summary Report** ([Appendix B-4-4: Enrollment Summary Report](#)): This report summarizes the number of participants in each randomization group, the mean age within each randomization group, the mean age overall, and the number of males and females in each randomization group. For the four age ranges, the report summarizes the number of participants in each age range, the mean age, and the number of males and females within each age range.

To facilitate the day-to-day management of SC operations, the SMS will also produce the following reports (**Note:** These reports, with the exception of the Study ID Assignment Report, are no longer available from the SMS):

- **Randomization Assignment Report** ([Appendix B-4-5: Randomization Assignment Report](#)): For a specified time period, this report shows the group assignment (intervention or control), gender, date of birth, and date of randomization for each Participant ID.
- **Study ID Assignment Report** ([Appendix B-4-6: Study ID Assignment Report](#)): This report lists the name, Participant ID, randomization date, gender, date of birth, modified date of birth, group assignment, and telephone number for each individual enrolled in the study. The report may be sorted alphabetically by last name or by Participant ID. It may be used as a reference report for a variety of SC management tasks and is for internal SC use only.
- **TASR/RAND Comparison Report** ([Appendix B-2-11: TASR/RAND Comparison Report](#)): This report compares the data for potential participants in the Tracking and Summarizing Recruitment (TASR) module with enrolled participants in the Randomization and Enrollment (RAND) module to highlight data inconsistencies as well as pending randomizations.
- **Report of BQ/RAND Discrepancies** ([Appendix B-4-7: Report of BQ/RAND Discrepancies](#)): Formerly the Randomized Ineligible Report, this report is generated from the Data Entry and Editing System (DEES) and identifies possible randomized ineligible based on participant

responses to questions on the Baseline Questionnaire regarding personal cancers and prior use of PLCO screening examinations.

The following PLCO system function supports the development of customized reports for management of SC randomization and enrollment activities.

- **Data Export:** This function will allow the SC to export data from the RAND data tables to files that may be used to produce customized reports. Appendix E of the *SMS User's Guide/SMS Upgrade Documentation* contains information regarding use of the data export option.

All of the above reports are designed for internal SC management use and may be printed as often as necessary. Reports that contain participant identifiers such as names, will be used internally at the SC, and their use and storage will be controlled by the SC Coordinator.

## 4.8 Reporting Participant Accrual to the Coordinating Center

The SC Coordinator will transmit participant accrual data to the CC on a monthly basis. Reporting will be done electronically through the transmission option(s) available in the Data Transmission application of the PLCO computer system. This module will automatically extract all data related to participant accrual that must be reported to the CC. No participant identifiers will be reported. Electronic data transmission is described further in the *SMS User's Guide/SMS Upgrade Documentation*.

## 5.0 ADMINISTERING THE BASELINE QUESTIONNAIRE AND BASELINE LOCATOR FORM

### 5.1 Overview

A questionnaire will be administered to all eligible participants recruited into the trial. The purpose of this questionnaire is to collect baseline information on demographics, cancer risk factors and history of cancer screening. Participant identifying and locating information will also be collected. Procedures for administration and processing of the **Baseline Questionnaire** and **Baseline Locator Form** are presented in the following sections. (**Note:** Entry of the Baseline Questionnaire and Baseline Locator Form are no longer available from the SMS.)

### 5.2 Administration of the Baseline Questionnaire and Baseline Locator Form

There are two versions of the Baseline Questionnaire, one for male participants ([A-5-1](#)) and one for female participants ([A-5-2](#)). The Baseline Questionnaire is used to collect information on demographics, occupational history, personal and family cancer history, lifestyle habits and history of screening for prostate, lung, colorectal and ovarian cancer. The Baseline Questionnaire is designed as a mail out questionnaire to be self-administered by the study participant. Although the Baseline Questionnaire has been designed for this method of administration, it can also be administered by Screening Center (SC) staff as an in-person interview during an SC visit or as a telephone interview, if preferred.

Accompanying the Baseline Questionnaire is the Baseline Locator Form ([A-5-3](#)). This form is used to collect information that will help the SC locate the participant in the future, including name, address and phone information, Social Security number, names of household members and two contact persons for each participant.

The Baseline Questionnaire and Baseline Locator Form may be administered to all PLCO participants either before or after randomization and enrollment have been completed, but they may *not* be administered before eligibility has been determined. Once eligibility has been determined, the Baseline Questionnaire and Baseline Locator Form will either be mailed or administered by the SC staff. If the Baseline Questionnaire is completed more than one month prior to randomization, it should be administered again.

Regardless of whether the Baseline Questionnaire is administered before or after randomization, the SC should make every effort to have it completed by the end of the participant's reporting window (1 month after randomization). At the latest, the Baseline Questionnaire must be completed by the end of the participant's delinquency period (3 months after randomization).

Specifications for completion of the Baseline Questionnaires and Baseline Locator Form are presented in Appendices [A-5-1](#), [A-5-2](#) and [A-5-3](#).

### 5.3 Preparing Mailings of the Baseline Questionnaire and Baseline Locator Form

The SC Coordinator may use the SMS to determine which participants are due to complete the Baseline Questionnaire and/or Baseline Locator Form. The **Baseline Directive** ([Appendix B-5-1: Baseline Directive](#)) generated from the Requests Module of the SMS, lists the participants who are in their reporting window for baseline forms but have not yet completed them. (**Note:** The Baseline Directive is no longer available from the SMS.)

SCs who choose to mail out the Baseline Questionnaire and Baseline Locator Form to study participants will be responsible for preparing and mailing the two forms and all related materials, including a cover letter. Each SC will develop their own cover letter for the Baseline Questionnaire and Baseline Locator Form mailing.

The mailing package will consist of a cover letter, the appropriate version of the Baseline Questionnaire booklet (male/female), the Baseline Locator Form and a postage-paid, return envelope. Prior to the mailing of questionnaires to randomized participants, the SC is responsible for labeling the Baseline Questionnaire and Baseline Locator Form with the appropriate Participant ID label. (Questionnaires that are mailed to non-randomized participants will require linking the participant by name and date of birth when the Participant ID is assigned after randomization.) The Participant ID labels and the address labels for both the mailing envelope and the return envelope may be generated by the individual tracking module of the Study Management System (SMS). Each SC may determine whether it is preferable to use the SMS or some other SC support system already in place for mailing efforts.

### 5.4 Receipt, Edit and Data Entry of Baseline Questionnaire and Baseline Locator Form Data

Baseline Questionnaire mailings will be done on a regular basis as determined by the recruitment schedule of each SC. With each batch of mailings, the SC will record in the SMS the date the package was mailed for each study participant. The SMS will allow the SC to record and review all activities associated with the Baseline Questionnaire mailings, including keeping a record of the first and latest mailing dates.

When the completed questionnaires are returned to the SC, the SC staff will receipt them into the SMS. This may be done through interactive data entry, through keyed batch receipt, or through an update of the SMS database from DEES. Regardless of the method of receipt, the forms should be receipted as expeditiously as possible since the system will not consider any activity as having occurred until the associated form has been receipted.

During the receipt process, the following data items are recorded in the SMS:

- date of birth (only entered during interactive data entry for purposes of identification of the participant);
- race;
- education level;
- cancer status; and
- date of completion

Note that if the date of completion is left blank on the questionnaire, the SC should either contact the participant to obtain the correct date, or use an estimated date of completion. (Refer to the specifications for completion of the Baseline Questionnaire).

Recording data on age, race and education level will allow the SCs to evaluate and prepare reports on the demographic characteristics of the study population. Recording data on cancer status will allow SCs to identify some randomized ineligibles and to monitor non-PLCO cancers.

A sample receipt control screen for the Baseline Questionnaire-Male is presented in Figure 5-1.

Participant ID: 202664-6 (View/Update) Form Type: BQM Date Received: 1/16/96

2. Which race group best describes you? Race: WH  
 2a. Are you of Hispanic origin (Y/N)?

3. What is the highest grade or level of schooling you completed? 7

29. Have you ever been diagnosed as having cancer? N

30.	Cancer Code	What type of cancer did you have?
1st CANCER		
2nd CANCER		
3rd CANCER		

48. Date this questionnaire completed: 12/30/95  
 If completion date was estimated, please mark "X":

Viewing Bqm (8273 records on file)

**Figure 5-1.** Receipt Screen for Baseline Questionnaire-Male

Receipt of the Baseline Locator Form will involve entering the form type and the Participant ID into the SMS. All of the Baseline Locator data will also be manually entered into the SMS. Because this data entry is time consuming, the Baseline Locator Forms may be receipted in batch and their data entered into the SMS at a later time. These data will be used for generating Follow-up Locator Forms, for annual follow-up mailings, and for merge files for cover letters to participants and physicians. A sample receipt control screen for the Baseline Locator Form is presented in Figure 5-2.



Although each SC will establish a schedule for making follow-up attempts to non-respondents, we recommend an initial recontact approximately three weeks after the Baseline Questionnaire has been mailed. The SC may arrange for either a reminder phone call, a second mailing of the Baseline Questionnaire, an in-person interview if the participant is coming to the clinic, or a telephone interview.

Data retrieval will be conducted for key items on the Baseline Questionnaire and the Baseline Locator Form as identified from the computer edit. The key items on the Baseline Questionnaire are data that NCI has determined are critical for analysis. Since items on the Baseline Locator Form are necessary for future contact of the participant, each SC will determine which are key for data retrieval. The SC will contact the participant for completion of any critical data item which is incomplete, missing, or illegible. The SC may, if desired, use this opportunity to also obtain information regarding data items which are considered non-critical. Listed below are the critical data items of the Baseline Questionnaire requiring data retrieval:

Critical Data Items	Question Number
Date of Birth	Cover Page
Race	2
Smoking	10,12
Personal Cancer History	29,30
Live Births (Female)	41
Ovaries Removed (Female)	49,50
Prostate Surgery (Male)	38
Screening Exams (Female)	55,58-62
Screening Exams (Male)	43-47

If a participant fails to complete the Baseline Questionnaire before the end of the delinquency period, the SC Coordinator will complete a Missing Data Form to indicate that the data will not be collected. If no other reason is identified, the reason for the missing data will be recorded as "Out of Window." If the participant returns the Baseline Questionnaire after a Missing Data Form has been received in its place, the Missing Data Form should be deleted from the SMS and the Baseline Questionnaire should then be received into the SMS. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for instructions on deleting Missing Data Forms from the system. (See [Chapter 17.0](#) for additional information on the Missing Data Form.)

There may be a small number of cases in which more than one Baseline Questionnaire is completed by the same participant. Some of the common situations involving duplicate Baseline Questionnaires and their resolutions are as follows:

1. **Situation:** Based on the participant's name, the SC may send a female participant a Baseline Questionnaire - Male in error and it may be completed and returned by the male participant.

**Resolution:** Do not receipt and scan the questionnaire for the wrong gender. The SC should transcribe non-gender-specific information onto the appropriate blank, gender-specific form, and then contact the participant to collect missing gender-specific data. If the wrong questionnaire was already receipted and/or scanned, it must be deleted from SMS and/or DEES.

2. **Situation:** After randomization, the participant completed the questionnaire and returned it late (by mail). The SC considered the participant a non-respondent and sent another questionnaire. The two questionnaires crossed in the mail.

**Resolution:** In this case, the form completed on the earliest date within the reporting window should be receipted and scanned. If both questionnaires were receipted and/or scanned before the error was detected, the one with the later date should be deleted from SMS and/or DEES.

Before any forms are deleted, it should be verified that the multiple forms were completed by the same person (rather than mislabeled).

## 5.6 Monitoring Completion of the Baseline Questionnaire and Baseline Locator Form

Reports generated by the PLCO computer system will assist the SC Coordinator in monitoring receipt of the Baseline Questionnaire and the Baseline Locator Form. These include:

- **Open Forms Report** (SMS) ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report will show delinquent or outstanding Baseline Questionnaires and Baseline Locator Forms by individual Participant ID.
- **Duplicate Report** (DEES) ([Appendix B-5-2: Duplicate Forms Report](#)): This report will list PIDs for which more than one Baseline Questionnaire is scanned.
- **DEES/SMS Comparison** (DEES) ([Appendix B-17-4: Population Profile Report](#)): This report compares like data items between SMS and DEES for forms receipted and scanned.
- **SMS/DEES Synchronization Reports** (DEES) ([Appendix B-17-6: Intervention Activities Report](#)): This report identifies forms scanned in DEES but not in SMS or receipted in SMS but not yet scanned.

## 5.7 Transmitting Data to the Coordinating Center

The Baseline Questionnaires and Baseline Locator Forms will be filed at the SC. Data from the Baseline Questionnaire will be transmitted to the Coordinating Center (CC) using the Data Transmission application module of the PLCO computer system. Problems identified by the CC will be sent to the SC Coordinator for resolution. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for specifications on data transmission.

## 6.0 SCHEDULING, CONDUCTING AND REPORTING BASELINE SCREENING TESTS AND ADMINISTERING THE DIETARY QUESTIONNAIRES

### 6.1 Overview

Screening Centers (SCs) will schedule and conduct baseline-screening visits with all participants randomized to the intervention arm of the study. The baseline-screening visit is referred to as T0. The purpose of this visit is to conduct screening tests for the PLCO cancers. Intervention participants will undergo the following tests at the baseline visit:

- All participants:** Chest X-ray  
Flexible Sigmoidoscopy
- Women Only:** Ovarian Palpation Examination\*\* (This exam was discontinued in December 1998)  
Transvaginal Ultrasound\*  
CA-125II Blood Test\*
- Men Only:** Digital Rectal Examination  
PSA Blood Test

The SC Coordinator will contact participants to schedule a baseline-screening visit to take place within one month of the participant's enrollment in the study. The screening tests will be conducted according to the PLCO protocols described in Chapters 10 through 15. All examinations for a study year should be scheduled to take place in one visit to the Screening Center. Only if necessary should the examinations take place in more than one visit. The SC Coordinator will monitor the completion or non-completion of all required examinations and study forms. The results of all screening tests will be transmitted to the Coordinating Center (CC) on a monthly basis. The SC Coordinator will also oversee the process of reporting screening test results to participants and physicians. The following sections describe the scheduling, conduct, monitoring, and reporting of the baseline screening tests.

Also included in this chapter are procedures for administration and handling of the PLCO dietary questionnaires. The **Dietary Questionnaire (DQX)** will be administered to all intervention group participants at baseline and the **Diet History Questionnaire (DHQ)** will be administered to all control group participants at baseline (in addition to intervention participants at T3).

### 6.2 Scheduling the Baseline Screening Visit

The baseline-screening visit will be scheduled to take place within one month after randomization and enrollment of the participant in the trial. This period of one month is called the participant's "reporting period." During the reporting period, the SMS has "expectations" that the screening exam forms will be receipted. After a participant has moved out of his/her reporting period, i.e.,

after one month, the SC should continue to attempt to collect data from the participant (i.e., perform screening examinations) until three months past the participant's randomization date. This period from one month to three months past the randomization date is called the "delinquency period." During the delinquency period, the SMS continues to have "expectations" for the data collection forms. After three months, the SC should discontinue all attempts to collect data until the following annual reporting window begins. (See Figure 6-1 below). If, however, a participant requests screening outside his or her annual activity window, the screening should be performed up to 1 month prior to the T1 randomization anniversary date. (See [Chapter 17.0](#) for a discussion of data collection outside the window). If the participant is unable to complete the T0 flexible sigmoidoscopy examination during his or her activity window, it may be performed at his or her request up to 1 month prior to the T1 randomization anniversary date.

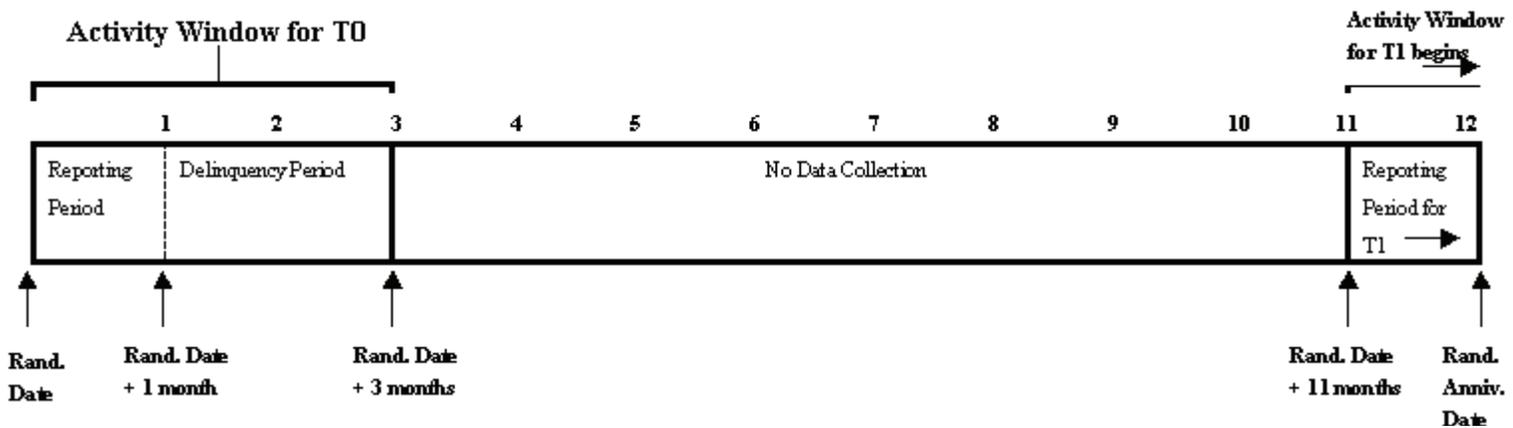


Figure 6-1. Baseline Study Year T0

A brief description of how the SC will schedule appointments for a baseline screening visit is given below:

- Appointments will be scheduled for participants who are currently in their reporting window or their delinquency period, and who have not completed all baseline-screening examinations.
- The SC may generate the **Intervention Activities Report** ([Appendix B-17-6: Intervention Activities Report](#)) from the SMS. This report lists participants who are currently in their reporting window or their delinquency period. [Chapter 17.0](#) contains a detailed explanation of the Intervention Activities Report. (**Note:** The Intervention Activities Report is no longer available from the SMS.)
- The SC may also generate the **Participant Overview Report** ([Appendix B-17-7: Control Activities Report](#)) which provides information about the status of study activities for individual participants.
- Once participants who need appointments are identified, the SC staff will contact the participants (by mail or phone) to schedule an appointment;
- Appointments will be recorded in a scheduling system. Each SC will develop its own scheduling system for tracking participant contact and appointment times.

- It is recommended that each participant be recontacted in advance of the appointment date either by phone or mail and given the following information:
  - ▶ a reminder of the appointment time and place, with maps or parking instructions, as appropriate;
  - ▶ a description of each of the procedures; and
  - ▶ instructions for preparing for the screening tests, such as how to use enemas, etc.

The SC may wish to develop “Participant Information Sheets” for this purpose. Such information sheets must be approved by the NCI prior to distribution to participants.

The SC Coordinator should aggressively attempt to reschedule no-shows and cancellations within the reporting window.

## 6.3 Documenting Non-Participation

When the SC Coordinator attempts to schedule an appointment for the baseline visit, s/he may encounter participants who are unable or unwilling to participate in one or more study activities. In addition, there may be situations in which the study protocol prohibits completion of a screening examination (e.g., when a PLCO organ has been removed or when a PLCO cancer has been diagnosed). Please refer to [Chapter 7.0](#) for a complete discussion of non-participation in screening activities.

When a participant does not complete one or more study activities, the SC Coordinator will complete a **Missing Data Form** ([Appendix A-17-1](#)) or a **Non-response Form** ([Appendix A-17-2](#)), depending on the situation. During the period from the end of the delinquency period until the beginning of the following year’s reporting period, the SMS has “expectations” for Missing Data Forms instead of data collection forms. The completion of these forms at baseline is described below.

### 6.3.1 The Missing Data Form

If a participant firmly refuses or is unable to schedule a baseline screening visit or to complete all of the tests during the reporting window or the delinquency period, but may be willing or able to complete study activities in the future, the SC Coordinator will complete the Missing Data Form as follows:

- Record the SC identifying information on the top of the form and affix the Participant ID label.
- Check the box for each baseline form that will not be completed.
- Record the study year code as “T0”.
- Record the reason code and the appropriate subcode indicating the reason for the missing data.
- Receipt the form into the SMS and file it in the participant’s folder.

If the participant returns a questionnaire or undergoes screening after a Missing Data Form has been receipted for that activity, the Missing Data Form should be deleted from the SMS and the appropriate data form should then be receipted into the SMS. Refer to the *SMS User’s Guide/SMS Upgrade Documentation* for instructions on deleting Missing Data Forms from the system.

### 6.3.2 The Nonresponse Form

If a participant firmly refuses or is unable to schedule a baseline screening visit and will no longer participate in any aspect of the trial that involves participant contact, such as screening visits and questionnaires, the SC Coordinator will complete the Nonresponse Form as follows:

- Record the SC identifying information on the top of the form and affix the Participant ID label.
- Check the reason for nonresponse and describe in detail medical conditions, refusals and loss of contact.
- Record the effective date (i.e. date of refusal, etc.).
- Receipt the form into the SMS and file it in the participant's folder.

The Non Response Form should be completed at the discretion of the SC Coordinator, but its use should be minimized. It should only be used when there is no reasonable chance that the participant will be willing or able to participate in study activities in the future.

Specifications for the completion of the Missing Data Form and the Nonresponse Form are included as [Appendix A-17-1](#) and [Appendix A-17-2](#), respectively. A further discussion of these two forms is given in [Chapter 17.0](#).

## 6.4 Preparing for the Baseline Screening Visit

Before the baseline-screening visit, the SC Coordinator will prepare the following study forms needed for the visit:

#### For Males:

Participant Control Record (PCR)  
Blood Collection Form (BCF3)  
Chest X-Ray Screening Examination Form (XRY2)  
Flexible Sigmoidoscopy Screening Examination Form (FSG2)  
Digital Rectal Screening Examination Form (DRE2)

#### For Females:

Participant Control Record (PCR)  
Blood Collection Form (BCF3)  
Chest X-Ray Screening Examination Form (XRY2)  
Flexible Sigmoidoscopy Screening Examination Form (FSG2)  
Transvaginal Ultrasound Screening Examination Form (TVU2)

The Participant Control Record is described below in [Section 6.5](#). The examination forms are described in Chapters 10 through 15. Note that female participants who do not have one or more ovaries intact will not be given transvaginal ultrasound or CA125II exams. As of December 1998, the ovarian palpation screening exam will no longer be performed for any female participants.

It is strongly recommended that SC office staff prepare the examination forms in advance of the visit by affixing Participant ID labels to them and completing the administrative section at the top of each form. Note: Only the administrative section of the data collection forms should be completed in advance of the visit. Pre-filling of other sections can result in data collection errors. It is also recommended that the complete study folder containing enrollment documents, correspondence, medical record abstracts, etc., not be sent to the clinic for the participant's screening visit; only the documents related to the screening should be sent to the clinic.

## 6.5 Conducting the Baseline Screening Tests

According to the study protocol, the baseline screening visit should take no more than two hours to complete. The SC is required to explain the procedures to the participant in advance of the tests. As noted above in [Section 6.2](#), this may also be done in writing (via participant information sheets) in advance of the visit. It is also recommended that the procedures be reviewed verbally during the visit. This can be accomplished in an intake interview in which the individual procedures and the flow of the visit are explained, and the participant's questions are answered. The SC may wish to also take the participant's medical history and vital signs at this time (a required activity for the flexible sigmoidoscopy examination - see [Chapter 13.0](#)). The procedures for conducting the screening tests are described in Chapters 10 through 15.

## 6.6 Documenting the Baseline Screening Visit

After each examination is completed, the examiner will document the results of the examination on the appropriate screening examination data collection form.

### 6.6.1 The Participant Control Record

A **Participant Control Record**, shown in [Appendix A-6-1](#), will be used to track the status of each screening test and level of referral for each test. The Participant Control Record may be completed, in part, by each examiner, or may be completed by staff at the end of the visit, based on a review of examination forms. The Participant Control Record will be completed as follows:

- At the beginning of the screening visit, the SC Coordinator will ensure that the administrative section at the top of the Participant Control Record is complete and that a Participant ID label has been affixed to the form.
- The SC Coordinator will record the time the participant arrived at the SC next to "Screening Visit Total: Time In."
- The Participant Control Record will accompany the participant as s/he goes from one examination to the next. The order of examinations, however, will not necessarily proceed according to the order in which the tests are listed on the Participant Control Record. Rather, the order will be dictated by protocol restrictions and by the setup of the SC facilities. (Protocol restrictions regarding the order for the blood collection, flexible sigmoidoscopy and transvaginal ultrasound are described in Chapters 10, 14 and 15, respectively.)
- The examiner will record the result of the examination in the Exam Result column. Possible exam results are as follows:
  - AS=Positive Screen
  - AN=Negative Screen, Other Abnormalities
  - NG=Negative Screen, No Abnormalities
  - IN=Inadequate
- If the examination was not done, the SC Coordinator will record "ND" in the "Not Done/Result Pending" column. If the result of the examination is pending, the SC Coordinator will record "RP" in this column.

- For all exams, the SC Coordinator will record a number in the Level of Referral column to indicate the level of referral.

Possible levels of referral are as follows:

- 1 = Significant Abnormality, Referral
- 2 = Moderate Abnormality, Referral
- 3 = Slight Variation from Normal, No Referral
- 4 = Normal/Result Not Available, No Referral

An exam result of Positive Screen must have a level of referral of 1. An exam result of Negative Screen, No Abnormalities must have a level of referral of 4.

- The examiner who assigned the final result to the examination should record his/her ID in the Staff ID column. If the examination result is pending (activity status of RP), the Staff ID should be left blank.
- At the end of the screening visit, the SC Coordinator will write the time the participant left the SC next to "Screening Visit Total: Time Out."

Specifications for the completion of the Participant Control Record are presented as [Appendix A-6-1](#)

At the end of the visit, before the participant leaves the SC, the SC Coordinator will review the Participant Control Record to make sure that all required tests were performed. If a screening test needs to be rescheduled, it should be rescheduled for a date that is within the reporting window (i.e., within one month of the randomization date), but not later than three months past the randomization date. The rescheduled date will be noted in the SC's appointment scheduling system.

After the visit, the examination forms must be entered into the Data Entry and Editing System (DEES) and the Study Management System (SMS). Once the exam forms are scanned and the Participant Control Record is entered, computer edits will verify that the referral codes correctly correspond to the result codes. In the majority of cases these edits will identify situations in which the SC should modify erroneous coding. In rare cases where the SC reviews the results and the mismatched coding is valid, procedures for results reporting will be handled on a case by case basis. In these instances, the SC should contact User Support for assistance. Please refer to [Chapter 17.0](#) for a discussion of PLCO forms processing.

### **6.6.2 Documenting a Duplicate Screening Visit**

If a participant is inadvertently screened twice in the same study year, the exams from the first visit should be considered the official PLCO exams. In order to document the situation, the following steps should be taken:

1. Any blood collected at the second visit should either be discarded or processed by the SC outside of the PLCO Trial.
2. The forms for the second visit should not be scanned. Instead, the exam results should be entered into the Participant Status Screen.
3. The hardcopy exam forms from the second visit should be kept in the participant's file with a note (initialed and dated) documenting the situation.

4. The participant and his/her physician should be informed of the error and given the results of all exams (from both the first and second visit).
5. A Protocol Violation Report ([Appendix A-17-7](#)) should be completed and sent to the CC.

## 6.7 Monitoring the Baseline Screening Tests

The SC Coordinator will monitor the completion of the baseline screening tests for all intervention participants using the following SMS reports:

- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report will show all delinquent, incomplete or outstanding forms for each participant. Since the receipt of forms and specimens indicates the successful collection of study data, the SC Coordinator will use this report on a regular basis for monitoring the status of intervention participants during the study.
- **Results Pending Report** ([Appendix B-6-1: Results Pending Report](#)): This report lists all participants for whom screening examination results are pending (status of RP). The report shows the PID, study year, form type, and examination date.
- **Results Pending Three or More Weeks Since Exam Date** ([Appendix B-6-2: One or More Exam Statuses = Results Pending Three or More Weeks Since Exam Date](#)): This report lists all participants for whom at least one examination is still pending (RP status) three or more weeks after the examination date. It shows the PID, study year, exam date, status of all examinations, and date the Screening Test Results Report was sent.
- **Referrals for Exam Forms** ([Appendix B-6-3: Referrals for Exam Forms](#)): This report displays the referral levels assigned to individual examinations. It may be requested for specific participant IDs, for all examinations that took place during a range of dates or for all participants. The report may be sorted by PID, examination date, referral code or study year.
- **QA Checks Report** ([Appendix B-6-4: QA Checks Report](#)): This report prints discrepancies between the results of regular examination and medical record abstract forms and their associated quality assurance forms. It presents counts as well as a listing of discrepant cases.
- **Examination Summary Report** ([Appendix B-6-5: Examination Summary Report](#)): This report generates summaries of exams performed. The user may select any combination of exams and a range of visit dates. This is a four part report: (1) exams performed, (2) exams by examiner ID, (3) exams by outcomes, and (4) outcome by examiner.

Instructions for generating and using the above reports are provided in the *SMS User's Guide/SMS Upgrade Documentation*. Reports can also be generated to track an individual participant's status with regard to the baseline screening tests. These reports are described in [Chapter 17.0](#).

The SC Coordinator should attempt to resolve all problems related to the screening tests and their associated forms before the participant moves out of his/her reporting window. If a participant reaches the end of his/her delinquency period without completing all of the required study activities, the SC Coordinator will complete a Missing Data Form to indicate which activities were

not completed. If no other reason is identified, the reason for the missing data will be recorded as Code 6 "Out of Window", subcode 666.

## 6.8 Reporting Results of the Baseline Screening Tests

The SC Coordinator is responsible for reporting the results of the baseline screening tests to the participant, to the participant's physician of choice, and to the CC. The procedures for reporting results are described below.

### 6.8.1 Reporting Results Immediately After the Screening Exam

The SC may choose to provide preliminary verbal results of an exam to the participant immediately after the exam. At this time the examiner should remind the participant that written results will also be sent in 3 weeks. Regardless of the outcome of a screening exam, no recommendations for specific methods of follow-up, such as colonoscopy, biopsy, etc., should be provided either to the participant or to his/her physician. It is also a violation of the PLCO protocol to provide follow-up recommendations based on information obtained outside of the PLCO screening examination. If the examiner is concerned about a participant's level of risk (due to family history, past results, etc.) s/he may want to encourage the participant to talk to his/her physician about these issues. For example, the examiner may say: "due to your family history of cancer, you may want to talk to your physician about the appropriate way to monitor your health..." If the SC provides follow-up recommendations either verbally or in writing to either the participant or to his/her physician, the SC must submit a Protocol Violation Report ([Appendix A-17-7](#)) to the CC.

### 6.8.2 Generating the Screening Test Results Report (STRR)

The **Screening Tests Results Report (STRR)** ([Appendix B-6-7: Screening Test Result Report Not Sent Three or More Weeks Since Exam Date](#)) may be used to report test results to participants and their physicians. There will be a version of this report for male participants and a version for female participants. This report will be automatically generated by the SMS upon receipt of the blood test results from UCLA. The report can also be reprinted, if necessary (refer to the *SMS User's Guide/SMS Upgrade Documentation* for more information on generating the Screening Tests Results Report). Note: Since the STRR may be automatically generated when the blood test results are received, the SC must be sure to generate the STRRs for participants who did not undergo the PSA/CA125II blood test or those samples that were not shipped.

The Screening Tests Results Report will contain the following information:

- Participant Name;
- Participant Address;
- Participant Telephone Number;
- Study Year;
- Examination Date;
- Results of Examinations; and
- Type of test, analysis lab, and reference range (for blood assays).

The report will list only those examinations appropriate to the participant's gender.

Several copies of the STRR should be made. One copy of the STRR will be sent to the participant, one copy will be filed in the participant's folder at the SC, and one or more copies may be sent to physicians as appropriate.

The SCs should generate all STRRs regardless of results, or lack thereof. For example, a woman without ovaries will not have any results after her T4 visit but an STRR documenting the visit should still be generated and filed in the participant's file for record keeping purposes. In addition, the SC may want to draft a letter to be sent to acknowledge and appreciate participant efforts even when there are no results to report. The SC should submit such a "No Results" letter to NCI for approval, with a copy to the CC.

### **6.8.3 Reporting Results Using an SC-Designed Report**

The SC may elect to send notification of the test results using a form other than the Screening Test Results Report generated from the SMS. The SC-designed form must include all of the elements listed above. In addition, SCs not sending the SMS STRR must generate one copy of it for the participant's file, in addition to maintaining a copy of the SC-designed report that was sent to the participant and physician. The SC should submit such a "No Results" report to NCI for approval, with a copy to the CC.

### **6.8.4 Reporting Detailed Findings of the Examinations**

If a SC wishes to report detailed findings to participants and/or physicians (to supplement the Screening Test Results Report), the SC may use the **Screening Examination Reports** that are available in DEES (Appendices B-11-1 through B-15-1). If the SC uses some other method to report detailed findings, the SC must obtain NCI approval of such reports. In addition, a copy of detailed findings reports that are sent to participants and/or physicians must be filed in the participant's study file.

### **6.8.5 Reporting Results of the Screening Tests to Participants and Physicians**

Screening test results will be sent to participants and physicians with a separate cover letter. Each SC is responsible for drafting its own cover letters, however the letters must include the elements described below.

*The participant letter must include:*

- A disclaimer stating that the examination is a screening examination, not a comprehensive examination;
- A statement advising the participant to seek medical attention in the case of abnormal screening test results;
- A statement that the results have been sent to his/her physician of choice (if he/she provided the name of a physician); and
- The SC telephone number and the SC Coordinator's and Principal Investigator's names for any questions or concerns the participant may have.

*The physician letter must include:*

- A statement that the PLCO trial is a NCI sponsored scientific study designed to evaluate screening tests for prostate, lung, colorectal and ovarian cancer;
- The name and date of birth of the participant whose results are being reported;
- A disclaimer stating that the examination is a screening examination, not a comprehensive examination;
- A statement indicating that the participant has been advised to seek medical attention in the case of abnormal screening test results;
- A statement encouraging the physician to see the participant for diagnostic follow-up of abnormal screening tests;
- A statement inviting the physician to contact the SC for more information regarding the diagnosis and treatment of PLCO cancers; and
- The SC telephone number and the SC Coordinator's and Principal Investigator's names for any questions or concerns the physician may have.

A sample participant results letter is presented in [Appendix C-6-1](#). A sample physician results letter is presented in [C-6-2](#). All cover letters must be approved by NCI prior to use at the SC.

Participants and physicians should be notified in writing of all test results within three weeks of the screening visit. A copy of all written correspondence to participants and physicians should be kept in the participant's study file. The SC Coordinator should monitor the mailing of test results on an ongoing basis. See [Section 6.7](#)

At the beginning of the study, each participant will be asked to provide the name, address, and telephone number of his/her primary care physician on the Baseline Locator Form. The SC will send the participant's test results to this physician. During the baseline screening visit, the SC staff should confirm with the participant that this is the appropriate physician to whom results should be sent, and that the name and address are correct. If a participant does not have a physician, or if a specialist is needed to follow-up a positive screening test result, the SC Coordinator will, at the participant's request, advise him/her to consult an appropriate physician, and will send the participant's screening test results to this referral physician. Participants and primary care physicians will be notified of both normal and abnormal test results. It is acceptable to send referral physicians the results of abnormal tests only.

### **6.8.6 Correcting an Erroneous Results Report**

If it is discovered that incorrect results were sent to the participant or his/her physician, the correct results must be reported, regardless of the type of error (underestimate or overestimate of seriousness). The manner and timing of this reporting should be handled on a case by case basis at the discretion of the screening center. In addition to reporting the correct results, the SC should also report this error to the CC as a protocol violation.

In situations where a DE form was completed, receipted and scanned for an erroneous "AS" exam—and no cancer was diagnosed—the DE form should be deleted as follows:

1. Update the hardcopy screening exam form with the correct exam result;

2. Delete the DE screening exam from both the SMS and DEES;
3. Rescan and re-edit the screening exam form in DEES;
4. Update SMS from the DEES screening exam data (or update the SMS exam result on the PCR interactively);
5. Review the cancer data on the SMS Participant Status Screen for appropriate data;
6. Contact PLCO User Support if the cancer suspicion record still appears on the Participant Status Screen for the exam form;
7. Record a note on the hardcopy DE form explaining why the DE was completed, initial and date it, and file it in the participant's file;
8. Report the correct results with an explanation of the circumstances to the participant and his/her physician.

### **6.8.7 Making Referrals for Abnormal Examinations**

All participants with a positive screen must be referred for follow-up with an appropriate specialist. Each SC is responsible for referring participants to appropriate medical professionals in accordance with standard practice at the SC. Participants with negative screening results but one or more significant abnormalities may also be referred for follow-up at the discretion of the SC. In some cases, the SC may wish to refer a participant "internally," that is, to a medical professional associated with the SC, for a review of a positive result.

### **6.8.8 Internal Referrals**

An internal referral involves the review of a positive lung screen by a SC physician or other qualified individual. In most cases, an internal referral entails a review of the examination data by the physician, and not an actual clinical examination of the participant. If the internal referral physician determines that further follow-up is necessary, the participant will then be referred "externally" to a physician of his/her choice. In some cases, the review may be performed by a nurse or other qualified individual. Internal referrals can be made for only lung examinations. If an internal referral indicates that an abnormality is stable and there has been no change, the SC is not required to refer the participant externally, but the SC must report the results of the PLCO examination and the internal referral to the participant and to the participant's physician of choice. If the participant requests an additional referral, the SC must refer the participant externally.

Reporting the results of internal referrals may be accomplished via an addition to the Screening Test Results Report or to the cover letter that accompanies it, or by some other type of written communication.

Internal referrals do not in any way affect chest x-ray results. All chest x-ray results should be assigned in accordance with the PLCO protocol, regardless of the results of any prior examinations or any subsequent referrals. For example, if a T0 chest x-ray shows an abnormality that is suspicious for cancer, the result of the exam must be recorded as "Positive Screen." If a subsequent internal review reveals that a film taken prior to the participant's enrollment in the study showed the same abnormality and there has been no change, the result of the T0 examination is still "Positive Screen."

Internal referrals represent the first step in the follow-up of a positive screen. The result of an internal referral resulting from a positive screen must be doc-

umented on a Diagnostic Evaluation Form (see [Chapter 8.0](#)), and not on the chest x-ray examination form. If there is a subsequent external referral for the positive screen, it should also be documented on the same Diagnostic Evaluation Form.

### **6.8.9 Monitoring the Reporting of Results**

The SC Coordinator will monitor the timeliness of reporting screening examination results using the following SMS report:

**Screening Test Result Report Not Sent Three or More Weeks Since Exam Date** ([Appendix B-6-7: Screening Test Result Report Not Sent Three or More Weeks Since Exam Date](#)): This report lists all participants whose screening visit took place three or more weeks previously, but a Screening Test Result Report has not been sent.

### **6.8.10 Transmitting Results of the Screening Tests to the Coordinating Center**

The SC Coordinator will transmit screening test results to the CC on a monthly basis. This will be done through the Data Transmission application of the PLCO computer system. When the SC Coordinator runs this application, the computer will automatically extract the data that should be reported to the CC. Refer to the *Network User's Guide/Network Upgrade Documentation* for information on transmissions.

## **6.9 Dietary Questionnaires**

As part of the studies of cancer etiology being conducted in conjunction with the PLCO trial, all intervention group participants will have blood drawn for storage at an NCI biorepository (see [Chapter 10.0](#)) and will be asked to complete the self-administered Dietary Questionnaire (DQX) at baseline. See [Appendix A-6-2](#) for the DQX and its specifications for completion.

In December 1998, a second dietary questionnaire was added to the PLCO Cancer Screening Trial. The Diet History Questionnaire (DHQ) is a 40-page opscan form designed to collect a wide range of nutritional information (see [Appendix A-6-3](#) for the DHQ form and its specifications).

The DHQ will be administered to all control participants at baseline (T0) and all intervention participants at T3. Because some participants will have already moved through these activity windows at the time of implementation, there will be a backlog of participants. This backlog will consist of Intervention participants who have moved through their T3 window, and Control participants who have moved through their T0 window. NCI has specified that backlog participants receive the DHQ at their next randomization anniversary and that this backlog be eliminated within two years of the initiation of the DHQ effort (by December 2000).

Any individuals who participated in the DHQ pilot will not be required to complete the DHQ (regardless of which form, if any, they completed during the pilot). Westat will enter MDF records into SMS for the DHQ for all pilot participants. Hardcopy MDFs will not be required for these participants. In addition, any control participants who mistakenly complete the DQX will not be approached to complete another dietary questionnaire. Such errors may have

occurred if a control participant was randomized a second time as an intervention and mistakenly given a DQX.

This section provides instructions for administering, receipting, editing and shipping the PLCO dietary questionnaires.

### **6.9.1 Administration of the Dietary Questionnaire (DQX)**

The SC Coordinator may use the SMS to determine which participants are due to complete the DQX. The **Baseline Directive** ([Appendix B-5-1: Baseline Directive](#)) generated from the Requests Module of SMS lists the participants who are in their reporting window for the Dietary Questionnaire but have not yet completed it. (**Note:** The Baseline Directive is no longer available from the SMS.)

The DQX should be given to each intervention participant at the beginning or end of the baseline screening visit (T0). The participant should be asked either to complete it during waiting times at the clinic or to take the questionnaire home, complete it and mail it back to the SC. Depending upon the SC enrollment procedures, it may also be appropriate to give the DQX during an orientation session and then ask the participant to return the form at the T0 visit.

Although the form is designed to be self-administered, it can be interviewer-administered either in-person or via telephone, at the discretion of the SC Coordinator. Specifications for the form appear in [Appendix A-6-2](#)

Intervention participants who are in their baseline study year and for whom biorepository blood specimens are not collected, should still complete the Dietary Questionnaire.

#### **6.9.1.1 Preparation**

To prepare the DQX for distribution to the participant, the following steps should be taken:

1. The Requests option in FAST (no longer available) can be used to determine which participants need to complete a DQX form. (See *SMS User's Guide/ SMS Upgrade Documentation*.)
2. Apply a Participant ID label to the front of the form (in the left corner). Please be sure that the PID label is straight and the bar code portion is closest to the edge of the form.
3. Clip a postage-paid return envelope to the questionnaire booklet.
4. Use the Requests/Mailing option to enter the date the questionnaire is given/mailed to the participant into the Forms and Specimens Tracking Module of the SMS. (See *SMS User's Guide/ SMS Upgrade Documentation*.)

#### **6.9.1.2 Timeframe**

The timeframe for the completion of the DQX is the same as for the Baseline Questionnaire. It should be completed, if possible, by the end of the participant's reporting window (1 month after randomization) and at the latest, by the end of the delinquency period (3 months after randomization).

## 6.9.2 Administration of the Diet History Questionnaire (DHQ)

### 6.9.2.1 Scheduling

The SMS can be used to determine which participants need to complete the DHQ. NCI has required that the DHQ be administered to all backlog participants within the first two years of the DHQ effort. To allow this, the DHQ expectations are designed so that the current DHQ participants and the "oldest" backlog participants (T4 and T5) are addressed in the first year of the DHQ effort (December 1998 to December 1999). The remaining "younger" backlog (control participants who at the time of implementation were in their T1 - T3 windows) are addressed in the second year of the DHQ effort (December 1999 to December 2000).

According to these expectation requirements, the following participants will be listed as requiring a DHQ in the specified timeframes:

Figure 6-2. Schedule for Administration of the DHQ

	First Year (Starting 12/98)	Second Year (Starting 12/99)	All following years (Starting 12/00)
<b>Current</b>	Intervention, T3 Control, T0	Intervention, T3 Control, T0	Intervention, T3
<b>Backlog</b>	Intervention, T4, T5, T6 Control, T4, T5, T6	Control, T1, T2, T3	Control, T0

Expectations will be triggered in the following manner: (same as for the ASU)

- 30 days prior through one month after the randomization date or anniversary, the DHQ status will be "outstanding;"
- between 1 and 3 months (90 days) after the randomization date or anniversary, the status will be "delinquent;" and
- after 90 days have past since randomization or the anniversary date, the expectation will switch to "MDF-DHQ." This expectation will remain until and MDF-DHQ is received.

**Note: All MDF-DHQs should be received by the SCs before the opening of the participant's next study year to prevent resetting of the DHQ expectation in the subsequent year.**

**Note:** If an SC is concerned about the participant burden associated with the administration of the DHQ in conjunction with the ASU or other PLCO activities, they may administer the DHQ outside of the activity window. If an SC administers the DHQ outside of the activity window, this time delay (amount of time between the activity window and administration of the DHQ) should be as uniform as possible for all participants. If they decide to administer these questionnaires months after the randomization anniversary, the system will still show the regular windows in terms of outstanding, delinquent and MDF expectations. The Requests module will still reflect the standard activity window rules. In these cases, the SC can use the Individual Directive (IDIRECTIVE) option of the Requests module to determine which participants need the DHQ and to generate a mail merge file.

### 6.9.2.2 Generating a Mailing List

The SCs will have the option of mailing the DHQ either alone or with the ASU. Regardless of which option they choose, the DHQ directive must be generated. This directive is required for all mailings because there may be participants who, at the time of the DHQ mailing, may have already completed or may not require the ASU (such as control participants at baseline).

#### Option 1: Mail the DHQ Alone

To prepare a mailing for the DHQ, the SCs can determine who requires the form by using the Directive option of the Requests module to generate the following directive:

**DHQ directive:** *(Required)* ([Appendix B-6-10: DHQ Directive/Late Directive](#)) This directive will list all participants who are due for their DHQ. It will not include those participants who were already mailed a DHQ with the ASU (those from the combined ASU/DHQ directive, see below). Because there will be participants who do not require the ASU but may still need the DHQ, it will be essential for the SCs to run this report. For example, when the DHQ window opens, some participants may have already completed their ASU for that study year. For those SCs that are not combining the ASU and DHQ mailings, this will be their only resource for identifying to whom the DHQ should be sent. (For more information see the *SMS User's Guide* and the *SMS Upgrade Documentation*.)

#### Option 2: Mail the DHQ with the ASU

For backlog control participants and intervention participants, the SCs may wish to add the DHQ to the ASU mailing. To prepare a combined ASU/DHQ mailing, the SCs can determine who requires these forms by generating the following directive:

**ASU directive:** ([Appendix B-7-1: ASU Directive - Participant due for New Form](#)) While running this directive, the SCs will be prompted with the question "Do you want to mail the DHQ too?" If they say yes, the report will list all those participants who require an ASU and a star will indicate those who also require a DHQ. When the SCs create a merge file for mailing, these participants will be "flagged" such that they will not appear on the DHQ directive. Unlike expectations, this directive *will* include those DHQ participants who, upon implementation of the DHQ effort, enter their DHQ expectation cycle as "delinquent" or "MDF-DHQ" - but only if they still require the ASU. (For more information see the *SMS User's Guide* and the *SMS Upgrade Documentation*.)

**Note:** The SCs will also have to run the DHQ directive to identify those participants who do not require an ASU but do still need to complete the DHQ.

### 6.9.2.3 Preparation of the DHQ

To prepare the DHQ for distribution to the participant, the following steps should be taken:

- Generate the DHQ Directive to determine which participants need to complete a DHQ. (As mentioned above, the ASU directive can also be used to identify participants who require the DHQ.)
- Apply a Participant ID label to the front of the form. The PID label should be placed in the label box in the bottom right corner (the lines in this box represent the correct orientation of the barcode portion of the label). The SCs should be sure that the PID label is on straight and the bar code portion is closest to the spine of the form.
- Clip an approved DHQ cover letter and a postage-paid return envelope to the questionnaire booklet. (See Appendices [A-6-3](#) and [C-7-4](#) for sample cover letters.)

#### 6.9.2.4 Administration

The DHQ is designed to be a self-administered questionnaire. In pilot testing of the form among PLCO participants, respondents needed an average of 60 minutes to complete the form, with most individuals needing little or no help.

The DHQ should be given to each control participant at baseline (T0). Intervention participants will complete the DHQ while in their T3 window. The T0 administration should involve mailing the DHQ within the first 3 months after randomization, and the T3 administration should involve mailing the DHQ within the first 3 months after the third anniversary of randomization. Backlog intervention participants (those intervention participants who have already exited their T3 window) should receive the DHQ by mail at their next randomization anniversary. As for the backlog control participants (those control participants who at the initiation of DHQ activities have already exited their T0 window), half will receive the DHQ in the first year of DHQ administration, and half will receive the DHQ in the second year of administration, as specified in Table 1.

The SCs are required to give or send the DHQ to participants within their activity window (one month prior to three months after randomization or the randomization anniversary). The SCs can determine whether or not it would be effective to send the DHQ with the ASU, mail it alone, or distribute it in person at the clinic. If a SC does decide to mail the DHQ with the ASU, it is very important that they closely monitor response rates, as NCI requires the SCs to maintain a minimum 90% response rate for the ASU.

Although the form is designed to be self-administered, it can be interviewer-administered either in-person or via telephone, at the discretion of the SC Coordinator. A copy of the DHQ specifications for completion can be found in [Appendix A-6-3](#)

### 6.9.3 Receipt and Editing the Dietary Questionnaires

#### 6.9.3.1 Receipt

Upon return of the completed DQX and DHQ forms, they should be receipted into the SMS. (**Note:** Receipt of the DQX Form is no longer available from the SMS.) The questionnaires should be receipted as expeditiously as possible since the system will not consider this activity to have been completed until the questionnaire has been receipted. Receipting dietary questionnaires involves entering the form type, Participant ID, and completion date into SMS.

If a dietary questionnaire is returned more than 3 months after it is mailed, it should still be receipted and sent to National Computer Systems (NCS).

### 6.9.3.2 Editing and Data Retrieval

After the questionnaire is receipted and before it is sent to NCS for processing, the SC staff should perform a manual edit. This edit should involve the following steps:

1. Check the form for completeness and machine readability. This includes verifying the correct placement of the PID label. If the form is completed in blue or black ink instead of in pencil, there is no need to transcribe the responses onto a new form using pencil.
2. Check that the PID, gender, date of birth, and form completion date (or "today's date") are valid and scannable (i.e. PID is bar coded, date bubbles are darkened). These are critical items so if they are invalid, data retrieval is required. It is acceptable to use participant files, rather than participant contact, to verify or correct gender and date of birth.

**Note:** The SC can estimate the completion date (or "today's date") by using the date the form was receipted. For, example, if the form was returned without a completion date and receipted at the SC on 10/19/97, then the estimated date of completion would be this receipt date, 10/19/97. In order to keep a record of the forms with estimated completion dates, the SCs should put a flag in the SMS DQX or DHQ receipt screen, noting the estimated date.

3. If information is present on the questionnaire but the participant did not fill it out in a manner suitable for optical scanning, SC staff should correct the form to the extent possible. This applies to items that are not zero-filled or those responses that are circled or checked rather than darkened. Answers should not be changed or adjusted for consistency reasons. Answers should only be changed if they are part of the data retrieval information provided by the participant.
4. Check that there are no extra note cards or loose pages of comments attached by the participant. Any notes, comments, complaints, etc., should be separated from the forms and carefully reviewed. When loose pages are separated from the forms, the SC should be sure to mark on the pages the PID and the batch number of the corresponding questionnaire. Only op-scan forms and transmittal/batch sheets should be forwarded to NCS. SCs should check each form for other study forms such as an ASU or FLF, as well as for inserted sheets or sticky notes, because these may disrupt the scanning process. SCs should carefully note on each loose sheet that is found the PID and batch from which it came, and store the original sheets in the participant's file. In addition, the SC should keep a log of complaints regarding the dietary questionnaires, so that NCI can decide if further action needs to be taken regarding complaints. Copies of this complaint log should be sent to the CC on a quarterly basis.
5. Since the DHQ does not have a forms processing box, attempted data retrieval should be noted either in the pink box on the cover of the form or next to the actual data item. All notes should be made in red pen or pencil and initialed and dated. Notes should not be made near the skunk marks or data bubbles. See the DHQ form completion specifications for more information regarding the correction of participant responses after data retrieval is conducted.

**Note:** Due to the increased time burden caused by the introduction of

the new DHQ, a manual review of non-critical items is no longer required. Computer edits at the CC will identify forms where ten or more consecutive items (which require completion) or an entire page or more has been skipped. In these cases, the forms will be returned to the SC for data retrieval. Occasional missing items (foods, portion sizes, or additional questions) are not major omissions and data retrieval for these items is at the discretion of the SC Coordinator.

## 6.9.4 Monitoring Dietary Questionnaire Completion

### 6.9.4.1 Tracking

The return of the DQX and DHQ will be tracked in SMS in the following manner:

- Up to 1 month after a participant's randomization date, the Open Forms Report (see description below) will list a DQX or DHQ that has not been returned and receipted in SMS as outstanding.
- If the questionnaire still has not been returned during the period 1-3 months after the participant's randomization, the Open Forms Report will list the dietary questionnaire as delinquent.
- If the dietary questionnaire has not been returned within 3 months after the participant's randomization anniversary, it will show-up as MDF-DQX Outstanding or MDF-DHQ Outstanding. In these cases, a Missing Data Form (MDF) should be receipted for the missing dietary questionnaire. After this 3-month period has passed, the SC should no longer ask the participant to complete the form; however, if the participant does return it after the end of the 3-month period, the SC should delete the MDF and receipt the dietary questionnaire.
- The SMS may also be used to facilitate mailings of the DQX and DHQ. An initial mailing date will be tracked by the system. Three weeks after the initial mailing date and up to three months after the participant's randomization or randomization anniversary date, the SMS may be used to generate a merge file and to print mailing labels for dietary questionnaires that have not been receipted into SMS.

### 6.9.4.2 Reports and Directives

The following reports and directives generated by the SMS will assist the SC in monitoring receipt of dietary questionnaires:

- **Open Forms Report** ([Appendix B-17-9: Production Edit Report](#)): This report will show all delinquent or outstanding forms, by individual PID. It can be used to identify those participants who have not returned a dietary questionnaire.
- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#)): This report gives a summary of the study information for a participant such as PID, Randomization Date, Randomization Group, Participant Name, Gender, Date of Birth, and Address. Other vital status and cancer information are also presented, as well as forms receipted or outstanding and exam results. This report can be run for selected PIDs or for a block of participants according to their randomization date.

- **Requests Module in SMS:** This module gives the ASU, DHQ, DQX, Late, and Individual Directives. These can be used to determine which participants are expected to complete the DQX, DHQ, and ASU. Here (except for the Idirective) SCs will have the option of combining the DHQ information with the ASU. The Mailing Option of this module also allows you to document the date a mailing file was generated.

#### 6.9.4.3 Duplicates

SMS should also be monitored for the detection of duplicate dietary questionnaires. If a duplicate is detected, SMS will reject the duplicate entry (for more information see the *SMS User's Guide*). This duplicate form should not be shipped to NCS, instead the SC should keep the form. If duplicate forms are received, the SC should take the following steps:

1. Verify that the forms were completed by the same person, rather than just mislabeled.
2. If they are from the same person, the form completed on the earliest date within the reporting window should be considered the official study questionnaire. This questionnaire should be receipted.
3. Only the official dietary questionnaire should be sent to NCS. The other form should be placed in the participant's file with a note explaining the situation.
4. If the incorrect form was already sent for processing, notify Beth Bridgeman at Westat as soon as the error is discovered. This notification may be made by telephone, fax, or email.

### 6.9.5 Follow-up of Non-Respondents

#### 6.9.5.1 Non-Respondents

The SC Coordinator should be prepared to carry out follow-up activities for those participants who do not return dietary questionnaires within three weeks of administration. Non-respondents should be contacted to determine if a second questionnaire should be sent. For the DQX, the number and type of contacts made is left to the discretion of the SC.

In contrast to the DQX, follow-up is *required* for those participants who do not return the DHQ within three weeks of administration or who have submitted an unacceptable questionnaire (see manual editing guidelines above). Non-respondents should be contacted once by telephone to remind him/her to complete the questionnaire and to determine if a second questionnaire should be sent. The following guidelines should be used to reach participants:

1. Up to three attempts may be made to contact a participant by telephone;
2. Each call should be placed on a different day of the week (Monday through Friday);
3. The calls should be made at different times each day (morning, afternoon, evening); and
4. The first and last calls should be separated by at least one week.

The SC will devise a strategy to ensure a high contact rate. If necessary, this may include contacts in the evening or on weekends. If the questionnaire has

been lost or misplaced, the center will provide one more complete mailing to the participant (if s/he is still in the DHQ activity window).

The Requests module of SMS will allow the SC to identify those participants who have not returned their dietary questionnaire and are still within the reporting window. The **ASU Late directive** ([Appendix B-7-2: ASU Directive - Late Respondents](#)) will give the option of combining this with the DHQ. The **ASU Individual directive** will not have this combined option. In these instances, the SCs will have to run the **DHQ Individual directive**. The SMS will support a second mailing by producing listings of outstanding questionnaires and allowing the SC Coordinator to generate merge files and print mailing labels. The labels can be prepared for all outstanding forms; for those forms that have not been returned within a specified number of days; or for a specific Participant ID. (See *SMS User's Guide/SMS Upgrade Documentation* for more information.)

#### **6.9.5.2 Missing Data Forms (MDF)**

If a participant refuses to complete the dietary questionnaire or fails to complete the form by the end of the delinquency period, the SC Coordinator will complete a MDF to indicate that the data will not be collected. If no other reason is identified, the reason for the missing data will be recorded as Code 6 "Out of Window," subcode 666. If the participant returns the dietary questionnaire after an MDF has been receipted in its place, the MDF should be deleted from the SMS and the DQX or DHQ should then be receipted into the SMS. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for instructions on deleting Missing Data Forms from the system. (See [Chapter 17.0](#) for additional information on the Missing Data Form.) The hardcopy MDF should be kept in the participant's file with a note explaining the situation.

### **6.9.6 Shipping Completed Dietary Questionnaires to NCS**

#### **6.9.6.1 Schedule**

Once each month, completed dietary questionnaires should be batched and shipped to National Computer Systems (NCS) for processing. As of July 2002, all completed DQXs will be mailed to Beth Bridgeman at Westat. Shipments should be made so that they are received at NCS within the first 10 working days of each month. Each year the SCs will be provided a DHQ/DQX Shipment Schedule outlining the appropriate shipment dates and cut-off dates. If, for a particular month this schedule is not possible, the SC must contact Data Prep. at NCS and Beth Bridgeman at Westat to notify them of a delayed or non-existent shipment (see [Appendix A-6-4](#) for the Shipment Notification Fax). If a shipment is received by NCS after the cut-off date for that month, NCS will hold the forms and scan them with the following month's shipment.

Generation of shipping address labels is available through the SMS. Starting January 1, 1999, questionnaires should be sent via a **traceable mail service** such as certified mail, UPS, FedEx, etc. to the following address:

Pearson NCS  
Attn: Finishing  
1313 Lone Oak Road  
Eagan, MN 55121  
FAX: (651) 681-6221

**Note:** The SCs should also be sure to list a return address on each package.

### 6.9.6.2 Preparation of Shipments

The following tasks should be completed in order to prepare a dietary questionnaire shipment:

1. Generate a **DQX Transmittal Log** and a **DHQ Transmittal Log** for this shipment. The transmittal lists the Participant ID of each receipted questionnaire not previously shipped. (See the *SMS User's Guide/SMS Upgrade Documentation* for more information on generating a transmittal). After the 4.3 upgrade (December 1998), the SMS will automatically group receipted DQXs and DHQs into separate batches of 35 and assign batch numbers. The first page of the transmittal will give the total number of forms in this shipment and each page will give the batch total (one batch per page).
2. Modify the transmittal log shipping date to reflect the date you plan to ship that month's forms. Transmittals should always be generated for a given month prior to transmitting data to the CC, to ensure that the data delivered to the CC will be current for the dietary questionnaire receipts and shipments. By doing this, all of the forms sent to NCS or Westat in a given month may not have the same date in their batch number but they will have the same ship date.

**Note:** Rather than generating all of the dietary questionnaire transmittals for a monthly shipment at once the SC may generate batch transmittals on an ongoing basis. This way, the task of ordering the forms by PID is much more manageable. If the SC is not planning to ship that day, they should change the ship date in SMS to the anticipated ship date. By doing this, all of the forms sent to NCS in a given month may not have the same date in their batch number but they will have the same ship date.

3. For each batch, organize the questionnaires in Participant ID order, the same order in which they appear on the transmittal.
4. Review the transmittal against the actual hard copy questionnaires. If any are lost or are not ready to be shipped, they should be crossed off the transmittal. Then, it is necessary to go into the SMS and remove the shipping date for any dietary questionnaires not being included in the shipment (do not send a transmittal with handwritten changes). A revised DQX and/or DHQ Transmittal Log should then be generated. Note: Because the first page of the transmittal gives the total number of forms in a shipment, it, along with any revised pages, will have to be replaced after any PIDs are removed.
5. Include one copy of the transmittal in the shipment and keep a second copy on file at the SC.
6. Complete a Shipment Notification Fax (see [Appendix A-6-4](#)). The information needed to complete this fax can be found on the pages of the transmittal logs. On the day of the shipment, fax a copy of the Shipment Notification Fax to Data Prep. at NCS (612-893-8325) for DHQs and Beth Bridgeman at Westat (301-294-2085) for DQX so that both NCS and Westat can be sure that all documents are received.
7. A sheet of cardboard should be placed on the top and bottom of a batch and bound, outside the cardboard, with a rubber band. Be sure that the rubber bands are not bending the forms, thus making them difficult to scan. Then, these wrapped batches should be placed inside a

17.25"x11.25"x10" box. **For the first year of shipments to NCS, these materials (boxes and cardboard) will be provided by Westat.** For the remainder of the years the SCs will be responsible for purchasing these supplies.

8. Each box should contain the transmittal pages for the enclosed forms (no boxes should be sent without a transmittal).
9. Mark each piece of a multiple shipment as box "#" of "total number of boxes," such as "box 3 of 5."

#### **6.9.6.3 Lost Shipments**

It is expected that the use of a traceable mail service will prevent the loss of shipments containing completed questionnaires. In the event that a shipment is lost, the receipt and shipping information (date shipped) for each form should be deleted from SMS. An MDF should be completed with a reason code of 8, subcode 801, and receipted in place of each lost form. NCS will use the **NCS Discrepancy Notification Fax** ([Appendix A-6-6](#)) to notify the SCs of any discrepancies between the transmittal information and those documents received at NCS.

### **6.9.7 NCS and Westat Processing and Data Retrieval**

#### **6.9.7.1 Processing**

Upon receipt by NCS, the shipments will be carefully inventoried. If NCS discovers any discrepancies between what they receive and what is noted on the Shipment Notification Fax, they will complete a **NCS Discrepancy Notification Fax** (see [Appendix A-6-6](#)). This fax describes the discrepancy and may call for SC investigation. Next, the dietary questionnaires will be processed using optical scanning. Monthly, NCS will ship all forms to Westat where the data will be reviewed and computer edits will identify errors and missing data.

#### **6.9.7.2 Westat Initiated Data Retrieval**

DQX and DHQ forms that are flagged as problematic as a result of the computer edits will be photocopied for data retrieval. The copies will then be returned to the SC along with a Data Retrieval problem sheet explaining the issues needing attention. It will be up to the SC to resolve the problem, either through record review or participant contact. Once the correct information is obtained, the SC should use a red pen or pencil to record the information on the enclosed form and complete the bottom section of each Data Retrieval problem sheet. If data retrieval is unsuccessful or not performed, this should be indicated on the problem sheet with an explanation for the missing information.

Within 2 weeks of the data retrieval request, corrected copies should be returned to Westat at the following address:

Beth Bridgeman  
Westat  
TB 294  
1650 Research Boulevard  
Rockville, MD 20850

It is expected that a thorough manual review at the SC, prior to the shipment of the forms to NCS or Westat, will prevent the need for extensive Westat initiated data retrieval.



# Part III: Follow-up Operations

## Introduction

Part III of this manual discusses the followup operations of the PLCO Cancer Screening Trial. This includes all study activities occurring after a positive screening examination and/or after the baseline year of data collection. Participants in the intervention group will receive annual screening examinations for five additional years after the baseline year. All study participants will be contacted annually, for approximately 13 years to determine vital status and whether a cancer has been diagnosed.

All positive screening examinations and cancers reported by participants and from other sources will be followed-up by contacting physicians and reviewing medical records. Diagnosis and treatment information will be abstracted for all PLCO cancers. For any participant determined to be deceased during the course of the trial, a death certificate will be obtained. The goal is to determine all PLCO cancer incidence and mortality in the study cohort.

Effective followup for endpoint determination is vital to the success of the PLCO Trial. Each Screening Center is responsible for developing procedures to help ensure a high rate of participant retention in the trial. This will include adequate followup and tracking of non-respondents, reluctant, moved and lost participants. Support for all followup activities is provided through the procedures and systems documented in Chapters 7 through 9 of this manual.

# 7.0 ANNUAL PARTICIPANT FOLLOW-UP ACTIVITIES

## 7.1 Overview

Follow-up activities will be conducted annually for each PLCO participant for at least thirteen years after randomization and enrollment into the trial. The purpose of these follow-up activities is to re-screen intervention participants and collect biospecimens in years T1 through T5, and to obtain information regarding medical care as well as to update locator information from participants in both the intervention and control groups.

Follow-up activities for intervention participants will include:

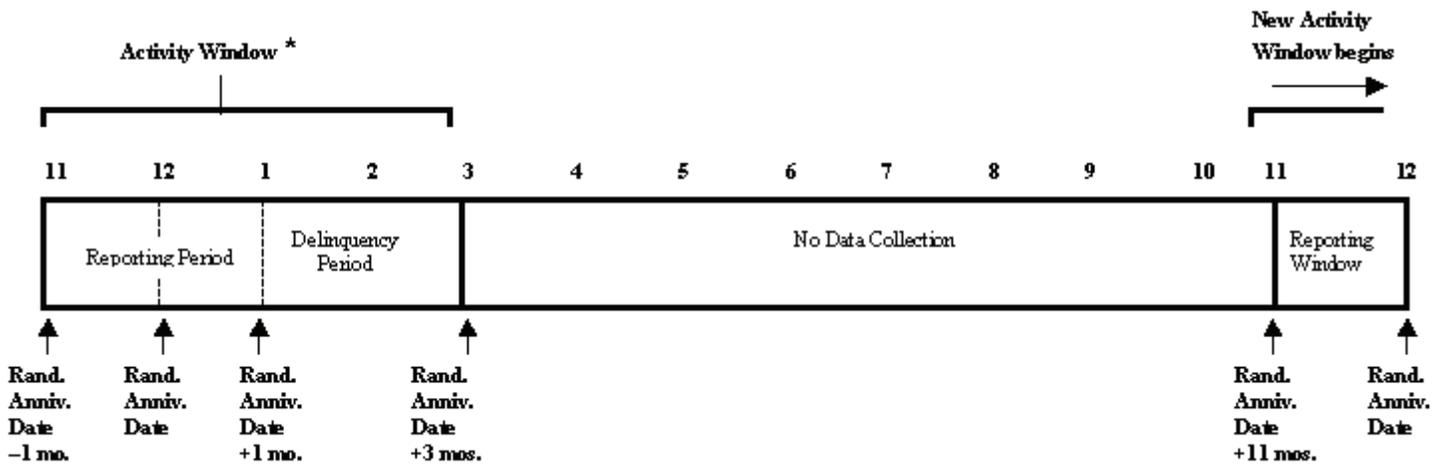
- Screening tests in study years T1 through T5
- Blood collection for etiologic studies in study years T1 through T5
- Administration of ASU for cancer and vital status confirmation
- Administration of FLF to obtain new contact information

Follow-up activities for control participants include:

- Administration of ASU for cancer and vital status confirmation
- Administration of FLF to obtain new contact information
- Administration of the Health Status Questionnaire (HSQ)
- Collection of Buccal Cell

The “activity window” for a study activity consists of the reporting period plus the delinquency period. The reporting period for most follow-up activities is from one month prior to one month past the participant’s randomization anniversary date (see Figure 7-1 below). The delinquency period for all activities other than screening exams is from one month past to three months past the randomization anniversary date. For most screening examinations, the delinquency period extends to six months following the anniversary of randomization. All screening examinations in study years T0 through T4 should be pursued for six months after the opening of the activity window. For the T5 FSG and the T5 PSA and CA-125II, the delinquency period should extend to 12 months following the anniversary of randomization. Regardless of the length of the delinquency period, once it ends, an MDF should be receipted for outstanding forms. If all of the required data have not been collected by the end of the delinquency period, all data collection efforts should be stopped until the following year’s reporting window begins. If, however, the participant requests screening or the Annual Study Update is returned outside his/her annual reporting period, the data should be collected. (See [Chapter 17.0](#) for a discussion of data collection outside the window.)

Figure 7-1. Follow-up Study Years (T1 through T13)



\* Please note that a 7-month activity window exists for all T0-T4 screening activities, and a 13-month activity window exists for T5 PSA, CA-125II, and FSG screens.

The SC Coordinator will monitor the completion or non-completion of all required follow-up activities. The results of all data collection will be transmitted to the CC on a monthly basis. The SC Coordinator will also oversee the process of reporting screening test results to participants and physicians. The following sections describe the annual follow-up activities.

## 7.2 Completing the Annual Study Update and Follow-up Locator Form

The **Annual Study Update (ASU)** ([Appendix A-7-1](#)) is a self-administered questionnaire that will be used to collect information from the past year's medical history from all participants, both intervention and control for all years of follow-up (T1-T13). Prior to July 1996, this form was called the Periodic Survey of Health (PSH). The following information will be collected on the Annual Study Update:

- cancer diagnoses since the *reference date*;<sup>\*</sup>
- type of cancer and date of diagnosis;
- physician's name and address where cancer was diagnosed;
- use of Proscar (men) since the *reference date*.

(\*The *reference date* is the date the participant last completed an Annual Study Update, or if the participant is in his/her T1 study year, it is the date of randomization.)

The specifications for the completion of the Annual Study Update are given in [Appendix A-7-1](#). These specifications may be used by the SC Coordinator to answer participants' questions about the completion of the form.

Periodically, participants in both the intervention and control groups may also be asked to confirm or update the participant location information the SC has on file by completing a **Follow-up Locator Form** (FLF) ([Appendix A-7-2](#)). The main purpose of the Follow-up Locator Form is to provide the SC with information that can be used to trace the participant if s/he becomes lost to follow-up. Its administration is not required and is at the discretion of the SC Coordinator, although it is recommended that it be administered at least every other year. There are two versions of the FLF. One is a computer-generated form which is specific to each participant and lists the participant's location information, as it appears in the SMS files, on the left side of the form. On the right side of the form, blanks are left for the participant to make additions when information is missing, or to correct the information. The second version of the FLF is a generic form that is similar to the Baseline Locator Form. It requires that all locator information be completed again, even if it is on file in the SMS. Both versions of the FLF as well as the specifications for their completion can be found in [Appendix A-7-2](#). These specifications may be used by the SC Coordinator to answer participant's questions about the completion of the form.

All participants entering their annual reporting window are due to complete the Annual Study Update and some or all may be asked to complete a Follow-up Locator Form. In situations where the participant is unable to complete the form(s), they may be completed by someone else such as a spouse, other family member, or friend. The following tasks will be completed in order to distribute the Annual Study Update and the Follow-up Locator Form in a timely manner for completion by study participants:

- Annual Study Update Forms may be generated through the Requests module of the SMS or through Word using a merge file generated from the SMS (refer to the *SMS User's Guide/SMS Upgrade Documentation*). The SC will generate the **ASU Directive** ([Appendix B-7-1: ASU Directive - Participant due for New Form](#)) and will print the ASU for all participants who are currently in or are entering their annual activity window.
- The ASU will be attached to a Follow-up Locator Form (if desired) and sent/given to the participant for completion.
- Intervention participants may complete the ASU and FLF at the SC at the time of the screening visit. At these visits, the SC staff will be available to provide assistance if the participant has questions regarding the forms.
- The forms may also be mailed to participants. Any mailed questionnaires will be accompanied by a cover letter which will introduce the forms and instruct household members to contact the SC if the participant is unable to complete the forms (due to death, illness, etc.) A sample cover letter for the ASU is included as [Appendix C-7-1](#). This letter may be customized for individual SC use.

If a participant fails to return the ASU (and FLF) within three weeks of the date they were mailed, the SC Coordinator will either send the materials again or will contact the participant as a reminder to complete and return the questionnaires. The quantity and nature of these follow-up contacts will be left to the discretion of the SC Coordinator. The SC Coordinator can determine which participants have not responded in a timely manner by generating the **ASU Directive for Late Respondents Report** ([Appendix B-7-2: ASU Directive - Late Respondents](#)).

If a participant fails to return the Annual Study Update before the end of the ASU delinquency period, the SC Coordinator will complete a Missing Data Form to indicate that the data will not be collected for that year. If no other reason is identified, the reason for the missing data will be recorded as Code 6 "Out of Window," subcode 666. A Missing Data form is not required for the FLF, but it may be receipted in place of an FLF, if desired. If the participant returns the Annual Study Update after a Missing Data Form has been receipted in its place, the Missing Data Form should be deleted from the SMS and the Annual Study Update should then be receipted into the SMS. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for instructions on deleting Missing Data Forms from the system. (See [Chapter 17.0](#) for additional information on the Missing Data Form.)

If an Annual Study Update form is lost prior to completing the double data entry and the form is less than one year old it should be re-administered to the participant. If the form is older than one year, the SC should not attempt re-administration. Instead, a MDF should be filed for the missing form and a Protocol Violation Report ([Appendix A-17-7](#)) should be completed and submitted to the CC.

In cases where the Annual Study Update was lost after the first data entry pass but before the second, the following steps should be followed:

1. The SC should recreate (printout) the ASU from the data in the system.
2. Call the participant to confirm the information for that time period.
3. Delete the old ASU.
4. Do double data entry using the new form.
5. Complete a Protocol Violation Report and submit it to the CC.

### **7.3 Receipting the Annual Study Update and Follow-up Locator Form**

After the Annual Study Update and Follow-up Locator Form are received, they will be manually edited for completeness and legibility. Item 1 on the ASU (cancer diagnosed since *reference date*) is considered by NCI to be a key item that is critical for analysis. Data retrieval must be performed for this item if the response is incomplete, unclear, missing, or illegible. A qualified abstractor needs to code the cancers reported on the ASU.

All items on the Annual Study Update will be entered into the SMS and the response to Item 1 (cancer diagnosed since *reference date*) will require double data entry.

The SMS screen for entry of this information is shown in Figure 7-2 below:

Annual Study Update: Male Participant

ASU

Participant ID: 800011-9 Study Year: T4

Date Received: 02/26/1998

1. In the period from last year to the present, have you been diagnosed with cancer by a healthcare provider (Y/N)? (If NO, SKIP ITEM 2): (excluding basal-cell and squamous-cell skin cancers)

2. What type of cancer was diagnosed during this period (MARK ALL THAT APPLY:)

Type	Diagnosis Date	Type	Diagnosis Date
	MM DD YYYY		MM DD YYYY
Prostate: <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Other: <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Lung: <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Enter Other Cancer Code(s):	
Colorectal: <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>
		<input type="text"/>	<input type="text"/>
		<input type="text"/>	<input type="text"/>
		If an Other Code is 888, Specify Cancer:	
		<input type="text"/>	

3. FOR MEN ONLY: In the period from last year to the present, have you taken the medication Proscar or Propecia (Finasteride) (Y/N)?

4. Today's Date: 02/26/1998 If date of completion was estimated, please check the box:

5. Who completed this questionnaire? (Please check)  Study Participant  Spouse  Someone else

6. Comments:

View Mode Record 1 of 1

Figure 7-2. Data Entry Screen #1 for Annual Study Update

If a Missing Data Form has been completed in place of the Annual Study Update, it will be receipted into the SMS. When processing of the Annual Study Update, the Follow-up Locator Form, or the Missing Data Form is completed, the forms will be filed in the participant's study folder.

## 7.4 Scheduling Annual Follow-up Screening Visits

Participants in the intervention arm of the trial will be scheduled for a follow-up screening visit in each of the five years following the baseline visit. These visits are referred to as T1, T2, T3, T4 and T5.

Appointments will be scheduled for participants who are entering or are currently in their screening activity window, and who have not completed all follow-up screening examinations for the study year. Depending on the screening examination, the activity window will extend to either 6 or 12 months following the anniversary of randomization. The length of this activity window will depend on the participant's study year. For T0 through T4, the activity window will extend until 6 months after the anniversary of randomization. For the T5 study year, the activity window will extend a full 12 months after the 5th anniversary of randomization. The SC Coordinator will contact these participants to schedule appointments for annual visits to take place any time after the start

of the activity window. Appointments will be recorded in the SC's scheduling system.

In order to minimize no-shows, it is strongly suggested that participants be recontacted in advance of their appointment date to remind them of the appointment. During this contact, they may also be given instructions for preparing for the screening visit. The SC Coordinator should aggressively attempt to reschedule no-shows and cancellations within the activity window.

## **7.5 Preparing for the Annual Follow-up Visit**

As described in Chapter 6, the SC Coordinator will pull the folders for all participants scheduled for an annual visit and will ensure that all required study forms have Participant ID labels affixed and that the administrative section at the top of each form is complete. As in the baseline-screening visit, a Participant Control Record ([Appendix A-6-1](#)) will be used to track the completion or non-completion of the screening tests. The use of the Participant Control Record is described in [Chapter 6.0](#).

## **7.6 Conducting Annual Follow-up Screening Tests**

Screening tests for prostate cancer and ovarian cancer will be done during each of the five annual follow-up visits. Screening for colorectal cancer through flexible sigmoidoscopy will be done only at the fifth annual visit (T5). Screening for lung cancer will be done during the first 2 annual follow-up visits for all intervention participants and only for current or former smokers at the third (T3) annual visit. In addition to the screening tests, blood will be collected for etiologic studies at each of the five annual visits. The visit to the SC, including all of the screening tests, and possibly completion of the ASU and FLF,, should take no more than 2 hours.

The procedures for conducting the screening tests and recording screening test results are described in Chapters 10 through 15.

A participant may not undergo a screening test for the following reasons listed in [Section 7.9](#) (Documenting Non-Participation). However, if a participant is undergoing chemotherapy, and has volunteered this information, the SC should encourage the participant to come in for their screening exam, unless it is chemotherapy for a PLCO cancer. The SC should record that the participant is receiving chemotherapy in the Scheduling Notes section on the Participant Status Screen.

## **7.7 Documenting the Annual Follow-up Screening Visit**

Each screening examination will be documented on an examination form and on the Participant Control Record. The result of an annual screening examination will be assigned by the examiner without knowledge of the results of previous examinations and should be based solely on the findings of the current examination.

At the end of the screening visit, before the participant leaves the SC, the SC Coordinator will review the Participant Control Record to make sure that all required tests were performed and will attempt to reschedule any examinations that were not done or were inadequate. Examinations will be judged

inadequate based on criteria defined in the screening protocols (see Chapters 10 through 15).

The SC Coordinator will process the Participant Control Record and the screening examination forms as described in [Chapter 6.0](#).

## 7.8 Documenting A Duplicate Screening Visit

If a participant is inadvertently screened twice in the same study year, the exams from the first visit should be considered the official PLCO exams. In order to document the situation, the following steps should be taken:

- Any blood collected for PSA or CA-125II at the second visit should either be discarded or processed by the SC outside of the PLCO Trial.
- Any Biorepository samples collected at the second visit should be discarded.
- The forms for the second visit should not be scanned. Instead, the exam results should be entered into the Participant Status Screen.
- The hardcopy exam forms from the second visit should be kept in the participant's file with a note (initialed and dated) documenting the situation.
- The participant and his/her physician should be informed of the error and given the results of all exams (from both the first and second visit).
- A Protocol Violation Report ([Appendix A-17-7](#)) should be completed and sent to the CC.

## 7.9 Documenting Non-Participation

A participant may not undergo one or more of the annual screening examinations for one of the following reasons:

- Refusal
- PLCO Organ Removal
- PLCO Cancer Reported
- Mental or Physical Illness
- Out of the Area

If a participant is unable or unwilling to schedule an annual screening visit before the end of the delinquency period, the SC Coordinator will complete a Missing Data Form to indicate that the data for one or more of the screening tests will not be available for that year. The length of this delinquency period will depend on the participant's study year. For T0 through T4, the delinquency period will extend until 6 months after the anniversary of randomization. For the T5 study year, the delinquency period will extend a full 12 months after the 5th anniversary of randomization. As in the baseline visit, if a participant undergoes screening after a Missing Data Form has been receipted for the screening activity, the Missing Data Form should be deleted from the SMS and the screening examination form(s) should then be receipted into the SMS.

**Note:** If an individual reports that they are currently taking Proscar, they are not excluded from any of the annual study exams or follow-up. For Intervention participants it is still acceptable to collect PSA samples as well as Biore-

pository samples. The SC is not required to ask about these medications prior to examinations. Information from the ASU will be sufficient to determine (for data analysis purposes) which participants are taking these medications.

### **7.9.1 Non-Participation Due to Refusal**

If a participant refuses screening, the SC should make an effort to “convert” the refusal. Such refusal conversion attempts should be made at the discretion of the SC Coordinator. If a participant refuses only one of the examinations (for example, the flexible sigmoidoscopy), s/he should be encouraged to undergo the remaining examinations. If the participant refuses all of the screening examinations, s/he should be encouraged to complete the Annual Study Update and Follow-up Locator Form.

### **7.9.2 Non-Participation Due to PLCO Organ Removal**

If a participant has had a PLCO organ removed, the examination should be performed (or not performed) according to the guidelines for each screening test (see Chapters 10 through 15). If a screening examination is not performed in the current year, a Missing Data Form should be completed to indicate that the examination data will not be available for the current year. The reason code should be “7” (PLCO Organ Removed), subcode 777. It is not necessary for the SC to receipt Missing Data Forms for any subsequent years of screening.

If a participant who has had a PLCO organ removed is erroneously given a PLCO screening exam, the MDF for the screening exam form should still be receipted (not deleted). The results of the exam should be entered in the Participant Notes section of the Participant Status Screen of the SMS, rather than receipting the form. The hardcopy exam form should be kept in the participant’s file with an initialed and dated note, explaining the situation. Also, the participant and his/her physician should be informed of the results and why the exam was done. Because this was an inappropriate screen, a Protocol Violation Report explaining the situation should be completed and sent to the CC.

If a participant reports that they have ovaries or a prostate but upon examination it is found that they do not have ovaries or a prostate, the exam forms should still be completed and receipted. An MDF should be receipted for the screening exam forms for that organ for all subsequent study years.

### **7.9.3 Non-Participation Due to PLCO Cancer Reported**

It is strongly recommended that the Annual Study Update be administered to intervention participants prior to annual follow-up screening visits to determine whether a PLCO cancer has been diagnosed. An intervention participant who reports a primary or metastatic cancer of the prostate, lung, colon, rectum or ovary, will not undergo the screening examination(s) for that cancer. The participant may, if willing, undergo the screening examinations for the other cancers. The SC is allowed to accept participant self-report of cancer diagnosis. There is no need to confirm this reported cancer diagnosis with the participant’s physician or consult medical records before the cancellation of the related screening test(s). If an exam has been started, however, it should be completed and an exam form should be completed and receipted as well. It is still necessary to follow-up with the medical record abstract forms but this confirmation process does not need to happen before the screening exams are cancelled.

If a participant does not undergo a screening examination because s/he has a PLCO cancer and the Diagnostic Evaluation (DE) form confirming that cancer has not yet been receipted into the SMS, there will still be an expectation in the system for the associated screening exam(s). In these cases, a Missing Data Form should be completed for the associated examination(s). The reason should be recorded on the Missing Data Form as "C" (Reported PLCO cancer).

If the SC determines that the PLCO cancer was, in fact, diagnosed prior to the participant's enrollment in the study, the SC should complete an Administrative Tracking Form as described in Chapter 4.

If a participant who has reported a PLCO cancer is erroneously given a PLCO screening exam, a MDF for the screening exam form should be receipted. The results of the exam should be entered in the Participant notes section of the Participant Status Screen of the SMS, rather than receipting the form. The hardcopy exam form should be kept in the participant's file with an initialed and dated note, explaining the situation. Also, the participant and his/her physician should be informed of the results and why the exam was done. Because this was an inappropriate screen, a Protocol Violation report explaining the situation should be completed and sent to the CC.

#### **7.9.4 Non-Participation Due to Mental or Physical Illness**

If a participant is declared mentally incompetent and a legal guardian is appointed, the SC may request that the guardian complete the ASU (and FLF). The participant's legal guardian, in consultation with the SC staff, and if possible, the participant's physician, should decide if the participant is able to accomplish the activities necessary to complete the screening examinations. If not, the Missing Data Form should be completed with a reason code "1", sub-code 113.

If a participant is physically unable to complete one or more of the screening examinations, the SC staff should encourage the participant to complete any exams s/he is physically able to complete, as well as the ASU (and FLF).

### **7.10 Reporting Results of Annual Follow-up Screening Tests**

The SC Coordinator is responsible for reporting the results of the annual follow-up screening tests to the participant, to the participant's physician of choice, and to the CC. Results will be reported to the participant and to the participant's physician of choice within three weeks of the screening visit. Refer to [Chapter 6.0](#) for detailed instructions on reporting results to participants and physicians.

If there are no results from a PLCO visit, for example a woman without ovaries will not have any results for her T4 visit, the SCs should still generate an STRR to be kept in the participant's file for record keeping purposes. In addition, each SC may want to draft a letter to be sent to acknowledge and appreciate participant efforts even when there are no results to report. The SC should submit the participant "No Results" letter to NCI for approval, with a copy to the CC.

Results of chest x-ray examinations may be compared to the results of previous chest x-ray examinations as part of the internal referral process. (See Chapter 6, [Section 6.8.8](#))

## 7.11 Transmitting Results of the Screening Tests to the Coordinating Center

The SC Coordinator will transmit screening test results to the CC on a monthly basis. This will be done through the Data Transmission application of the PLCO computer system. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for information on using the Data Transmission application.

## 7.12 Tracing Lost Participants

When participant contact is attempted for any follow-up activity, it may be determined that the participant can no longer be reached at the last known address and/or phone number. In this situation, tracing activities must be initiated. If a participant has been deemed lost to follow-up, the SC should indicate that the participant is "in tracing," and his/her status should be changed to such in the SMS (See *SMS User's Guide/SMS Upgrade Documentation*.) The **Tracing Log** ([Appendix B-7-3: Tracing Log](#)) may be generated to facilitate the tracing process. This report provides all current locator information on the participant, obtained from the Baseline Locator Form and Follow-up Locator Forms (if available). Sufficient space is provided on the report so that tracing results may be recorded directly on it. Alternately, tracing results may be recorded on a separate form that can be attached to the Tracing Log.

The information collected on the locator forms should greatly facilitate the tracing process. It is suggested that this information be used initially to try to locate the participant. Subsequently, especially in later years of the trial, outside sources such as the Department of Motor Vehicles, the Social Security Administration, National Death Index, Post Office checks, cancer registries, credit bureaus, etc. may be utilized. Every effort must be made to minimize the number of participants lost during the course of the trial.

Once a participant has been determined as lost-to-follow-up, the SC should change the participant's status to "In Tracing" and should enter "IT" in the SMS Participation Status field on the Participant Status screen. The SC should begin tracing lost-to-follow-up participants by using Post Office address correction requests or other tracing sources as mentioned above.

### 7.12.1 Post Office Address Correction Request

The **Post Office Address Correction Request** (POA) form ([Appendix C-7-5](#)) is a one-page form that can be used to obtain new address information for participants whose forwarding address information has expired.

The SC will use a Post Office Address Correction Request (POA) form to obtain new address information for participants whose forwarding address information has expired. The Post Office Address Correction Request form can only be used by a government agency requesting new address information for an individual. This requires that the Post Office Address Correction Request form be printed on National Cancer Institute (NCI) letterhead and signed by Christine Berg. The SCs must also use National Institutes of Health (NIH) envelopes for mailing requests to local Postmasters. The SC will mail the Post Office Address Correction Request form(s) in the NIH envelope to the postmaster located in the same city, state and zip code in which the participant last resided. The SC will be responsible for paying the postage for mailing the Post Office address correction requests. The Postmaster will record the known address information

(whether new information or the same) on the Post Office Address Correction Request form and return it to the SC.

Following are the details of the procedures for preparing, mailing and receipting the Post Office address correction requests:

#### **7.12.1.1 Post Office Address Correction Request Forms**

- The Post Office Address Correction Request form is a one-page form that follows a standard format required by the Postal Service. For the PLCO study, each Screening Center will have a SC specific form.
- The standard format requirements include:
  - ▶ The form be on government agency letterhead;
  - ▶ The top portion of the form states the request from the government agency;
  - ▶ Includes the participant name and last known address information;
  - ▶ The bottom portion of the form has mandatory language, as required by the Postal Service, for completion by the Post Office only;
  - ▶ Return address information, which is the Screening Center specific address (the Postmaster will return the request forms to this address); and
  - ▶ The Postmark/Date Stamp, which is stamped by the Post Office with the Postmark and date.
- Christine Berg is the signatory on the Post Office Address Correction Request forms.
- The SC specific Post Office Address Correction Request form will be printed on NCI letterhead. Westat will maintain the master copy of the POA form.
- The SC will need to submit the PLCO Reorder Form to Westat to request additional copies of the POA form, as well as additional NIH envelopes for mailing Post Office address correction requests.

#### **7.12.1.2 Preparation of Post Office Address Correction Request Forms**

1. The SC should prepare a participant label to include the participant's name, address and the Participant Identification Number (PID). The participant label should be placed on the POA form in the blank space provided in the top portion of the form, below the first paragraph but above the second paragraph.
2. The SC can prepare the participant label (participant name, address and PID): (1) by creating their own label outside the Study Management System (SMS); (2) by handwriting the label; (3) by typing the participant label directly on the POA form; or (4) by using the mergefile created from the "Labels/Address" option in SMS.
3. The SC should separate POA forms by the participant's zip code, since POA requests will be mailed to the Postmaster in the same City, State and Zip Code as the City, State and Zip Code of the participant who is being traced.

### **7.12.1.3 Mailing Post Office Address Correction Request Forms**

1. The SC must use NIH envelopes (brown) for mailing Post Office address correction requests, which is printed with the NIH return address in the upper left corner including a space to record the NCI room number.
2. The SC will need to submit a PLCO Reorder Form to Westat to request additional NIH envelopes. The NIH envelopes will NOT include the NCI room number "EPN 3100." The number must be stamped or handwritten by the SC prior to mailing Post Office address correction requests.
3. The POA request will be mailed to the Postmaster in the same City, State and Zip Code as the City, State and Zip Code of the participant who is being traced.
4. The SC should place a printed or handwritten label on the NIH envelope. The envelope should be addressed as follows:

Postmaster  
City, State, Zip Code
5. Multiple requests to the Postmaster in the same City, State and Zip Code can be placed in the same NIH envelope. The SC should batch no more than 10 POA request forms per envelope. The SC should make sure that the zip codes on the POA request forms correspond with the zip code on the NIH envelope.
6. The SC will need to pay the postage to mail the POA requests.

### **7.12.1.4 Receipt of Post Office Address Correction Request Forms**

1. The Postmaster will return POA request forms to the SC address provided at the bottom of the POA form. The Postmaster will return the POA forms in post office envelopes; therefore it is not necessary for the SC to include return envelopes with their Post Office address correction requests.
2. Two months after the original POA request mailout, the SC should evaluate outstanding Post Office address correction requests. The SC should consider sending a second Post Office address correction request for POA requests that are outstanding. Based on experience from other Westat studies, the majority of the POA requests should be returned within 2-3 weeks.
3. Upon receipt of new address information for a participant, the SC will need to validate the new address. The SC should confirm the new address by contacting the participant either by telephone, if the telephone number for the new address can be obtained, or by sending a test mailing to the new address. The test mailing should consist of a SC contact letter notifying the participant that the SC is trying to contact him/her and request the participant to contact the SC.
4. Once the participant's new address has been confirmed, the SC should remove the participant from "In Tracing" status by deleting "IT" from the Participation Status field on the Participant Status screen of the SMS.
5. If the new address information cannot be confirmed, the participant should remain in tracing and the SC should consider using other tracing sources as mentioned.

6. The SC will need to decide how many test mailings should be sent in an effort to confirm new address information and when to pursue other tracing sources. Westat recommends that the SC send at least a second mailing to confirm new address information for a participant who does not respond to the first test mailing.
7. The SC will need to manually track and monitor the Post Office address correction request activities. There is no system support for these activities.

### 7.12.2 Termination of Tracing

Once tracing attempts are terminated, the SC Coordinator will update the participation status in the SMS to indicate the outcome of the tracing. Alternately, the SC Coordinator may enter the number of tracing attempts compiled either manually or by a separate tracing management system (not part of the SMS).

Through tracing efforts, it may be determined that the participant has moved to the location of another SC of the PLCO Trial. The SC may offer intervention participants who are still in their screening years (T0 through T5), the opportunity to transfer to another SC. Control participants and intervention participants who have completed screening are contacted by mail only, and should not be transferred to other SCs. (See [Chapter 17.0](#))

## 7.13 Monitoring Follow-up Activities

The SC Coordinator will monitor the completion of annual follow-up activities for all intervention and control participants. The following SMS reports may be used to facilitate this monitoring activity.

- **Intervention Activities Report** ([Appendix B-17-6: Intervention Activities Report](#)): This report lists the PIDs of intervention participants who are entering, continuing in, or leaving their reporting window, and those who are in their delinquency period.
- **Control Activities Report** ([Appendix B-17-7: Control Activities Report](#)): This report lists the PIDs of control participants who are entering, continuing in, or leaving their reporting window, and those who are in their delinquency period.
- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report shows all delinquent, incomplete or outstanding forms for each participant. Since the receipt of forms and specimens indicates the successful collection of study data, the SC Coordinator will use this report on a regular basis for monitoring the status of all participants during the study.
- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#)): This report gives a summary of the study information for a participant such as PID, name, gender, date of birth, address, randomization date, and randomization group. Other vital status and cancer status information are also presented, as well as forms receipted and exam results for the participant.
- **ASU Forms Received** ([Appendix B-7-5: PSH/ASU Forms Received](#)): This report lists ASU forms received within a specified date range.

- **Results Pending Report** ([Appendix B-6-1: Results Pending Report](#)): This report lists all participants for whom screening examination results are pending (status of RP). The report shows the PID, study year, form type, and examination date.
- **Results Pending Three or More Weeks Since Exam Date** ([Appendix B-6-2: One or More Exam Statuses = Results Pending Three or More Weeks Since Exam Date](#)): This report lists all participants for whom at least one examination is still pending (RP status) three or more weeks after the examination date. It shows the PID, study year, exam date, status of all examinations and, date the Screening Test Results Report was sent.
- **Referrals for Exam Forms** ([Appendix B-6-3: Referrals for Exam Forms](#)): This report displays the referral levels assigned to individual examinations. It may be requested for specific participant IDs, for all examinations that took place during a range of dates or for all participants. The report may be sorted by PID, examination date, referral code or study year.
- **QA Checks Report** ([Appendix B-6-4: QA Checks Report](#)): This report prints discrepancies between the results of regular examination and medical record abstract forms and their associated quality assurance forms. It presents counts as well as a listing of discrepant cases.
- **Examination Summary Report** ([Appendix B-6-5: Examination Summary Report](#)): This report generates summaries of exams performed. The user may select any combination of exams and a range of visit dates. This is a four part report: (1) exams performed, (2) exams by examiner ID, (3) exams by outcomes, and (4) outcome by examiner.
- **List of PIDs in Tracing** ([Appendix B-7-4: List Of Participants in Tracing](#)): This report lists the PIDs for participant currently "In Tracing." Each time a Tracing Log is generated for a participant, the number of tracing attempts is automatically updated in this report. The report shows the PID, DOB, gender, randomization group, participant status, number of tracing efforts.

The SC Coordinator should attempt to resolve all problems related to the Annual Study Update, Follow-up Locator Form and screening examination forms before the participant moves out of his/her reporting window. If a participant reaches the end of his/her delinquency period without completing all of the required study activities, the SC Coordinator will complete a Missing Data Form to indicate which activities were not completed.

## 7.14 Procedures for Contamination Assessment

### 7.14.1 Overview

As part of the PLCO Cancer Screening Trial, a study is being conducted to assess contamination among control participants. This is necessary in order to fairly and accurately evaluate the results of the PLCO Trial. To initiate contamination assessment, a sample of approximately 1000 control participants (approximately 100 per SC proportional to the numbers enrolled) stratified on Screening Center (SC), study year and gender are randomly selected to complete a **Health Status Questionnaire (HSQ)**. (For samples of the men and women's version of the HSQ see Appendices [A-17-8](#) and [A-17-9](#)) Those control

participants who indicate on the Baseline Questionnaire - Female (BQF) or Baseline Questionnaire - Male (BQM) that they have received one or more flexible sigmoidoscopy, colonoscopy or barium enema in the past 3 years, or more than one PSA in the past 3 years (males only), are not eligible for sample selection. In addition, T0 participants, participants past the T6 window, and transferred participants are not eligible for sample selection, along with randomized ineligible participants and participants for whom a Non-Response Form (NRF) has been completed.

As part of this contamination assessment study, the Coordinating Center (CC) is responsible for printing the Health Status Questionnaires, affixing PID/study year labels to the questionnaires, distributing them to the SCs, and performing data entry on completed questionnaires. Systems support is provided for generating mailing labels, tracking the receipt of completed questionnaires, generating call records and shipping the questionnaires. The SCs are responsible for mailing the questionnaires and obtaining completed questionnaires on 100% of the selected sample. The SC is also responsible for shipping completed questionnaires to the CC. The NCI requires a response rate of 100% to measure bias in participant response. Detailed procedures for the administration and processing of the HSQ are presented in the following sections.

#### **7.14.2 Administration of the Health Status Questionnaire**

The HSQ is gender specific. See [Appendix A-17-8](#) for the **Health Status Questionnaire for Men (HSM)** and its specifications and [Appendix A-17-9](#) for the **Health Status Questionnaire for Women (HSW)** and its specifications. The HSQ is designed for self administration and telephone administration. The questionnaires are generated at the Coordinating Center (CC) and distributed to the SCs. SCs are responsible for adding a cover letter (discussed below) and mailing the cover letter and questionnaire to selected controls. The questionnaires are site-specific and are labeled with each participant's PID and study year. In addition, blank questionnaires (without PID/study year labels) are provided by the Coordinating Center for remailing or telephone administration. Extra PID/study year labels are provided for each participant in the sample. Each page of the blank HSQs must be labeled with these labels.

Each SC must include a cover letter to accompany the HSQ. The cover letter should include the following elements: 1) a statement emphasizing the importance of completing the questionnaire; 2) a recommendation to the participant to contact his/her physician as necessary to obtain the information; and 3) a reference to maintaining confidentiality of reported information. SC cover letters should be submitted to the NCI for approval prior to use. (A sample cover letter is given in [Appendix C-7-2](#))

#### **7.14.3 Mailing the Health Status Questionnaire**

HSQ forms complete with PID/study year labels affixed are provided by the Coordinating Center (CC) to the SCs for mailing to participants. The selected sample is loaded into the SMS at the SC. The following steps should be completed to prepare the HSQ for mailing to participants:

1. Upon receipt of the forms and sample, generate a Directive from the SMS. Select Requests/Annual/HSQ/Directive. Then select Requests/Annual/HSQ/Mailing. This step must be performed to obtain a mailing date for the HSQ and to create the merge file. The mailing date is used with the HSQ receipt date to identify responders and non-responders.

The merge file contains information needed for the HSQ cover letter and address labels for the mailing envelope. Some or all of the information can be used as required by the SC. Detailed specifications for this procedure are provided in *SMS User's Guide/SMS Upgrade Documentation*.

2. Mail the forms, along with the cover letter and a postage-paid return envelope. Mailing procedures should be designed to enhance response rates. Forms should be mailed the same day or the day after the directive is generated.

#### **7.14.4 Receipt, Follow-up, and Data Retrieval of the Health Status Questionnaire**

SCs should attempt to obtain completed questionnaires for 100% of the participants so that bias in participant response can be measured. To achieve this, data retrieval should be done on all missing or conflicting responses. Follow these steps for receipt, follow-up and data retrieval of the HSQ.

1. Receipt completed forms into the SMS. To ensure that a questionnaire was receipted for the correct participant, compare the date of birth on the hard copy questionnaire against the DOB in the SMS as printed on the Batch Receipt session report. Specifications for this procedure are provided in *SMS User's Guide/SMS Upgrade Documentation*.
2. Because we are trying to assess bias in responders (defined as participants who return a completed questionnaire within three weeks of the initial mailing), SCs should not attempt follow-up calls or mailings for questionnaires that are not received within the first three weeks following the initial mailing. A full three weeks (21 days) after the initial mailing, SCs should begin follow-up procedures. Use Requests/Annual/HSQ/ LDirective in the SMS to generate a listing of participants for whom questionnaires have not been receipted. This will generate a merge file containing information needed for address labels and a call record. The SC may choose to do a second mailing to listed participants or may initiate telephone follow-up. In either case an HSQ should be prepared with the correct PID/study year label on each page and either mailed or used for telephone administration. Mailing labels can be generated for second mailings or call records can be produced for telephone follow-up. (A sample call record is provided in [Appendix C-7-3](#)) Guidelines for conducting telephone follow-up are given below:
  - ▶ Make at least five attempts to contact a participant by telephone.
  - ▶ Place each call on a different day of the week, Monday through Friday.
  - ▶ If necessary, place two additional calls, one on Saturday and one on Sunday.
  - ▶ Separate first and last calls by at least one week.
  - ▶ Make calls at different times each day: morning, afternoon, and evening.
3. Six weeks after the initial mailing generate the LDirective a second time to identify participants for whom a questionnaire has not been receipted. However, do not mail a questionnaire on a third follow-up attempt. Use the Requests/Annual/HSQ/Mailing merge file to generate

a call record for initiation of telephone follow-up. Detailed specifications for this procedure are provided in *SMS User's Guide/SMS Upgrade Documentation*. SCs should continue to perform telephone follow-up for questionnaires not receipted up to eleven months past the date of initial mailing to obtain a 100% response rate.

4. Receipt returned questionnaires into SMS as described in step 1 above.
5. For all questionnaires received, perform data retrieval on missing, illegible or inconsistent responses. All items on the HSQ will be considered critical, requiring data retrieval. Following are some examples of problems that may occur and how to resolve them:
  - ▶ If the item was left blank and, upon data retrieval, the participant is unwilling or unable to supply the data, leave the item blank, and mark your initials and date near the question.
  - ▶ If the item was left blank and, upon data retrieval, the participant supplies the data, complete the item and mark your initials and the date near the question.
  - ▶ If the item was completed incorrectly (e.g. more than one response is marked, or you are unable to tell which response is marked), perform data retrieval, make the changes on the form, and mark your initials and date near the question.
  - ▶ If a verbatim response was given, attempt to interpret, or contact the participant to interpret the response and mark the response on the form that is most appropriate. Mark your initials and date near the question. Do not erase the verbatim response. If a coding decision (i.e. interpretation) is made without the input of the participant, the decision must be recorded in a Coding Decision Log (see [Section 17.6.1](#) and [Appendix A-17-3](#) of the MOOP).
6. After three weeks from the date of the initial mailing, all outstanding forms will be considered delinquent for up to eleven months past the date of initial mailing. At the end of the delinquency period, a Missing Data Form (MDF) must be completed and receipted for any missing questionnaires.

#### **7.14.5 Shipping the Health Status Questionnaire to the CC**

The SCs should follow these procedures for shipping of the HSQ forms to the CC. Only finalized questionnaires (i.e., edited, with data retrieval performed) should be shipped.

1. HSM and HSW forms should be shipped to the CC during the first week of each month with a transmittal generated out of the Shipping module of the SMS. Specifications for this procedure are provided in *SMS User's Guide/SMS Upgrade Documentation*. The transmittal lists the Participant ID of each receipted questionnaire not previously shipped. The transmittal should be carefully reviewed against the actual hard copy questionnaires. If any are lost or are not ready to be shipped, they should be crossed off the transmittal. The SC Coordinator should then go into the SMS and remove the shipping date for any HSQ not included in the shipment. A revised transmittal should be generated. Do not send a transmittal with handwritten notes. One copy of the transmittal should accompany the shipment. The second copy of the transmittal should be kept on file at the SC.

2. All forms to be shipped should be photocopied prior to shipment. The SC will keep the copies on file and ship the original questionnaires. The questionnaires should be organized for shipment in Participant ID order, the same order in which they appear on the transmittal.
3. Questionnaires should be sent to the CC via certified mail. The SC Coordinator should send an e-mail message to Beth Bridgeman the day the forms are sent, to inform her of the shipment.

At the CC, the forms are keyed and progress reports are generated. Questions or problems regarding the shipment or specific forms should be reported to the SC Coordinator for resolution.

#### **7.14.6 Monitoring the Completion of the Health Status Questionnaire**

There are several ways to monitor the completion of the HSM and HSW. Each of them is described below.

- **HSQ Directive** ([Appendix B-7-8: HSQ Directive](#)): This lists participants to whom a new request should be made to complete their HSQ.
- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report shows all delinquent or outstanding forms for individual PIDs. Since the receipt of forms and specimens indicates the successful collection of study data, the SC Coordinator will use this report on a regular basis for monitoring the status of all participants during the trial.
- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#)): This report gives a summary of the study information for a participant such as PID, name, gender, date of birth, address, randomization date, and randomization group. Other vital status and cancer status information are also presented, as well as forms receipted and exam results for the participant.
- **HSQ Status Report** ([Appendix B-7-10: HSQ Status Report](#)): This report lists the date the HSM or HSW sample was generated, loaded into the SMS, first and last mailing dates, date receipted, and date shipped to the CC. This report also lists participation status, vital status, and transfer status. This report can also be used to determine for whom an MDF needs to be receipted. For example, if the participation status, vital status, or transfer status is not blank, then an MDF should be receipted.
- **HSQ Summary Report** ([Appendix B-7-11: HSQ Summary Report](#)): This reports gives summary numbers for the total number of HSMs, HSWs and overall HSQs in terms of forms loaded, mailed, received, and shipped to the CC. Counts are also given for the number of outstanding forms, those that have been followed-up, and the number of MDFs receipted for HSQs.

## 8.0 ASCERTAINMENT OF CANCER STATUS

### 8.1 Overview

Screening Centers (SCs) will implement procedures to determine cancer incidence for all randomized individuals during the entire period of the Trial. All reports of cancer will be followed up to ascertain whether or not cancer was diagnosed. For every case of primary prostate, lung, colorectal and ovarian cancer ascertained, information on diagnostic evaluation, cancer diagnosis and initial cancer treatment will be collected and abstracted onto the appropriate medical record abstract forms. In addition, for every non-PLCO cancer ascertained, information on the cancer diagnosis will be collected and abstracted onto the appropriate medical record abstract form for non-PLCO cancers.

The main goals of the cancer confirmation process (i.e., medical record abstraction) for PLCO and non-PLCO cancers are:

- To confirm whether or not a participant was diagnosed with a cancer;
- To document the diagnostic evaluation process for a suspected PLCO cancer (including any medical complications);
- To document the cancer diagnosis information (such as date of diagnosis and ICD-O-2 code) for all cancers; and
- To document the staging procedures and the results of the procedures that the participant underwent for a PLCO cancer.

Information collected as part of the cancer confirmation process is also important for other aspects of the PLCO Trial, including death review, pathology review, staging, and for evaluating the intermediate endpoint (cancer) and the final endpoint (mortality). This type of information will allow the Trial to:

- Evaluate the human costs of screening by assessing the flow of events following a positive screen that lead to a diagnosis, including morbidity and mortality, and adverse experiences; and
- Evaluate the cost effectiveness of cancer screening.

This chapter will discuss the procedures for complete cancer ascertainment. The main steps for cancer ascertainment are as follows:

1. Ascertain each participant's cancer status at least annually (i.e., determine suspected cancer from a positive screen, the Annual Study Update, cancer registries, etc.).
2. For all participants for whom cancer is suspected, obtain medical records related to the cancer suspicion or the cancer diagnosis to confirm whether or not cancer was diagnosed;

If a cancer was diagnosed, the medical record should be abstracted:

1. **For a PLCO cancer:** Abstract diagnosis, staging and treatment information (including coding) on to appropriate medical record abstract form (diagnostic evaluation and treatment) and attach a copy of the pathology report that supports the diagnosis;
2. **For a non-PLCO cancer:** Abstract diagnosis information (including coding) on to the Other Cancer Confirmation Form (OCF) and attach a copy of the pathology report that supports the diagnosis.

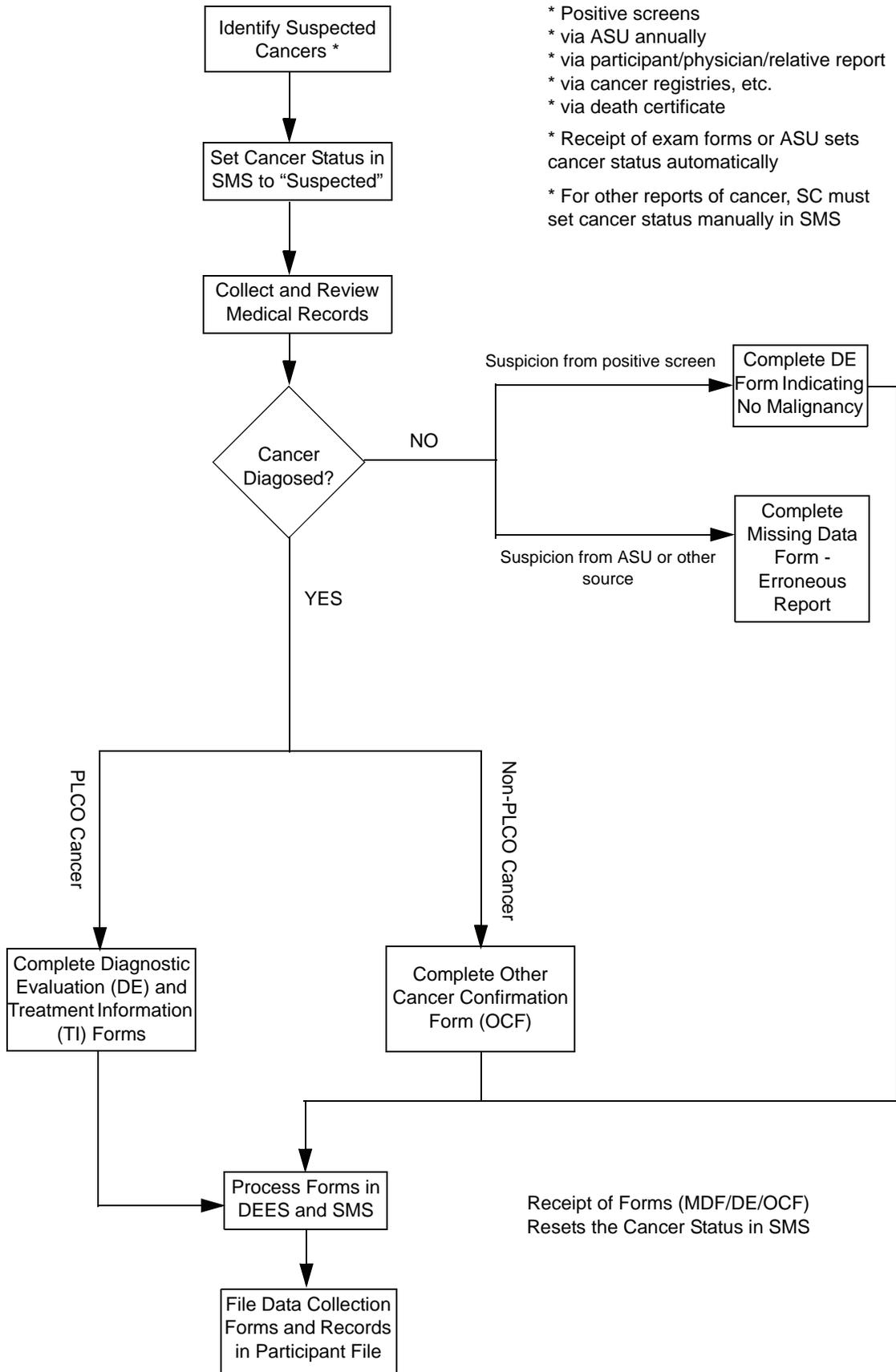
If a cancer was *not* diagnosed, the medical record may or may not be abstracted:

1. **When the cancer suspicion was a result of a positive PLCO screening examination:** Abstract diagnostic evaluation and diagnosis information for the participant's non-cancer condition (if any) onto the appropriate medical record abstract form.
2. **When the cancer suspicion was from a source other than a positive PLCO screening examination:** Complete a Missing Data Form to indicate that the cancer was erroneously reported.

When the medical record abstract form or Missing Data Form is completed:

1. Scan and edit and finalize the medical record abstract form in DEES;
2. Receipt the medical record abstract form(s) or MDF into SMS;
3. File the medical records and the data collection forms in the participant's file.

The above cancer ascertainment and documentation procedures are presented in the following flowchart.



## 8.2 Methods to Ascertain Cancer Status

The SC should attempt to ascertain cancer status for all participants on an annual basis. This will be accomplished mainly via the Annual Study Update (See [Chapter 7.0](#)) and through the screening process for intervention participants (See [Chapter 6.0](#)). There are several additional methods through which the SC may determine that a participant is suspected to have a PLCO cancer, including search of cancer registries, search of SC information systems, notification by the participant, notification by the participant's physician, and acquisition of death certificates for participants who are reported as deceased. Each SC is responsible for developing procedures to utilize all available sources to help ensure complete ascertainment. The participant's cancer status may be updated to "suspicious" in one or more of the following ways.

### 1. From a Positive PLCO Screening Test.

Upon the completion of the screening examinations, the result of each screening examination is recorded in the SMS (see [Chapter 6.0](#)). When a result of "Positive Screen" (AS) is recorded for a particular participant, the SMS assigns to the participant a cancer indicator code viewable on the Participant Status Screen to indicate that cancer is suspected but not confirmed and that a Diagnostic Evaluation Form is outstanding.

**It is the SC's responsibility to encourage participants to seek medical attention in a timely fashion, following a positive screen.** The SC is then required to follow-up with the participant and/or the physician or hospital to determine whether a PLCO cancer is identified. This will generally be accomplished by contacting the participant's physician to determine what diagnostic tests have been performed and the results of those tests. In cases where no diagnostic follow-up procedures were recommended and the physician cannot be contacted, the SC may accept verification from the participant. However, if a diagnostic workup was performed, all information regarding procedures and their outcomes should be obtained from a physician or hospital, not from the participant.

If the SC refers a participant "internally" after a positive lung, the internal referral is part of the cancer ascertainment process and must be documented on the appropriate Diagnostic Evaluation Form. (See Chapter 6, [Section 6.7](#) regarding internal referrals.) If the internal referral physician does not recommend additional follow-up but the participant does undergo additional diagnostic evaluation, both the internal referral and the additional follow-up should be documented on the same Diagnostic Evaluation Form.

Each participant must be followed until the first of the following situations:

- ▶ a conclusive diagnosis (either malignant or non-malignant) is made;
- ▶ for 12 months from the date of the positive screen; or
- ▶ the next screening exam, *whichever comes first*.

It is expected that in most cases, the diagnostic workup will be completed within 12 months of a positive screen. At the end of 12 months or on the date of the next screening examination, if the diagnostic eval-

uation is not conclusively malignant, the result of the diagnostic evaluation should be documented on the Diagnostic Evaluation form as "No Malignancy." The participant will then continue to be screened once each year for the remaining screening years of the trial.

If the participant is diagnosed with a primary PLCO cancer, cancer confirmation and treatment information must also be obtained and documented on the appropriate Diagnostic Evaluation and Treatment Information Forms (see [Section 8.4](#)). These participants may continue to be screened for the other PLCO cancers in subsequent years of the trial.

## **2. From the Annual Study Update (ASU).**

The Annual Study Update ([Appendix A-7-1](#)) will be administered each year of the study (after the baseline year) to all randomized participants. The administration of this instrument is the primary method of ascertaining cancers among the control group, interval cancers among the intervention group and cancers among intervention group participants who have withdrawn from or completed all years of screening. The questionnaire asks if a participant has been newly diagnosed with any type of cancer, and collects the type of cancer and the date of diagnosis.

When a participant reports that s/he was diagnosed with a cancer the SC staff will enter the cancer and the reported date of diagnosis into the ASU data entry screen in the SMS. Non-PLCO cancers will be coded into a 3-digit cancer code, which is entered during receipt of the ASU. It is important to properly code the cancer reported on the ASU before entering this information to the system. The coding of the ASU should be performed under the direction of the Lead Medical Record Abstractor. Coding of responses on the ASU is an important part of the MRA process and is described fully in [Appendix A-7-1](#) and in [Appendix I: Cancer Codes](#). A flag indicating that cancer is "Suspected" will then be set in the SMS and receipt of the medical record abstract forms will be expected. If the cancer was already confirmed and this is a second report of the cancer, the cancer code will indicate that this cancer type was previously confirmed and no additional medical record abstract forms will be expected for that cancer type. (See [Section 8.2.2](#) below).

Note that there may be situations in which it is inappropriate to set expectations for cancer confirmation and it would be preferable to simply not key the ASU response into the SMS, thereby reducing paperwork burden. These situations may include repeated reports of the same cancer that are confirmed with the participant to be the same cancer, and reports of conditions that the SC determines are not cancer. Outcomes of investigation or review of cancer confirmation should be noted on the ASU and initialed. These should also be reviewed under the direction of the Lead Medical Record Abstractor. The SCs should consult the ICD-9-CM coding manual to determine whether reported conditions are cancer or not. All conditions that are coded in ICD-9-CM as a primary malignant neoplasm (140-195, 200-208), non-PLCO carcinoma in-situ (230-234) or neoplasms of uncertain behavior, including carcinoids, but excluding villous adenomas (235-238) are considered cancer.

### **3. From a report (telephone, letter, etc.) from the participant, a relative, physician, etc.**

The SC may be notified of a cancer diagnosis by the participant, a relative or friend of the participant, or some other method. The SC should implement a system, such as a telephone log or event form, to record such information when it is received. The information must then be keyed manually into the cancers table via the Participant Status Screen. If the cancer reported is a non-PLCO cancer, the cancer type should be coded into the appropriate 3-digit code (see [Appendix I: Cancer Codes](#)) prior to entry into the SMS. These should be coded under the direction of the Lead Medical Record Abstractor.

### **4. From a Diagnostic Evaluation (DE) form.**

If the result of a diagnostic evaluation for a PLCO cancer is a non-PLCO malignancy or a different PLCO malignancy (for example, a diagnostic evaluation for a positive x-ray reveals a prostate malignancy), the SC codes this malignancy in ICD-9 in Part B of the Diagnostic Evaluation Form. Upon receipt of the Diagnostic Evaluation form into the SMS, the ICD-9 code will be translated into the 3-digit cancer code and the cancers table will automatically be updated with a record showing a new cancer suspicion.

### **5. From the death certificate.**

On a monthly basis, the SCs will ship death certificates to the CC for cause of death coding. A list of death certificates with PLCO or non-PLCO cancers appearing on them will be generated at the CC and sent to the SCs on a monthly basis (**Cancers on Death Certificates Report** ([Appendix B-9-5: Participants with Cancer on Death Certificate Report](#))). The three-digit code for non-PLCO cancers will be provided to the SCs on this list. The SC staff will manually key the cancer suspicion into the cancers table in the SMS.

### **6. From a Cancer Registry.**

Local or state registries, if available, may be used to identify PLCO cancers in either control or intervention participants which were not ascertained via follow-up of a positive PLCO screening test or via administration of the Annual Study Update. It is the responsibility of each SC to determine which registries might be appropriate in the local area and to seek the approval of the registry to release the requested information. It is suggested that requests for information be made on an annual basis.

In the future, the SMS will be used to generate the **Cancer Registries Request List** ([Appendix B-8-1: Cancer Registries Request List](#)), a listing of all participants for whom the SC has not received a death notification or a confirmation of cancer. This list will contain participant identifiers which would likely be required for a registry search including name, date of birth, sex and social security number. The Cancer Registries Request List will be generated either as a hard copy list or as an ASCII file.

The SC will need to establish guidelines for determining matches from information received back from a cancer registry search. Once a match is determined and a PLCO cancer is identified, the participant cancer

indicator code in the SMS will be updated to indicate that a PLCO cancer is suspected.

**Note:** *The Cancer Registries Request List is not yet implemented in the SMS.*

### 8.2.1 Reports for Tracking Cancer Suspicions

The SC will monitor the cancer confirmation process for all intervention and control participants. The following SMS reports may be used to facilitate this monitoring activity.

- **Cancer Confirmation List** ([Appendix B-8-3: Cancer Confirmation List](#)): This report lists all participants for whom a possible PLCO cancer has been reported. The listing contains the following information for each participant: Participant ID number, participant status, vital status, type of cancer reported, date of notification, and source from which the cancer was reported. This form can be used by the SC Coordinator to rapidly identify the participants for whom information on diagnostic follow-up and cancer confirmation and treatment must be obtained.
- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report lists all participants and all delinquent, incomplete or outstanding forms for each participant. In terms of cancer ascertainment, this report can be used by the SC Coordinator to track the completion of the medical record abstract forms.
- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#)): This report may be used to monitor the status of cancer confirmation for a specified individual or group of individuals. Expected/receipted medical record abstract forms and cancer status are listed on this report.
- **Medical Record Background Report** ([Appendix B-8-2: Medical Record Background Report](#)): This report may be used to monitor the status of cancer confirmation for a specified individual or group of individuals. It contains contact information for the participant and his/her physicians and hospitals. It also includes the participant's cancer status table as it appears in the SMS Participant Status Screen.
- **Cancers on Death Certificates Report** ([Appendix B-9-5: Participants with Cancer on Death Certificate Report](#)): This report is generated by the CC and lists all participants with cancer reported on the death certificate as a cause of death. For each death, the report shows the PID, study year of death, cancer type, date of death, 3-digit cancer code (if applicable) and cancer description.

### 8.2.2 Updating Cancer Status to “Suspected” in the SMS

Cancer suspicions may be automatically set in the SMS, upon receipt of a form such as an examination form or an Annual Study Update, or they may be manually keyed by the SC staff. The data elements that must be entered into the SMS when keying cancer suspicions are as follows:

- Type of cancer  
*Types of Cancer:*  
P – Prostate  
L – Lung

C – Colorectal  
O – Ovary  
T – Other (+ 3-digit cancer code to indicate the type of cancer)

- Study year cancer was reported to the SC
- Source of the suspicion.

*Sources:*

- ▶ ASU – Annual Study Update
  - ▶ 3-character exam form type (DRE, FSG, etc.)
  - ▶ DCF – Death Certificate
  - ▶ REL - Relative
  - ▶ PHS – Physician
  - ▶ OTH – Other (participant, cancer registry, review of medical records, etc.)
- Date the cancer was identified by the SC. This is the date that the SC learns of the cancer and *not* the date of diagnosis of the cancer.

Upon updating of cancer suspicions, expectations for the appropriate medical record abstraction form (DE or OCF) are set. If the primary cancer was already confirmed in a previous study year, no new expectations are set. The cancer status is automatically set to “P” - previously confirmed.

## **8.3 Collection of Medical Records**

Once a suspected cancer has been identified, the SC will initiate activities to confirm the reported cancer. This process includes contacting the participant and/or physician to obtain information. The nature and quantity of medical records to be collected differs depending on whether the suspected cancer is a non-PLCO cancer or a PLCO cancer, and, in the case of PLCO cancers, whether or not the suspicion is due to a positive screen. For additional guidelines on obtaining follow-up information from the medical records, see [Attachment 1](#).

### **8.3.1 Collection of Medical Records for Confirmation of PLCO Cancers**

Collection of medical records may involve contacts to physicians and hospitals to determine the status of screening followup, the collection of medical records documenting the participant’s cancer status, and in the case of cancer diagnosis, the diagnostic evaluation and staging information, including the pathology report and pathology slide. (See [Chapter 16.0](#) for information on obtaining pathology slides.)

The process of cancer confirmation differs slightly depending on whether the participant is in the intervention group and has a positive screening test or whether the cancer was reported from some other source. Participants with positive screening results will be followed forward in time, through the process of additional diagnostic testing and possibly cancer diagnosis. For these participants, a DE form will always be completed, even if cancer was not diagnosed. For situations in which no cancer is diagnosed, the DE is used to document the followup that resulted from a positive screen.

For suspected cancers identified through sources such as the Annual Study Update, the SC must contact the participant's physician and/or obtain medical records to determine whether or not cancer was, in fact, diagnosed. If so, the appropriate medical record abstract forms will be completed. In this case, the cancer will be identified after diagnosis, so the participant's medical record will be abstracted historically, beginning with the first visit for initial assessment and ending with the diagnosis.

To facilitate the process of requesting medical records, the **Medical Record Background Report** ([Appendix B-8-2: Medical Record Background Report](#)) may be generated from the SMS for a participant for whom cancer has been reported. This form lists participant and physician identifying information and information on the reported cancer, which may be needed to request the medical record. In addition, the SC may use the tumor registry information to help obtain additional source documents, but the SC should not complete PLCO abstracts on the basis of a tumor registry abstract.

In some instances the hospital may not accept the PLCO Cancer Screening Trial consent form as sufficient for release of the records. Additional authorization may need to be requested from the participant or the participant's next of kin. In addition, some institutions require that the authorization be recent (within 6 months, for example). A sample **Medical Record Release Authorization Form** that may serve the purpose of obtaining authorization to obtain records is provided in [Appendix C-8-1](#), however some hospitals or insurance plans may require a release in a specific format.

If the hospital where the participant was diagnosed and treated is located in the local area, it is preferable to have the abstractor travel to that hospital to review the record and complete the medical record abstract forms. This allows for review of the complete record. If the hospital is not in the local area or if the SC is unable to abstract off-site, then the records must be requested to be sent to the study office. A sample request letter to a hospital or physician for medical records is provided in [Appendix C-8-2](#). Because it may not be possible to request the complete record, certain key parts have been identified which will be needed to complete medical record abstract forms for PLCO cancers. These include (for each admission):

- Admission History for diagnosis and initial treatment
- History and Physical
- Treatment History or Reports
- Discharge Summary for all hospitalizations related to diagnosis and treatment
- Operative Reports
- Pathology Reports
- TNM Classification Form/Cancer Staging Form
- Reports of Diagnostic Work-up

If information is available in the medical record regarding metastatic sites when the primary site is a PLCO organ, this information should be collected and kept with the participant's record as it may be useful for death review and pathology review. This information should include a photocopy of the pathology report and the ICD-O-2 classification (if available). The SC should not pursue additional information about metastatic sites if it is not already available in the medical record.

In some cases, the SC may be charged fees for obtaining copies of medical record documentation. Since PLCO is a federally funded research study, the SC may attempt to obtain a waiver of fees from each institution from which they obtain medical records.

### **8.3.2 Collection of Medical Records for Confirmation of Non-PLCO Cancers**

For non-PLCO cancers, sufficient medical records must be collected to enable the abstractor to record the following data items on the OCF.

- Result of Investigation (non-PLCO primary, non-PLCO metastasis, PLCO primary, etc.)
- Date of diagnosis
- ICD-O-2 code
- Basis for diagnosis
- Metastatic Sites

The SC should obtain the pathology report from the initial definitive diagnosis and a discharge summary, if the participant was hospitalized. If the participant was not hospitalized, and/or was not diagnosed with pathology, the abstractor must use his/her judgement to determine the appropriate records to collect. The SC should not collect extensive records on diagnostic evaluation procedures or on treatment.

Medical record release authorization forms may be required for collection of records as described in [Section 8.3.1](#) above.

### **8.3.3 Tracking the Medical Records Collection Process (Epi-Info)**

Each SC is responsible for tracking the medical records collection process, that is, to track the requests to participants for signed medical records release forms and to physicians and hospitals for copies of the medical records. The tracking may be done manually using methods such as tickler files, or using an automated system. This is left to the discretion of the SC Coordinator.

The SMS provides some support for the medical records collection process (for PLCO cancers only) via a link to a database management system called Epi-Info. For each participant with a cancer status of "Suspected," or with a status of "Confirmed" or "Not Confirmed" (i.e., confirmed as non-malignant), but the DE and TI forms have not been finalized, a record with selected data items such as PID, date of birth, randomization group, cancer status, etc., will be exported to Epi-Info. The SC can then access Epi-Info and use these data items, together with other SC-specified data items to request to view, edit, or run reports for medical records collection tracking purposes. Refer to the SMS Version 3.2 Upgrade documentation for more information about Epi-Info. (**Note:** Support for Epi-Info is no longer available from the SMS.)

### **8.3.4 Acquisition of the Histopathology/Cytopathology Report**

For each case of cancer diagnosed histologically or cytologically during the trial, the SC will obtain a photocopy of the histopathology or cytopathology report which confirms the initial cancer diagnosis. Information from the pathology report will also be abstracted onto the Diagnostic Evaluation or Other Cancer Confirmation Form. If the cancer was diagnosed both histologically and

cytologically, information should be abstracted from the earliest procedure that yielded tissue, with an adequate specimen, that gives a definitive diagnosis of cancer. In PLCO, a histologic basis of cancer diagnosis is preferred, even if there is an earlier cytologic confirmation of the cancer. If there are several tissue specimens that confirm the cancer, the information should be abstracted from the earliest tissue specimen that confirmed the diagnosis of cancer, even if it does not provide the most complete picture of the cancer.

## 8.4 Abstraction of the Medical Record

Once the records have been obtained, they should be placed in date order and carefully reviewed to confirm that they are for the correct participant. A Participant ID label should be attached to each page. Each document should be reviewed for legibility and completeness. Consistency of information between documents should be compared and, if necessary, the physician or hospital should be contacted to resolve any problems. In addition, if the records are not complete, the diagnosing physician or hospital may need to be (re)contacted for additional information.

The first step of the abstraction process is to determine whether or not the reported cancer was diagnosed, and if it was primary or metastatic. If a cancer was diagnosed, information from the record about the diagnosis of the cancer should be abstracted onto the appropriate medical record abstract form (DE/TI/OCF). In cases where followup of a positive screen revealed no cancer, information about the diagnostic evaluation and the non-malignant diagnosis should be abstracted onto the DE form.

The medical record abstract forms are as follows:

- Diagnostic Evaluation Form-Prostate (DEP2) ([Appendix B-8-1: Cancer Registries Request List](#))
- Treatment Information Form-Prostate (TIP) ([Appendix B-8-1: Cancer Registries Request List](#))
- Diagnostic Evaluation Form-Lung (DEL2) ([Appendix B-8-2: Medical Record Background Report](#))
- Treatment Information Form-Lung (TIL) ([Appendix B-8-2: Medical Record Background Report](#))
- Diagnostic Evaluation Form-Colorectum (DEC2) ([Appendix B-8-3: Cancer Confirmation List](#))
- Treatment Information Form-Colorectum (TIC) ([Appendix A-8-3](#))
- Diagnostic Evaluation Form-Ovary (DEO2) ([Appendix A-8-4](#))
- Treatment Information Form-Ovary (TIO) ([Appendix A-8-4](#))
- Diagnostic Evaluation-Diagnostic/Staging Procedures Supplement (DSS) ([Appendix A-8-6](#))
- Other Cancer Confirmation Form (OCF) ([Appendix A-8-5](#))

These forms have been developed to facilitate standardized documentation of information concerning diagnostic evaluation; cancer diagnosis, including pathology, histology, and staging evaluation; and initial cancer treatment. The item-by-item specifications for completing each set of medical record abstract forms are provided with the forms in Appendices A-8-1 through A-8-6.

A trained and approved medical record abstractor will abstract information regarding diagnostic evaluation, cancer confirmation and initial treatment onto the appropriate medical record abstract forms. A certified nosologist (medical coder) is required for coding cancer diagnoses. (Refer to [APPENDIX L](#) for qualifications and certification requirements for the medical record abstractor and the study nosologist.) In addition, a copy of the corresponding histopathology or cytopathology report, which supports the diagnosis of cancer, must be obtained and attached to the Diagnostic Evaluation Form.

There will be situations in which a cancer will be reported erroneously, that is, there is no evidence in the medical record to substantiate the report of a cancer diagnosis. Once the SC determines that a report of cancer was, in fact, erroneous, a DE or OCF form should *not* be completed. Instead, a Missing Data Form should be completed. (See [Section 8.6](#) below).

#### **8.4.1 Abstracting Diagnostic Evaluation Information**

Diagnostic evaluation information is recorded in the five sections of the DE form and the Diagnostic and Staging Procedures Supplement form (DSS), if necessary. These forms are described below.

- **Part A - Diagnostic Evaluation and Staging Information** - This section is used to document clinical presentation, procedures performed for diagnostic evaluation and staging, results of selected procedures, the medical complications of the diagnostic evaluation and staging, and the final result of the diagnostic evaluation. If the participant undergoes more than 12 diagnostic/staging procedures, the additional procedures are recorded on the Diagnostic/Staging Procedures Supplement (DSS) form.
- **Part B - Diagnosis Information For Any Condition Other Than (PLCO) Cancer** - This section is used to record the diagnosis of specific conditions other than prostate, lung, colorectal, or ovarian cancer.
- **Part C - Cancer Diagnosis Information** - This section is used to document the source of the cancer confirmation, the date and description of the cancer diagnosis, the ICD-O-2 code, the histologic classification, TNM staging, and the stage of disease appropriate to the cancer. It also requests that the histopathology or cytopathology report which supports the diagnosis be photocopied and attached.
- **Part D - Date of Diagnostic Evaluation Determination** - This section is used to note when a workup is completed or stopped in three circumstances:
  - when the result is “No Malignancy” and no specific diagnosis
  - when the result is “No Malignancy” and there are no diagnostic procedures per participant report
  - when the result of the diagnostic evaluation is “No Information Available” because the participant discontinued the evaluation
- **Part E - Physician/Hospital Location Information** - This section is used to document all physicians, hospitals or clinics where the participant received diagnostic evaluation and cancer confirmation. This section collects the name, address, and telephone number of the physician, hospital and/or clinic, and the participant’s medical record

number. Recording of these data is recommended, but not required, and these data are *not* entered into the DEES.

As noted earlier, participants with a positive PLCO screening result will be followed forward in time from the time of the positive screen. Diagnostic evaluation information will be collected until one of the following occurs:

- a conclusive diagnosis (either cancer or non-cancer) has been made;
- for 12 months from the date of the positive screen; or
- the next screening exam, *whichever comes first*.

If, despite SC efforts to encourage a participant to seek medical attention for a positive screen, the participant does not initiate follow-up of the screen until late in the year, such as 10 months after the positive screen for example, the SC should still collect only the diagnostic evaluation data until 12 months after the positive screen or the next screen, whichever comes first. In the example given, this would mean two months of diagnostic evaluation data.

In the case of a confirmed cancer, diagnostic evaluation information should be collected up to (and including) the date the conclusive diagnosis is made. All staging information related to the initial diagnosis should be collected, even if a staging procedure was performed after the date of the initial diagnosis or after the first definitive treatment. For example, if a participant is diagnosed with lung cancer by an endoscopic bronchoscopic biopsy, and then has a CT-chest, CT-brain, bone scan, or lobectomy with lymph node sampling, all of the latter would be recorded on the DEL3 form as staging procedures, even though they follow the confirmation of the lung cancer diagnosis. Some treatments, such as surgical resection of lung tissue or lymph node sampling, can be considered both staging and treatment procedures, so they would be recorded on both the DE and TI forms. Any treatment procedure that could not also be considered staging, such as chemotherapy, radiation therapy, or hormone treatment would not be recorded on the DE form. Any procedure that follows chemotherapy or radiation therapy would not be considered staging procedures and would not be included on the DE form unless the treatment is considered neoadjuvant. A special consideration is "watchful waiting" as in the case of prostate cancer. Watchful waiting is considered to be a first line of treatment; consequently, diagnostic/staging information would only be collected up to the date when watchful waiting begins. If there is any question whether watchful waiting is taking place, abstractors should consult with the Principal Investigator at the Screening Center. Staging procedures that are recorded should correspond to the TNM or stage of disease classifications recorded in Part C of the DE form. Staging information on cancer recurrence or disease progression should not be collected. should not be collected.

Staging procedures that are recorded should correspond to the TNM or stage of disease classifications recorded in Part C of the DE form. Staging information on cancer recurrence should not be collected.

In conducting medical record abstractions for PLCO cancers, the SC may encounter some special situations:

- When no followup procedures were performed based on an SC internal referral or a physician's decision that follow-up of a positive screening examination was not necessary. In such cases, the SC should complete a Diagnostic Evaluation Form and document the result of the diagnostic evaluation as "No Malignancy." The SC must also document that the

case was an SC internal referral or must record verbatim what the physician stated (whether written or verbal) regarding no need for follow-up and the date the physician made the statement. In the situation where only a participant's report can be obtained that his/her physician decided not to do follow-up on a positive screening exam, this information should be collected. Refer to the specifications for the DEP, DEL, DEC and DEO forms for specific instructions for completing the forms in such situations.

- When the participant begins diagnostic evaluation but then decides (against the recommendation of his physician) not to continue: In such cases, the SC should complete a Diagnostic Evaluation Form and document the result of the diagnostic evaluation as "No Information available" and provide an explanation of the situation. Refer to the specifications for the DEP, DEL, DEC and DEO forms for specific instructions for completing the forms in such situations.
- When a participant reports cancer on the ASU for the study year *following* a positive screen and the SC has no record of follow-up directly related to the positive screen: The SC should contact the participant and the participant's physician to determine if the cancer diagnosis was made as a result of diagnostic evaluation following the positive screen or because the participant developed new symptoms. If the diagnostic evaluation was made as a follow-up to the positive screen, then a DE form should be completed for the same study year as the positive screen. If the diagnostic evaluation was made because the participant sought medical care for new symptoms, a DE form for the same study year as the ASU should be completed. Sometimes it is not clear what the motivation is for seeking an evaluation. It is assumed that if follow-up occurred within 12 months of a positive screen, the follow-up was motivated in part by the positive screen.
- **When a participant has more than one diagnostic evaluation during the year following a positive screen:** If, following a positive screen, a participant has a negative evaluation for cancer from one physician, then later (within the same study year) decides to go for a second opinion, at which time the second physician diagnoses a PLCO cancer, the SC should contact the participant and the participant's physician(s) to determine whether the participant was seeking additional care as a result of the screening test or because s/he developed new symptoms, or some other reason.

If the participant was seeking additional care as a result of the screening test, *only one* DE form should be completed and information from diagnostic follow-up performed by both physicians should be recorded. The final diagnosis should be prostate, lung, colorectal or ovarian cancer. If the participant was prompted to seek additional medical attention due to a change in his/her condition, *two* DE forms should be completed. The first form should reflect the negative diagnosis following a work-up for a positive screen. The second form should reflect a positive cancer diagnosis. The SC should enter an expectation for a DE *for the next study year* into the cancers table in the SMS, with a source of "OTH." The abstractor should then document the second workup on a DE for the next study year.

- **When multiple primary cancers of the same PLCO organ are diagnosed:** If multiple primary cancers are diagnosed at the same

PLCO site, during the same diagnostic evaluation process and prior to the first definitive treatment for the cancer that is being confirmed, individual DE forms should be completed for each primary cancer. Once treatment has been initiated, SCs are not required to follow-up or document any additional reported cancer (a new primary, a recurrence, or metastases) of the organ. Refer to the specifications for the DEP, DEL, DEC, and DEO forms for specific instructions for completing the forms in such situations.

**Note:** *If the SC becomes aware of multiple primary cancers, recurrences or metastases occurring after treatment of the first cancer, and has access to the medical records, the hardcopy data should be collected and maintained in the participant's study file. They may be used for the death data review process.*

- **When a participant is diagnosed with a metastatic PLCO cancer:** Only a *primary* PLCO cancer should be recorded in the cancer section of the DE form. If the diagnostic evaluation for a suspected PLCO cancer reveals a PLCO malignancy, but it is a metastasis from another cancer site (including a different PLCO cancer site), the result of the diagnostic evaluation should be recorded as "Other Malignancy Confirmed Histologically or Cytologically," and the primary cancer type should be recorded in section of the DE form for Diagnosis Information for Any Condition Other Than [PLCO] Cancer. An OCF for the primary cancer will then be expected by the system.

The Diagnostic Evaluation Form should always be completed before the Treatment Information Form because the Treatment Information Form is only required if a PLCO cancer has a confirmed diagnosis documented on the Diagnostic Evaluation Form. The follow-up of positive screening examinations and confirmation of reported cancers from the Annual Study Update and other sources may show that the participant had a non-malignant condition or a non-PLCO cancer. In such situations, the Treatment Information Form need not be completed.

#### 8.4.2 Abstracting Treatment Information

The Treatment Information Form is organized into two sections.

- **Part A - Initial Treatment Information** - This section is used to document all *initial* treatment information for the cancer diagnosis. This section also includes, when appropriate, a section for recording comments.
- **Part B - Physician/Hospital Location Information Form** - This section is used to document all physicians, hospitals or clinics where the participant received PLCO cancer treatment. **Note:** The SC has to track metastatic PLCO cancer sites manually for those intervention participants who are still undergoing screenings in order to prevent additional cancer screenings for that particular organ.

Initial treatment is defined as the first treatment received, and is usually within six months of diagnosis (before cancer progression or recurrence). Six months should be long enough to collect information, at the least, about initiation of adjuvant treatment after diagnosis. If treatment begins after six months, it is possible that this treatment is not related to the initial disease, but perhaps to a recurrence of the disease. Cases in which primary therapy is begun *after* 6 months post-diagnosis should be referred to the SC Principal

Investigator for adjudication. If necessary, photocopies of the appropriate information should be sent to the MRA Coordinator at the CC, who will send the information to NCI for final adjudication. NCI will decide with the SC the best way in which to handle each specific case.

### 8.4.3 Abstracting Non-PLCO Cancer Information

The purpose of the Other Cancer Confirmation Form (OCF) is to document the SC investigation of non-PLCO cancer reports, to document the ICD-O-2 code for primary non-PLCO cancers, and to document metastatic cancer. The OCF is organized into two sections.

- **Part A – Confirmation of Cancer** - This section is used to document the result of the investigation of the cancer report (primary, meta-static—unknown primary, metastatic—PLCO primary), and information about the diagnosis such as date, ICD-O-2 code, basis for diagnosis. This section also includes an item for recording cancer reports that are initially reported as primary cancer but, after further investigation, are found to be metastases of an unknown primary cancer.

**Note:** Only metastasis of unknown primaries should be recorded.

- **Part B - Physician/Hospital Location Information Form** - This section is used to document all physicians, hospitals or clinics where the participant was diagnosed with the cancer.

A separate OCF should be completed for each primary non-PLCO cancer diagnosed. Up to three cancers that were initially reported as primary cancers, but are later determined to be metastatic sites of an unknown primary, (in Item A.12 of the OCF), may be confirmed using one OCF. If the investigation of the reported cancer reveals a metastasis from an unknown primary, the site and date of diagnosis of the metastasis will be recorded on the OCF.

In conducting medical record abstractions for non-PLCO cancers, the guidelines below should be followed:

- Do not complete an OCF for active recurrences of a primary non-PLCO cancer that were diagnosed prior to randomization.
- If a reported “cancer” is confirmed to be a primary non-PLCO cancer, the SC will not be required to complete another OCF for any subsequent reports of this cancer, even if it is a multiple primary cancer in the same organ (i.e. melanoma or breast). NCI is interested in the first primary only.
- For multiple reports of a cancer that has been confirmed as a metastatic site in a previous study year, the SC will be required to determine (via a method chosen by the SC such as a review of diagnosis dates, contact with the participant, review of medical records, etc.) whether or not it is the same metastasis or a new primary.
- When a non-PLCO cancer is reported via a Diagnostic Evaluation Form, the ICD-9 code recorded in the Non-PLCO Cancer Diagnosis section (Part B) of the DE form will be translated into the three-digit cancer code and an expectation for an OCF will be set for that cancer.
- While confirming a reported non-PLCO cancer, if the primary cancer site is identified to be a PLCO site, it is necessary to indicate this in Items A.6 and A.6a of the OCF. Depending on whether or not the PLCO

cancer was confirmed in the past, it may or may not be necessary to complete a DE form for the PLCO cancer. For example:

*The SC reviews the medical record to confirm a reported liver cancer, and finds that the primary cancer site was prostate. The circle for prostate should be darkened in Item 6a. If the liver cancer was a metastasis from a prostate cancer that was already confirmed in the study (the cancer status code is "C"), then a new DE is not required. If the prostate cancer had never been confirmed in the study, a DEP form is now required.*

- When there is an unknown primary with a PLCO metastatic cancer site, this should be recorded in Items A.6 'Result of Confirmation of Reported Non-PLCO Cancer' and A.12 'Reported Metastatic Sites' of the OCF. The SMS and DEES options will reject the receipt of this data. User Support should be contacted to get this data receipted into the SMS.
- The OCF should be used to document metastases of unknown primary cancers only.
- Up to three metastatic sites of an unknown primary cancer may be recorded on one OCF. If there were more than three metastatic sites, the SC should contact the MRA Coordinator for an appropriate resolution.
- The SC is not required to document metastatic sites revealed upon review of the medical record.
- There is no "window" for abstracting information about non-PLCO cancers, it is expected that once the SC is notified of the non-PLCO cancer, that every attempt should be made to investigate and complete the OCF, if appropriate, in a timely manner.

## 8.5 Receipt and Processing of the Medical Record Abstract Forms

When medical record abstract forms are completed, they should be receipted into the SMS as soon as possible so that the participant's cancer status can be updated. Receipt may be accomplished by interactive data entry or via the DEES-SMS Update (see [Chapter 17.0](#) for more information on the receipt process). Data items from the forms that are entered into the system as part of the receipt process include:

### Diagnostic Evaluation Forms:

- Date receipted
- PID
- Study Year
- Date Abstracted
- Abstractor ID
- Result of diagnostic evaluation
- ICD-9-CM code for diagnosis (if non-PLCO cancer)
- Date of physician diagnosis (for non-PLCO cancer)

- Date for first cancer diagnosis (if PLCO cancer)
- ICD-O-2 code for diagnosis (for PLCO cancer)

**Treatment Information Forms:**

- Date received
- PID
- Study Year
- Date Abstracted
- Abstractor ID

**Other Cancer Confirmation Forms:**

- Date received
- PID
- Study Year
- Date Abstracted
- Abstractor ID
- Result of Confirmation of Reported Non-PLCO Cancer
- date of diagnosis
- ICD-O-2 code
- Up to three 3-digit codes for reported metastases

The SMS receipt screen for the Diagnostic Evaluation is given below.

The screenshot shows a software interface for a 'Diagnostic Evaluation - Prostate' form. At the top, there is a title bar and a toolbar with various icons. Below the toolbar, the form displays the following information:

- Participant ID: 800014-7
- Study Year: T2
- Date Abstracted: 05/17/1996
- Date Received: 05/20/1996
- Abstractor ID: 1001
- A-9. Result of Diagnostic Evaluation for Prostate Cancer: 0
- B-10. Earliest Specific Prostate Dx Date: [ ] [ ] [ ]
- B-11. ICD-9-CM Classification of Other Cancer Dx 1: 600XX
- Other Cancer Dx Date 1: 04 / 11 / 1996
- ICD-9-CM Classification of Other Cancer Dx 2: [ ] [ ] [ ]
- Other Cancer Dx Date 2: [ ] [ ] [ ]
- C-12. Primary Prostate Cancer Dx Date: [ ] [ ] [ ]
- C-14. ICD-O-2 Cancer Classification: C - - -
- D-21. Date of Dx Evaluation Determination: [ ] [ ] [ ]

At the bottom of the form, there is a 'View Mode' button and a 'Record 1 of 2013' indicator.

**Figure 8-1.** Receipt Screen for DEP Form

If a PLCO cancer is confirmed, the SMS will be expecting future receipt of a Treatment Information Form. It is possible that several weeks or months may elapse between the completion of the two medical record abstract forms. This would likely occur if the Diagnostic Evaluation Form is completed close to the

time of diagnosis. Since the Treatment Information Form includes treatment in the six months following diagnosis, completion of the form must necessarily wait until this period of time has elapsed. Note that if a cancer is not confirmed until treatment is performed, the information regarding the treatment should be abstracted onto both the Diagnostic Evaluation Form and the Treatment Information Form. For example, if a participant does not have the diagnosis of cancer prior to a surgical resection, then the surgical resection would be considered diagnostic staging and treatment, and would be recorded on both the DE form and the TI form.

Medical record abstract forms should be manually edited using the procedures described in [Chapter 17.0](#) of this manual. After a form has undergone a manual edit, it will be scanned using the Optical Mark Reader into the DEES. Since it may take several months to collect all of the required data and complete the medical record abstract form, the SC may scan the form even if it is not finalized. It should be assigned a form disposition of "Interim Complete" and scanned each time it is updated. (See *DEES User's Guide/DEES Upgrade Documentation* for more information.) After scanning, the computer edit should be run. If items are incomplete or unclear as identified from the manual or computer edits, data retrieval should be requested from the abstractor. If the form is final, a final disposition code of "Final Complete" or "Final Incomplete" should be assigned by the SC Coordinator (see [Chapter 17.0](#)). Completed abstracts should be filed in the participant's folder. In addition, all medical records received at the study office should be filed in the participant's folder or, if required, copied, with the copy retained and the original returned to the physician or institution from which they were requested.

## 8.6 Updating Cancer Status in the SMS

Below are the cancer indicator codes that may be set during cancer confirmation activities:

S = suspected cancer – This status is set when a cancer that has not previously been reported or confirmed, is reported to the SC from a source such as the ASU, a participant phone call, etc.

C = confirmed cancer – This status is set when a DE or OCF is receipted that confirms the cancer.

P = previously confirmed cancer – This status is set when a cancer that was previously confirmed is reported to the SC again. This status is set automatically by the system, without receipt of a DE or OCF form.

N = case confirmed as non-cancer - This status is only used for PLCO cancer suspicions that result from positive screens. This status is set when a DE form is receipted with the result of Diagnostic Evaluation.

M = Missing Data Form – This status is set when a Missing Data Form is filed in place of a DE, TI or OCF form.

Figure 8-2 presents the screen display of the cancer information maintained by SMS. Cancer information may also be viewed on the Medical Record Background Report.

Participant Status Information

Participant ID: 202664-6

Study Year	Cancer Type	Cancer Source	Cancer Status	Identify Date	Determination Date	Determination Source	Other Cancer Code	Other Cancers Specify
T00	C	FSG	N	01/03/1996	04/24/1996	DEC		
T00	C	FSQ	N	01/23/1996	04/24/1996	DEC		
T03	P	BCF	S	01/26/1999				

Study Year: T0 Cancer Type: C Cancer Source: FSG Other Cancers Code:

Identify Date: 01/03/1996 Cancer Status: N

Other Cancers Specify:

View Mode Record 1 of 1

Figure 8-2: Screen Display of Cancer information

## 8.7 Documenting Non-Response for Cancer Confirmation

In some cases, the SC will not be able to complete a Diagnostic Evaluation, Treatment Information, or Other Cancer Confirmation form for the participant. The following are the conditions under which a Missing Data Form (MDF) should be completed:

- When the medical records necessary for the completion of the DE, TI, or OCF are not available (i.e., records are lost, institutional refusal, foreign or non-local institution). Reason code R ("could not be obtained" and the appropriate subcode) should be recorded on the MDF;
- When the SC is unable to find the participant to determine whether or not s/he had follow-up for a positive screen. Reason code 5 ("Can't locate contact" and the appropriate subcode) should be recorded on the MDF;
- When the SC determines that the participant will not ever be obtaining diagnostic follow-up for a positive screen (that is, the participant refuses to obtain diagnostic follow-up). Reason code 1 ("Refused study activity" and the appropriate subcode) should be recorded on the MDF. If the participant refused to follow-up, the MDF can be completed at the time of the refusal. If the participant states that s/he plans to follow-up but does not, an MDF should be completed after 12 months from the positive screen, or the next screening visit (whichever comes first);

- When the participant had no follow-up for a positive PLCO screen due to other, more critical illnesses. Reason code 1 (“Refused study activity” and the appropriate subcode) should be recorded on the MDF;
- When the SC determines that the participant will not ever be obtaining treatment for a confirmed cancer that is, the participant has decided not to undergo treatment). Reason code 1 (“Refused study activity” and the appropriate subcode) should be recorded on the MDF;
- When the SC is unable to find the participant to obtain consent to collect medical records. Reason code 5 (“Can’t locate” and the appropriate subcode) should be recorded on the MDF;
- When a participant refuses to sign a Release of Information form for us to obtain medical records to document cancer diagnostic/staging procedures or treatment information. Reason code “R” (records could not be obtained, subcode R01) should be recorded on the MDF.
- When the participant may have sought follow-up attention but has since died, and the SC cannot obtain consent forms from the participant’s family to obtain medical records. Reason code R (Records could not be obtained) should be recorded on the MDF. If the SC is unable to locate the participant’s family to obtain consent or to obtain medical records, use Code 5 (“Can’t locate,” subcode 504).
- When the participant dies before seeking follow-up for a PLCO positive screen, record Reason code D, subcode DDD on the MDF;
- When the SC obtains records for a participant who reported an interval cancer (PLCO or non-PLCO) but the records do not substantiate the report of the cancer diagnosis. Reason code E record (“Erroneous Report of Cancer,” subcode F01) on the MDF;
- When the cancer reported by the participant is found to be a primary, or a recurrence, or a metastasis from a primary cancer that was diagnosed *prior to randomization*. Reason code “E” (“Erroneous Report of Cancer,” subcode E02) should be recorded on the MDF. If the primary cancer that was found to have been diagnosed before randomization is a PLCO cancer, an ATF should also be completed to document the participant as a randomized ineligible. (See [Chapter 4.0](#));
- When the cancer reported by the participant is found to be a recurrence or metastasis from a primary cancer diagnosed after randomization, reason code E (“Erroneous Report of Cancer,” subcode E03) should be recorded on the MDF.
- When the participant sees a physician for treatment of the cancer, but the SC is unable to obtain any information from the participant’s physician or a medical facility regarding the details or outcome of the treatment. Reason code R (Records could not be obtained and the appropriate subcode of R03, R04, or R05) should be recorded on the MDF.

**Note: Only the reason codes, 1, 8, E, and R should be used on the Missing Data Form for DE, TI or OCF Forms. Each reason code must be accompanied by an appropriate subcode.**

A MDF should *not* be completed for a DE form if the SC or the participant consults a physician for follow-up and the physician indicates, based on the screening exam result and/or a review of the participant’s medical record, that

no follow-up testing is necessary. In this situation, a DE form should be completed as described in the form completion specifications.

Refer to [Chapter 17.0](#) and [Appendix A-17-1](#) for information on the completion of the Missing Data Form.

## 8.8 Monitoring Cancer Ascertainment Activities

The SMS will produce reports that can be used by the SC Coordinator to assist in monitoring cancer confirmation activities. These reports are described below:

### SMS Reports:

- **Medical Record Background Report** ([Appendix B-8-2: Medical Record Background Report](#)): This report is generated for participants with a suspected or confirmed PLCO cancer. It lists locator information, date of birth, modified date of birth, and cancer information (such as outstanding DE forms, cancer status, cancer type, and ICD-9-CM codes). The report may be generated to facilitate the collection of Medical Record Abstracting information.
- **Cancer Confirmation List** ([Appendix B-8-3: Cancer Confirmation List](#)): This report lists all participants for whom a possible PLCO cancer has been reported. The listing will contain the following information for each participant: Participant ID number, participant status, vital status, type of cancer reported, date of notification, and source from which the cancer was reported. This form will be used by the SC Coordinator to rapidly identify the participants for whom information on diagnostic follow-up and cancer confirmation and treatment must be obtained.
- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report lists all participants and all delinquent, incomplete or outstanding forms for each participant. In terms of cancer ascertainment, this form will be used by the SC Coordinator to track the completion of the medical record abstract forms. Although there is no "deadline" for these forms, it is expected that they should be able to be completed within six months of notification of an unconfirmed cancer. For participants in the intervention group with a positive screening test, it is expected that the Diagnostic Evaluation Form should be able to be completed before the activity window the for the next study year begins.
- **Participant Overview** ([Appendix B-17-10: Participant Overview Report](#)) This report may be used to monitor the status of cancer confirmation for a specified group of participants. This report also provides a summary of study information for each participant in the group.

### DEES Reports:

- **Summary of Scanned Forms** ([Appendix B-17-11: Summary of Scanned Forms Report](#)) This report may be used to determine the cumulative number of medical record abstraction forms (DE, TI and OCF) scanned and counts by date scanned.
- **DEES Final Disposition** ([Appendix B-17-12: Report of DEES Final Disposition](#)) This report lists forms according to their final disposition (FCM, FIC, ICM). This report will enable SC staff to identify MRA forms that are not yet final and have a disposition of Interim Complete (ICM).

### **Semi-Annual SAS Reports:**

- **Completion Status of Expected Other Forms Relative to Activity Windows** – This report is generated by the CC and sent to the SCs on a semi-annual basis. It may be used to monitor the cumulative number of DEs, TIs and OCFs and MDFs completed out of the total number expected. It may also be useful in estimating abstracting workload. Note that the expected number of DEs is taken from Cancer Status = Suspected. If there are multiple positive screens per cancer type per person in a study year, only one screen is counted.

[Chapter 17.0](#) and the *SMS User's Guide/SMS Upgrade Documentation* contain additional information on producing reports to monitor cancer ascertainment activities.

## **8.9 Reporting Cancer Status to the Coordinating Center**

Once a month, the SC will transmit all medical record abstract information from DEES to the Coordinating Center (CC). This will be done through the Data Transmission application of the PLCO computer system. Refer to the *SMS User's Guide/SMS Upgrade Documentation*.

## **8.10 Quality Assurance for Cancer Confirmation**

The Medical Record Abstraction Quality Assurance Plan ([APPENDIX L](#)) consists of six components, regular communication, registration, training and external quality assurance, internal quality assurance, workshops and conference calls, problem resolution and response to medical record abstraction issues. Each abstractor or nosologist will be required to submit a registration form which will be reviewed and approved by NCI. The MRA Coordinator at the CC will facilitate regular communication between the SCs and NCI on medical record abstraction issues and problem resolution as well as coordinate training and the quarterly external quality assurance cycles. The Lead Abstractor at each SC will assist the CC in monitoring internal quality assurance at their SC and provide input for medical record abstraction issue resolution. Please see [APPENDIX L](#) for more details of the plan.

# Attachment 1

## Minimum Requirements for SC Contact of Participants Following a Positive Screen

- 1 There is considerable variation in the approach and effort that Screening Centers use when collecting information on the follow-up to a positive screening exam. One concern is that an insufficient or inconsistent effort may preclude the SC from contacting the participant in a timely manner to encourage follow-up and verify that follow-up is occurring. A second concern is that a number of SCs are not contacting the health care provider (HCP) early and frequently enough to obtain all medical records. As the goal of these guidelines is the reduction of the MDF-DE rate, these requirements may be followed by all SCs, but specifically apply only to any SC with a MDF-DE rate that exceeds 10%.

- a **What is the minimum requirement for participant contact attempts following a positive screen?**

**Resolution:** The SC staff should make timely and frequent follow-up contacts with the participant to determine the status of the follow-up. Follow-up contact begins with the results letter that the participant and the participant's HCP should receive each within three weeks of the screening exam.

The SC should begin contact attempts 3 months after the results letter is sent and should continue to contact the participant every 3 months if earlier attempts are unsuccessful. Each quarterly contact attempt should consist of five calls over two weeks, with calls at different times of the day and week, and with at least one call at night and on weekends until the SC is able to reach the participant. If telephone contacts are unsuccessful, the SC needs to send a follow-up letter. The letter should encourage the participant to obtain follow-up, and request that the participant call the SC as soon as possible. The letter should also indicate that the SC will continue to re-contact the participant to confirm that s/he has contacted her/his physician for follow-up.

If the SC has been unable to contact the participant prior to the next screening exam or until 12 months from the screen, whichever comes first, then a MDF can be completed.

When the SC has been unsuccessful in contacting the participant, the SC should contact the HCP to enlist his/her help in encouraging the participant to get follow-up. HCP contact is recommended two weeks following each unsuccessful cycle of five calls and one letter.

If the SC has successfully contacted the participant, but the participant still has not had an evaluation, the SC should make one final effort to encourage the participant to get follow-up, even though it means that any follow-up information obtained beyond the window of data collection would not be collected.

The SC staff should document any successful contact with a participant on the Telephone Screening Exam Follow-up form. The form should be placed in the participant's folder. The SC should also document that the participant has discussed the results of the positive screening exam with his/her HCP or the reason why the participant has not discussed the results with his/her HCP.

- b If the SC verifies that follow-up has occurred, how often should the SC attempt re-contacting the participant to determine the status of the subsequent follow-up.

**Resolution:** The SCs need to re-contact the participant every three months to determine the status of the evaluation. Timely and frequent contact will improve

the quality and completeness of data collection. Each attempt to re-contact should include a minimum of five phone calls and one letter. Attempts to contact the participant and verify the status of the work-up should continue until a conclusive diagnosis is made, until the next screening exam, or until 12 months from the screen, whichever comes first.

- c To date there has been no standard approach for the collection of information from a participant regarding his/her follow-up of a positive screen. Furthermore, when the participant says s/he has not had an evaluation, there has not been a standard approach for determining the reasons for lack of follow-up. How can the SCs improve the collection of information describing the reasons why follow-up has not occurred?

**Resolution:** To standardize the collection and coding of follow-up information obtained during this process, the SC should refer to the Telephone Screening Exam Follow-up form and ask the participant probing questions. Record the participant's responses each time the SC has a conversation with the participant regarding follow-up to a positive screen. This form includes sections formatted to document the health care provider's name and address and to list any procedures that have occurred or are planned.

When an evaluation is either not obtained or discontinued, this form provides questions to probe for reasons and space available to record the participant's responses.

A separate Telephone Screening Exam Follow-up form should be used each time the SC reaches the participant to verify the status (or lack of progress) of the evaluation following a positive screening exam. Each completed script should to be placed in the participant's folder.

- d How often should the SCs collect medical records?

**Resolution:** The SC should collect medical records as soon as possible. Since the SC will call the participant quarterly to determine the status of the follow-up evaluation, the SC should request medical records within one month of the call if any evaluation has occurred in the previous quarter. The longer the SC waits to collect medical records, the more difficult it may be to obtain medical records.

## 2 When can the SC complete an MDF? Is there a way to capture the additional information that is obtained during follow-up phone calls?

**Resolution:** The SCs will not complete an MDF until there has been at least three separate attempts (one attempt is defined as a minimum of five calls and one letter) to contact the participant. In addition, the SC needs to wait until the window of data collection closes for any follow-up evaluation—that is, until 12 months after the screening exam or until the next screening exam, whichever is first. NCI wants the SC to contact each participant frequently to encourage retention and follow-up, particularly when no follow-up to a positive screening exam has occurred. The SC will use the information recorded on the script to complete an MDF when three separate attempts have failed to produce a result. While the MDF has not changed in appearance, the SCs will be able to record additional reason codes to clarify why follow-up was not obtained. The additional reason codes will match the codes and explanations included in the sample script. Separate specifications for the completion of the MDF are attached.



## **9.0 VITAL STATUS ASCERTAINMENT AND THE DEATH REVIEW PROCESS**

### **9.1 Introduction**

#### **9.1.1 Background**

The primary objective of the PLCO trial is to ascertain whether screening exams for prostate, lung, colorectal or ovarian cancer can reduce mortality from these cancers. A statistically significant reduction in the PLCO cancer mortality rate for intervention participants would provide strong evidence for the value of these screening exams. The Screening Centers (SC), the Coordinating Center (CC) and a Death Review Committee (DRC) will participate in activities to implement a review of cause of death for all PLCO participants who die during the course of the trial. The purpose of the Death Review Process (DRP) is to determine whether or not death was due to a PLCO cancer. This review process plays an important role in minimizing bias in assignment of PLCO cancer as cause of death on the death certificate, and therefore ensures a more accurate assessment of the value of these screening exams.

Intervention arm participants in the PLCO screening trial may be diagnosed with a cancer earlier in its natural history than they would have been in the absence of these screening exams. Moreover, since these participants undergo repeated screening tests, it is possible that a cancer may be diagnosed that may never have presented in that individual's lifetime. Therefore, during each year of follow-up in the PLCO trial, there is likely to be a greater incidence of newly diagnosed cancers in the intervention arm than in the control arm. This may affect mortality data, since it has long been established that if an individual has been diagnosed with cancer, this will impact the cause of death entered on the death certificate. This influence, known as "sticking diagnosis," may lead to an overdiagnosis of PLCO cancers among intervention participants.

Alternatively, control arm participants may be underdiagnosed with PLCO cancer since they will not have had repeated screening exams and may die before the cancer was diagnosed. In the absence of a directed autopsy this bias cannot be corrected, however, certain ICD-9 codes, which are closely related to PLCO cancers, can be investigated. For example, the medical records of a participant whose death certificate suggests a primary liver, bone, brain or spinal cord cancer (ICD-9 155,170) can be further evaluated to determine if the participant had a PLCO cancer. Other examples include, causes of death which suggest uncertainty of the diagnosis of cancer, such that prostate, lung, colon-rectum or ovarian cancer cannot be excluded, or a metastatic cancer with unknown primary (ICD-9- 184.9, 199). Further investigation of medical records may reveal that some of these deaths were due to PLCO cancers. Review of these deaths should minimize the level of underreporting of PLCO cancers on the death certificate in the PLCO trial and reduce the influence of this bias.

Because the DRP will involve a review of all PLCO cancer deaths, as well as other closely related ICD-9 cancer deaths, it will minimize the effect of over- and under-reporting of PLCO cancers as the death certificate cause of death. This process will further ensure that ascertainment of the fact of death is equally applied to the intervention and control arm participants.

### 9.1.2 Overview of the Death Review Process

The SCs are responsible for ascertaining all deaths, collecting all death certificates, and shipping all death certificates to the CC.

The following is a brief overview of the activities to be completed by the SCs, the CC and the DRC to implement the DRP:

- **Ascertainment of the Fact of Death:** Each SC is responsible for implementing procedures to follow-up all PLCO participants for vital status ascertainment during the course of the trial. For participants who are reported as deceased, the SC is responsible for confirmation of death through procurement of the death certificate.
- **Cancer Ascertainment:** Each SC will determine cancer incidence for all PLCO participants during the course of the trial as described in [Chapter 8.0](#)
- **Identification of Deaths for Review by the DRC:** The CC will be responsible for identifying deaths to be submitted to the DRC for review. The CC will code cause of death from SC-supplied death certificates, enter the information into a central database and then apply a computer algorithm to select, from the coded cause of death and coded cancer status and cancer diagnosis, all deaths which meet the criteria described in [Section 9.8.3](#). For those deaths not selected by the computer algorithm, the case will be deemed as "Certified" and no additional action is required.
- **Collection of Medical Records for Death Review.** The SC will be responsible for providing all necessary documentation to the DRC. All records will be carefully read by the SC, and the relevant portion of any record that identifies a cancer as screen-detected, or makes mention of the PLCO trial, will be deleted. On a quarterly basis, the SC will prepare 1 copy of all DRP documentation, batch the DRP folders, and forward them to the CC. The CC will verify that the DRP folders are complete and forward the information to the NCI consultant for review prior to sending them to the DRC.
- **Analysis by the Death Review Committee.** The DRC is composed of five physicians/oncologists who have experience with treating a variety of cancers and are not affiliated with the PLCO study or any of its screening centers. Each of these experienced reviewers will review all medical record documents for each death to:
  - ▶ evaluate the adequacy of the information;
  - ▶ decide whether they consider the participant death to be: "due to," "probably due to," "probably not due to," or "not due to," prostate, lung, colorectal or ovarian cancer;
  - ▶ decide whether or not other competing disease processes contributed to death.
- If a DRC member determines that additional documentation or pathology information is needed, the committee member will submit a request to the CC.
- If the results of the DRC are discordant, a conference call will be held with all the DRC members and the NCI consultant to reach consensus on the underlying cause of death.

- All results of the DRC review will be documented by the CC and reported to the SCs. The committee's decision will be binding.

Figure 9-1 provides a visual representation of this process.

The remainder of this chapter will describe in detail the SC procedures and review activities to be completed for ascertaining and confirming participant deaths, providing death certificates to the CC, identifying cases for submission to the DRC, and obtaining, editing and processing all medical record documentation to be submitted to the DRC. Systems support for some SC activities will be provided by the CC and documented in the appropriate User Upgrade memos. Central death certificate coding, data processing and coordination procedures to be completed by the CC will be documented in the "Death Review Manual – Coordinating Center Procedures." Procedures to be completed by the DRC will be documented in the "Death Review Manual – Death Review Committee Procedures."

**Figure 1:** Death Review process

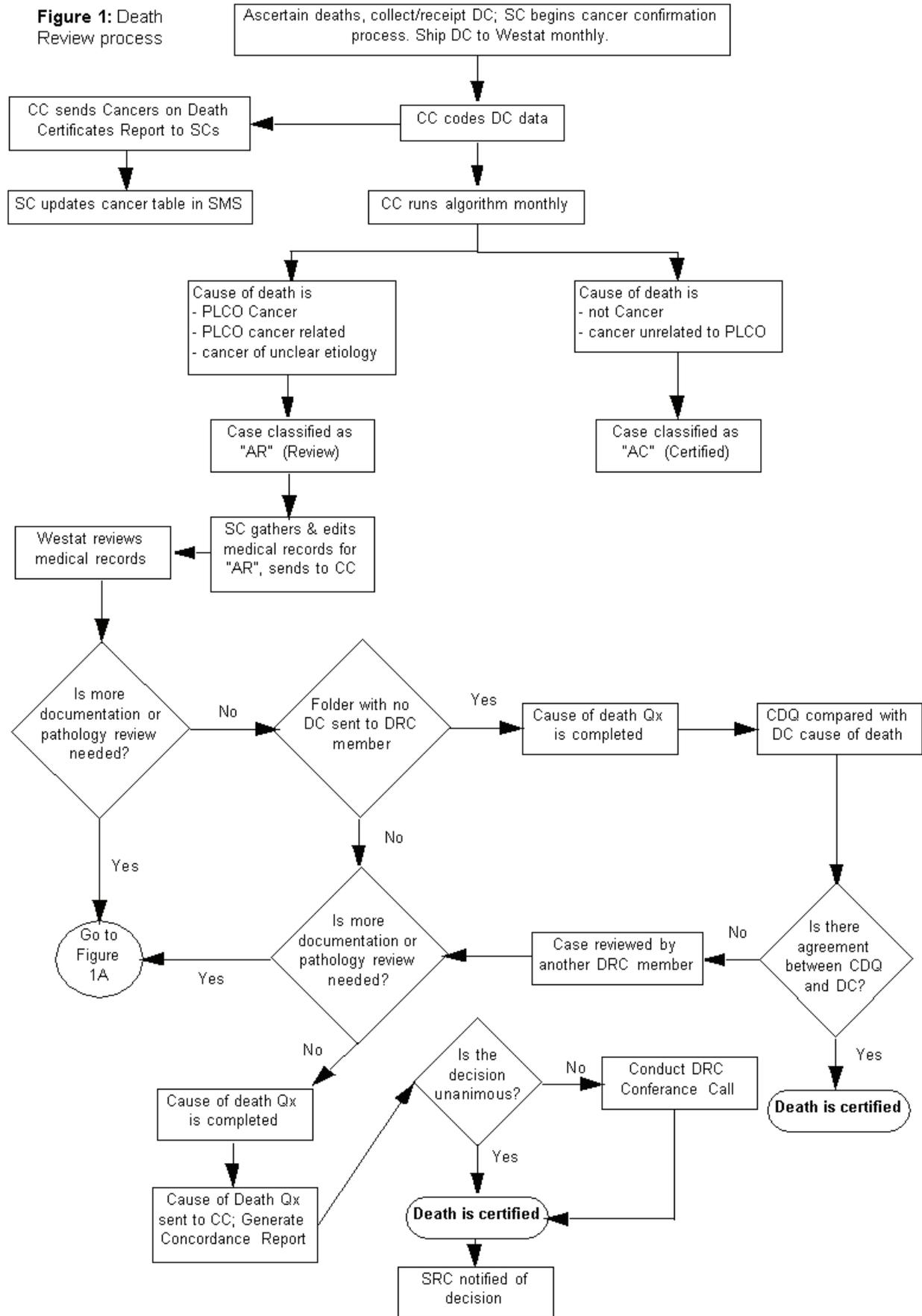
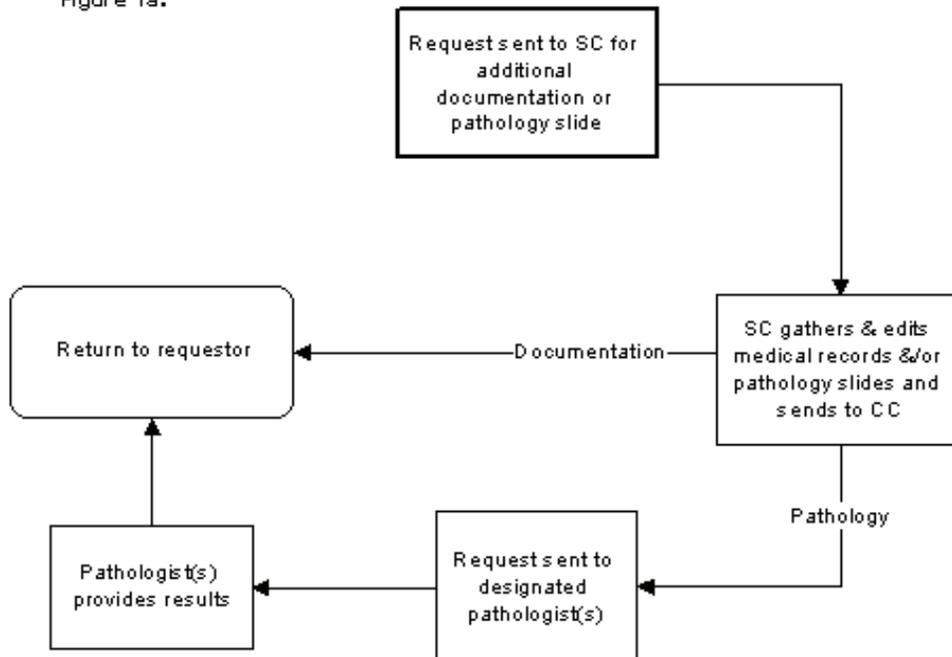


Figure 1a.



## 9.2 Death Ascertainment Activities

### 9.2.1 Introduction

The SC will determine the vital status of all participants during the course of the trial and obtain death certificates for those participants reported as deceased. Tracing procedures will be implemented for all participants who are considered lost-to-followup in order to ascertain their vital status. The results of vital status ascertainment will be entered into the SMS.

If a Non-Response Form (NRF) has been receipted, vital status ascertainment should only be performed for those participants who are classified as a level 1 - "No Active Contact with Participant". For more information please refer to [Section 17.4.6 Documenting a Participant's Request to Withdraw from the Study](#).

### 9.2.2 Vital Status Ascertainment

Ascertainment of vital status is the first step in the DRP. The second step is the acquisition of death certificates, which is described in [Section 9.3](#). The primary method for determining vital status is the Annual Study Update (ASU), which is sent to all participants on a yearly basis. Participants who do not respond to the ASU will require follow-up tracing activities to determine whether they are alive or deceased. In some cases, the participant's relatives or friends may complete and return the forms indicating the participant has died. In addition, the envelope containing the ASU form may be returned from the post office

marked "Deceased." If a participant is reported as deceased through this process, his/her vital status will be updated in the SMS to "presumed deceased." When presumed deaths are identified, the SC Coordinator should initiate procedures to confirm the death. When a participant is reported as deceased, the SC Coordinator will need to obtain the date of death and state of death in order to obtain the death certificate from the appropriate state Vital Statistics Bureau. The SC Coordinator will determine the most appropriate strategy to obtain this information.

When participants are considered lost-to-follow-up because of failure to return the ASU or to keep an appointment for a screening visit, relatives, friends and/or physicians may be contacted for information. The **Baseline Locator Form** ([Appendix A-5-3](#)) and the **Follow-up Locator Form** ([Appendix A-7-2](#)) collect location information on the participant's relatives, friends and physicians. If the participant was identified as having a positive screening exam and/or a PLCO cancer at some time during the trial, the Physician/Hospital Location Information (part of the medical record abstract forms) would provide additional information about physicians and hospitals where the participant was seen. In the absence of contact within a year, standard SC tracing procedures should be initiated. These procedures may include a search for fact of death with the National Death Index (NDI), the Health Care Financing Administration (HCFA), the Social Security Death Index (SSDI), tumor registries, Departments of Motor Vehicle Administration and Vital Statistics Bureaus.

Critical identifying information, essential for making submission requests for vital status determination and for tracing participants will be maintained by the SC and stored in the SMS. This information is collected on the Baseline Locator Form (BLF) and the Follow-up Locator Form (FLF). It includes:

- Name: first, middle, and last;
- Sex;
- Date of Birth: month, day and year;
- Social Security Number;
- Address and date of address; and
- Mother's place of birth.

See [Chapter 7.0](#) for more information regarding tracing lost participants.

### **9.2.2.1 National Death Index**

The National Death Index (NDI) is an important source for identifying deceased individuals. The NDI is a computerized database of death records for the nation since 1979. NDI plus provides the underlying and multiple causes of death coded using the International Classification of Diseases. The National Center for Health Statistics, the agency that maintains the database, updates the NDI on an annual basis to include deaths through the previous year. For example, at the beginning of 2004 the database would include deaths through December 2000. This excellent source for vital status determination is rapid and only requires social security number, a full date of birth, and the gender of the participant for matching with death certificate information. Submission of additional participant data, however, may provide more certainty in the matches.

Prior NDI approval is required by the National Center for Health Statistics for all submissions for death searches of the NDI files. Westat will submit a central application to NCHS for search of the NDI. Approval will be for the project and

each SC will be able to submit their files to the NDI and the results will be returned to the SC. Once approval has been received for the initial NDI submission, the SC will be given guidance on submitting requests to NDI and interpreting NDI results. In addition to receiving the results of the NDI search, the SC will also receive an NDI User's Manual and a Repeat Request Form. The Repeat Request Form is provided for making future NDI submissions.

NDI updates the death records approximately 10 months after the end of a particular calendar year. It is recommended that the annual searches be conducted in January or February in order to take full advantage of updated information. The SC Coordinator will be responsible for preparing the data file for the NDI submission, for reviewing the returned NDI output, and for determining good matches. The address and phone number of the National Death Index are:

National Death Index  
Division of Vital Statistics  
National Center for Health Statistics  
3311 Toledo Road, Room 7318  
Hyattsville, MD 20782  
(301) 458-4444

The NDI output will be returned directly to each SC for review and determination of good matches. This output will be returned on CD-ROM and will contain eight different output files. One of the eight files included on the CD-ROM is the NDI Retrieval Report. Whenever a participant record matches with one or more NDI records, it will appear on this report. The other seven reports provide information on the records that were submitted and a file for forms to request death certificates from the State's Vital Statistics Office.

#### **9.2.2.1.1 Submitting Files to NDI**

Beginning in March 2001, SCs will begin annual NDI searches, any SC not planning to perform an annual NDI search, must provide written justification to the NCI.

The SC Coordinator will use the SMS to facilitate the NDI searches by generating the submission file for the NDI which contains all participants whose vital status is unknown (in-tracing, lost contact, NRF receipted, or missing 2 or more consecutive ASUs) or presumed deceased as of the date through which the NDI database is currently updated. The file will contain the participant's name (including maiden name), date of birth, social security number, sex, and city and state of residence (and state of death if presumed deceased). These data will be submitted to determine the vital status of participants who are lost to follow-up. These data are included to enable as close a match as possible with NDI records. The NDI results include the state file number for the death certificate which may facilitate (and perhaps reduce the cost of) obtaining the death certificate from the state Vital Statistics Bureau. Participants whose vital status has been determined as deceased within the past calendar year will not be included because NDI would not yet have a record of their death. A hard-copy listing of the PID and most recent date submitted to NDI will be generated **National Death Index List** ([Appendix B-9-1: National Death Index List](#)).

#### **9.2.2.1.2 NDI Reports**

Approximately four weeks after NCHS receives the data file the NDI retrieval report and several related reports containing information on the resulting pos-

sible record matches will be sent to the SC. This section describes each of the reports. The NDI Retrieval Program generates eight different files of information stored on one CD-ROM. Following is a summary of the different reports. For more detailed information, please refer to the NDI User's Manual. The page associated with the report is provided.

1. **Summary Retrieval Statistics** – This file contains a three- page report which provides the summary information about the NDI search. The information includes the SC coordinator's name and address, years of death searched, number of NDI records involved in possible record matches and other statistics related to the NDI search.
2. **NDI Retrieval Report** – The NDI Retrieval Report indicates which participant records matched with the NDI records. This report is explained in more detail below in [Section 9.2.2.1.3: Determining NDI Matches](#).
3. **Compressed NDI Retrieval Report** – The Compressed NDI Retrieval Report contains the same information as the NDI Retrieval Report, but without the column headings and line spacings to reduce the amount of paper generated when printing this report.
4. **Death Certificate Request Forms** – This report lists all the possible NDI matches grouped by the States in which the deaths occurred. A separate form is generated for each state that had at least one NDI match. The report is explained in greater detail below in [Section 9.2.2.1.5: Requesting Death Certificates for NDI Matches](#).
5. **Combined File** – This file combines the participant record with the matching NDI record(s). A separate Combined Record is created for each NDI record match. The file is intended for users who receive a large number of matches and would like to write a computer program to assess the quality of these matches.
6. **Matching User Records** – This file only contains those records submitted by the SC that were involved in possible matches with one or more NDI records.
7. **Non-Matching User Records** – This file only contains those records submitted by the SC that were not involved in matches with any NDI records.
8. **Rejected User Records** – This file contains the records that did not satisfy the basic criteria of the NDI edit program and were thus rejected prior to the search of the NDI file. Records are rejected if they did not contain the participant's social security number, date of birth and the sex code.
9. **Cause of Death File** (NDI Plus manual page 9) - This file contains only those possible NDI record matches, which are ranked first or have a high probabilistic score. This file is for users who would like to write a computer program to link causes of death with the matched results in the Retrieval report.
10. **Cause of Death Report** (NDI Plus manual page 19) - This file allows for quick inspection of coded causes of death of those records which are ranked first or have a high probabilistic score. The matches are grouped by State and year of death.

Please notify Westat if any records are rejected.

### 9.2.2.1.3 Determining NDI Matches

When evaluating each NDI match, it is important to realize that many submitted subjects will either have false matches, or will not have a match at all. Specific matching criteria have been developed which should be satisfied for a possible match to be considered a true match.

In general, a record is considered a match if *first name* (F) and *last name* (L) and *middle initial* (M) (if available); *Social Security Number* (Soc Sec No), *month* and *year of birth* and *sex* are in agreement.

On the NDI Retrieval Report the results of each match are listed in rank order. If *each item* submitted by the SC matches *exactly* to an NDI record, the NDI record will have an asterisk next to the state of death. This can be interpreted as a match, however, prior to assigning NDI results code, all matching items should be verified.

The guidelines for selecting and classifying matches are as follows:

**EM** = Exact Match to NDI record. The following fields must match exactly:

- ▶ F, L and M
- ▶ Soc Sec No
- ▶ Date of Birth (DOB) – month and year
- ▶ Sex code

**PM** = Probable Match should be considered if all or some of the items do not match exactly to warrant a code of EM. PM should be used:

- ▶ If F has an NDI code of 'I' is given indicating that the first initial of the F match.
- ▶ If L, has an NDI code of 'N' is given indicating that the name matched only on NYSIIS (New York State Identification and Intelligence System) phonetic codes.
- ▶ At least 6 digits of the Soc Sec No match. If the Soc Sec No is not provided then the DOB should match exactly i.e. month, day and year.
- ▶ Month of birth within 1 month before or after the participant's date of birth
- ▶ Year of birth within 10 years before or after the participant's date of birth
- ▶ Sex code must match.

If a record does not meet the criteria for an EM or PM then one of the two following codes can be assigned.

**NM** = No Match. Use this code if:

- ▶ Not enough items listed above match to indicate that the information returned from NDI are for the participant.

**NF** = Not Found.

- ▶ Use this code to indicate that no information was returned from NDI for the participant. These participants can be easily identified using the Non-Matching User Records report.

The death certificate should be requested for all NDI matches designated as EMs and PMs. The information on the death certificate should be matched with information in the participant's file to verify that the correct death certificate was received.

#### **9.2.2.1.4 Updating SMS for NDI Matches**

To indicate the results of the NDI match, the participant's vital status and Source for Vital Status should be updated for those participants assigned a code of **EM** or **PM**. If the participant's vital status code is "blank", update the vital status code to 'P' – presumed deceased and enter '**NDI-EM**' or '**NDI-PM**' in the Source for Vital Status. If the participant was previously assigned a vital status of 'P' before the submission to NDI, the vital status should be left as 'P' and in the Source of Vital Status **NDI-EM** or **NDI-PM** should be added to the existing Source of Vital Status. Once the death certificate has been received and the information is verified, then change the Vital Status from 'P' to 'C' – confirmed deceased. *Do not change any information in the Source for Vital Status. This information will be used to determine the utility of NDI.*

If the NDI code assigned is **NM** or **NF**, the SMS does not need to be updated.

#### **9.2.2.1.5 Requesting Death Certificates for NDI Matches**

With the return of the results of the NDI search you will also receive a document entitled *Obtaining State Death Certificates*. This document contains the most recent available information on each state's requirements and charges for the release of copies of death certificates. The document also includes a contact person's name, address and phone number in each state vital statistics office, release policies, procedures and charges.

When requesting copies of death certificates from the state's vital statistics office, the SCs are strongly encouraged to use the Death Certificate Request Forms from NDI. The Request Forms lists the NDI record matches for each state are sorted first by year of death and then by death certificate number. Selected information from each matching record is also presented. This information is to assist the vital statistics office to confirm that they are releasing the correct death certificate. The request forms for some States may involve several pages. Except for the first page of the form, any pages that do not contain any certificates that are being requested should be eliminated.

1. Place a check mark (√) in the left margins of the Death Certificate Request for those death certificates that you would like to obtain.
2. Always complete the first page of a state's death certificate request form. Eliminate all other pages that do not contain requests for death certificates.
3. Contact the vital statistics office to determine (a) their fees, (b) how to make payment and (c) what additional information you need to attach before the office will release copies of the death certificates.
4. Mail the forms along with payment to the appropriate state office.

For more detailed information on any of the reports provided by NDI, please refer to the NDI Users Manual.

#### **9.2.2.1.6 Cause of Death Report**

After matches have been determined on the Retrieval report, the record should be located on the Cause of Death report. The matches are first grouped by State, then by year of death and within a given year by death certificate

number. A copy of the Cause of Death report, with the participant's name removed should be sent to Westat for translation from ICD-10 codes to ICD-9.

#### **9.2.2.2 Centers for Medicare & Medicaid Services**

The Centers for Medicare and Medicaid Services (CMS) formerly known as The Health Care Financing Administration (HCFA) is a good resource for determining the vital status of participants who are lost-to-follow-up. CMS is the government agency that administers the Medicare program. For individuals who received Medicare benefits, the CMS files can provide date and state of death. Prior approval is required by CMS for all submissions for record searches. An application/instructions can be obtained by contacting the Centers for Medicare and Medicaid Services at the address given below.

Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

CMS files can be searched either by social security number or by name. Submission requirements include a valid social security number for the social security number search, or the first and last name and full date of birth for the name search. The social security number match is strongly recommended over the name search because of the quality of information provided. Once a submission is made, the response time is quick and the information provided is accurate. The SC Coordinator will use the SMS to facilitate preparing submissions to CMS. *(Note: This facility is not yet implemented in the SMS.)*

#### **9.2.2.3 Social Security Death Index**

The Social Security Death Index (SSDI) is an online search index of deceased individuals whose social security benefits have been paid out. It provides the last and first name, the social security number, birth and death dates, city, county, state and zip code of the last residence and city, county, state and zip code to which the final lump sum payment was made. It is useful for verifying a death or completing information about a death prior to submission to the state vital statistics office. The SSDI is updated monthly. The main disadvantages to using this system are that it includes only those individuals assigned a social security number and who have had social security benefits paid out, and the accuracy of information is not guaranteed. The SSDI may be accessed on the Internet at

<http://ssdi.genealogy.rootsweb.com/>

or

<http://www.ancestry.com/search/rectype/vital/ssdi/main.htm>.

Both of these web sites provide information about using the SSDI.

#### **9.2.2.4 Other Sources for Vital Status Determination**

It is expected that most deaths will be ascertained through the methods described above. Other tracing resources that may be useful for locating lost-to-follow-up participants and for determining vital status include: cancer registries, Departments of Motor Vehicle Administration, and Vital Statistics Bureaus. These sources may be most useful in latter years of the trial when there has been an increase in the number of participants who are lost-to-follow-up. The SC Coordinator will be responsible for establishing the tracing methodologies to be used and for conducting all searches. The SC Coordinator will use available SMS functions to facilitate these tracing activities, as appropriate.

### 9.2.3 Updating Vital Status in the Study Management System

When the SC learns of a death, from any of the sources discussed above, the participant's vital status must be updated to "P" (presumed deceased) on the Participant Status Screen in the SMS (Figure 9-2). The SMS will also have fields in which to record the source and date of the report of the death, and the date of death. *A death is not considered confirmed until the death certificate is received.* The date of death in the SMS is "presumed" until the death certificate is obtained and the date is confirmed. It is acceptable to enter an estimated date for an unknown date of death. The only field that can be estimated is the day, which should be entered as the 15th. For example, if October 1996 is the only known date of death (prior to receiving the death certificate), it should be entered as 10/15/96. If the month and/or year are unknown, the entire field should be left blank.

Once the vital status is updated to "presumed deceased," this participant will no longer appear on reports of participants who require an Annual Study Update or a screening examination visit.

The screenshot shows a web-based interface titled "Participant Status Information" for Participant ID: 202664-6. The interface is divided into three pages:

- Page 1:** Participation Status (code, source, date assigned) and Recruitment (tracking number, ID source).
- Page 2:** Vital Status (code, source, date assigned, date of death) and Transfer Data (status, date, screening center, transfer number).
- Page 3:** Demographic information including Date of Birth at Randomization (06/29/1934), Gender (M), Randomization Date (12/08/1995), and Group (I).

Additional fields at the bottom include "Total number of tracing efforts" (0) and "Corrected DOB if needed" (10/10/2000). The interface includes navigation arrows, a "View Mode" button, and "Record 1 of 1" indicator.

Figure 9-2. Participant Status Screen

## 9.3 Death Certificate Acquisition

Death certificates must be obtained for all participants who are reported as deceased during the entire duration of the trial. The death is not considered to be confirmed until the death certificate is obtained. The SC will conduct the necessary procedures for the procurement and processing of all death certificates. A certified copy of the death certificate is not required for the DRP; the SC may obtain a photocopy of the death certificate. Once a copy of the death

certificate is received in SMS the vital status will be changed to 'C' (confirmed deceased). Copies of all death certificates will be edited to delete identifying information and shipped monthly to the CC for cause of death coding. Collection of a death certificate should trigger preparation of a **Death Documentation Sheet** (DDS, [Appendix A-9-1](#)) which will be used to track receipt of medical records and other DRP activities. A new folder will be prepared to store the medical record information relating to the DRP separately in the participant's file (see [Section 9.6](#)). This documentation is in addition to the documentation collected for record abstraction that is used for the cancer ascertainment process.

A brief description follows of the various activities associated with death certificate acquisition and processing:

- Prepare and submit all necessary application forms to the various state Vital Statistics Bureaus for approval to obtain death certificates;
- Once approval has been received, prepare and submit death certificate requests to the state vital statistics bureaus. A NCI-approved summary of the PLCO protocol is given in [Appendix C-9-1](#) This protocol may be attached to applications to state vital statistics bureaus;
- Receive and review results of the death certificate acquisition efforts;
- Determine good matches of death certificates based on comparisons with the data submitted to the state;
- Conduct quality assurance by ensuring the death certificate matches the participant for whom the request was made, check death certificates for legibility and, if necessary, follow back to the Vital Statistics Bureau for clarification;
- Verify that the death certificate contains date of death, date of birth, race, occupation and cause of death information (Some states, such as Florida, have two versions of the death certificate, one with the cause of death, and one without). **[Note: Do not receipt an illegible or incorrect certificate into the SMS if you plan to obtain a replacement certificate];**
- Place a PID label on the death certificate where it does not obscure any information, preferably in the upper right hand corner of the death certificate;
- Receipt the death certificate into the SMS. When the form is receipted, the fact that the certificate matches the participant and the date of death are entered into the system. After receipt, the SMS will print the **Death Certificate Receipt Report** (one per PID) ([Appendix B-9-3: Death Certificate Receipt Report](#)) showing the death certificate information that was receipted. The vital status will now show 'C' – confirmed deceased. File the death certificate and the Death Certificate Receipt Report in the participant's DRP folder.

It is expected that death certificates can be obtained for all deaths occurring in the United States. For deaths occurring outside the U.S., every attempt should be made to obtain the death certificate from the country in which the participant died or through the State Department. If the death certificate cannot be obtained, the SC will update the participant's cancer status in the Participant Status Screen of the SMS to "N" - death confirmed without a death certificate, and no further activity will be required.

## 9.4 Shipment of Death Certificates

Once a death certificate is receipted, it is then available to be shipped to the CC. All death certificates must be edited to delete identifiers, then shipped monthly (on the last day of the month) to the CC following the procedures described below:

- Photocopy the death certificate and place the original in the participant's DRP folder (see [Section 9.6](#)).
- On the photocopy, delete the following identifying information: Deceased name, social security number, and address, spouse or other relative names and addresses, and informant name and address. It is recommended that a black magic marker or white out be used.
- Verify that the identifiers cannot be read.
- Prior to the end of the month, use the SMS to generate a **Death Certificate Transmittal** ([Appendix B-9-4: Death Certificate Transmittal Log](#)). The transmittal lists in PID order, the PID for each death certificate not previously shipped. (See the *SMS User Guide/Upgrade Documentation* for more information on generating this transmittal).
- Assemble the death certificates listed on the transmittal in the order in which they appear on the transmittal. Verify that all death certificates are present. If any death certificates are lost or are not ready to be shipped, cross off the corresponding PID on the transmittal. Use the SMS Shipping Module to remove the shipping date for any death certificate not being included in the shipment. Generate a revised Death Certificate Transmittal.
- Include one copy of the Death Certificate Transmittal with the package of death certificates sent to the CC. FAX a copy to:  

Beth Bridgeman  
TB 294 - DRP  
(301) 294-2085
- Keep one copy for the SC files.
- Package the death certificates in a Tyvec envelope and send it to:  

Beth Bridgeman  
TB 294 - DRP  
1650 Research Blvd.  
Rockville, MD 20850
- Send the death certificates to the CC using Federal Express, UPS or another certified mail carrier. Keep a record of the package number.
- Any month that the SC will not be shipping death certificates, the SC needs to notify Beth Bridgeman via e-mail [BridgeB1@Westat.com](mailto:BridgeB1@Westat.com) with this information.

The CC will receive and verify all shipments of death certificates from the SC. Upon receipt of a shipment, the CC will check the transmittal log. If there is a discrepancy between the transmittal log and the contents of the shipment, or if any of the certificates are incorrect or illegible, the DRP Coordinator will contact the SC Coordinator by telephone, FAX or e-mail to resolve the discrepancy. The SC may be instructed to remove certain certificates from the transmittal and to regenerate the transmittal.

## 9.5 Monitoring Vital Status Ascertainment and Death Certificate Processing Activities

Notification of death of participants in both randomization groups may be received through a number of sources as previously discussed in this chapter. The SMS will facilitate the tracking and monitoring of activities associated with vital status ascertainment and death certificate acquisition. Reports, which support this process, include:

- **National Death Index List** ([Appendix B-9-1: National Death Index List](#)). This list contains all participants who are selected for the NDI submission (presumed deceased and lost-to-followup). The list includes the Participant ID number name and most recent date submitted to NDI.
- **Vital Status Confirmation List** ([Appendix B-9-2: Vital Status Confirmation List](#)). This report lists all participants who have been identified as deceased during the PLCO trial (i.e., all participants who have a vital status on the Participant Status Screen of P - Presumed Deceased, C - Confirmed Deceased, and N - Confirmed Deceased without the receipt of a death certificate.) The list includes the following identifying information: Participant ID number, vital status (P, C, or N), source of reported death, date of report, and date of death and is automatically sorted by Vital Status, then by PID.

Specific instructions for using the SMS to generate these lists are given in the *SMS User Guide/Upgrade Documentation*.

## 9.6 Folder Preparation and the Death Documentation Sheet (DDS)

Once a death has been confirmed through acquisition of the death certificate, a new folder should be prepared for the participant's file. The folder should be a color or type unique to the DRP and it should be labeled with the participant's PID number. All documentation relating to the DRP, including the death certificate, should be placed in the DRP folder to facilitate access and review. A DRP folder should be created for all deceased participants, regardless of whether or not they are selected for death review.

In addition to the death certificate, each DRP folder should contain a **Death Documentation Sheet (DDS)** ([Appendix A-9-1](#)). The DDS is provided as a manual tracking record to document and monitor completion of each step of the DRP. It should be used to indicate completion of cancer ascertainment, ongoing medical record collection and editing, and shipment of DRP materials. The SC may wish to develop an addendum to the DDS to meet SC specific procedures for requesting and obtaining medical record documentation. The specifications for completion of the DDS are given in [Appendix A-9-1](#).

## 9.7 Cancer Status Determination and Confirmation

Once a participant's vital status has been confirmed through collection of the death certificate, the cancer confirmation process must be completed as well. Cancer confirmation in preparation for death review includes three major steps:

- Identify and enter into the SMS all reports of cancer from the ASU and other sources;
- Identify all reports of cancer from the death certificate (CC report: Cancers on Death Certificates refer to [Section 9.7.2](#)) and enter them into the SMS;
- Administer the History of Malignancy Form (HOM) ([Appendix A-9-2](#)) for those death certificates which list the cause of death as 'Natural Causes' and enter into the SMS all reports of cancer noted on the HOM; and
- Complete and process the DE or OCF forms for all suspected cancers.

These steps are described in detail in the following sections.

### 9.7.1 Cancer Reports from ASU and Other Sources

Cancer in participants may be reported on the ASU or the SC may be notified by a participant, a relative, a physician, etc., that a cancer has been diagnosed. The SC may also incidentally find a primary cancer diagnosis upon review of the participant's medical record. The SC is responsible for entering these cancer suspicions into the SMS.

When cancer is reported on the ASU, the cancer is entered during the ASU receipt process. (See [Chapter 7.0](#)). When a cancer is reported by the participant, a relative, etc., usually via telephone, or incidentally found upon review of the participant's medical record for some other purpose (e.g., a prior breast cancer identified while the SC was confirming suspected lung cancer), the SC will record this information on an SC form and then enter the report into the SMS. The SC will access the Cancer Suspicion and Confirmation History tab of the Participant Status Screen and enter the cancer suspicion with the following information:

<b>Study Year:</b>	T0, T1, T2, etc.
<b>Cancer Type:</b>	P, L, C, O, T (If type is T (other cancer), the SC must enter the 3-digit cancer code)
<b>CCode:</b>	Three digit PLCO cancer for other (non-PLCO) cancers.
<b>Source:</b>	REL (Relative), PHS (Physician), OTH (Other, used for participant, and any other sources that are not specified)
<b>Status:</b>	S (Suspected)
<b>Identify date:</b>	Date of the report by the participant, relative, etc

Refer to the SMS documentation for information on keying cancer information into the Participant Status Screen.

Upon saving of this record, the participant's cancer status will either remain 'S' if this cancer was not previously confirmed, or will be updated to 'P' if the cancer was previously confirmed. For all cancer types with a status of 'S', cancer confirmation activities (completion of the DE and/or OCF) must be initiated.

### 9.7.2 Cancer Reports from the Death Certificate

All death certificates will be sent to the CC for coding of the cause(s) of death. The CC will notify each SC of the PIDs and cancer types for all participants with

cancer reported on the death certificate as a cause of death. This notification will be via a hardcopy report, **Cancers on Death Certificates (ConDC)** ([Appendix B-9-5: Participants with Cancer on Death Certificate Report](#)), that will be sent to the SCs on a monthly basis. The report includes the ICD-9 code associated with each PLCO code of '999'. Currently there are two ICD-9 codes that are translated to '999'. They are 199.1 for metastases and 234.X for carcinoma in situ. These codes are shown so that the SC can determine which metastatic cancers on the death certificate require medical record abstraction.

If the death certificate contained a primary cancer site and a metastatic site, both will be shown on the ConDC report. The primary site must be entered in to the participant's cancer status table in SMS, but entering the metastasis is optional. However, if there is only a metastasis (199.1) with an unknown primary reported that has not been previously confirmed, then it must be entered into SMS.

Upon receipt of this report, the SC will access the Participant Status Screen and enter the cancer suspicion with the following information for each PID on the report:

<b>Study Year:</b>	T0, T1, T2, etc.
<b>Cancer Type:</b>	P, L, C, O, T (If type is T (other cancer), the SC must enter the 3-digit cancer code)
<b>CCode:</b>	Three digit PLCO cancer for other (non-PLCO) cancers.
<b>Source:</b>	DCF (Death Certificate)
<b>Status:</b>	S (Suspected)
<b>Identify date:</b>	Date of death

It is important that the participant's cancer table be updated in a timely manner. The CC will monitor this data to determine any inconsistencies between the SCs cancer data and cancers reported on the death certificates.

Refer to the SMS documentation for information on keying cancer information into the Participant Status Screen.

Upon saving this record, the participant's cancer status will either remain 'S' if this cancer was not previously confirmed, or will be updated to 'P' if the cancer was previously confirmed. For all cancer types with a status of 'S', cancer confirmation activities (completion of the DE and/or OCF) must be initiated.

### **9.7.3 Death Certificates Causes of Death – 'Natural Causes'**

The cause of death on death certificates is often listed as "natural causes." In such cases, additional information needs to be collected for the Death Review Committee (DRC) in order to determine a more specific cause of death. In addition, the committee needs to confirm that there was no PLCO cancer.

To obtain this information, the History of Malignancy Questionnaire (HOM) should be sent to the deceased participant's primary care physician. The SC should send the HOM to the physician with a cover letter. A sample cover letter is provided in [Appendix C-9-2](#). The HOM should be sent only for those individuals who died of "natural causes."

#### 9.7.4 Completion of DE and OCF Forms for Suspected Cancers

Cancer ascertainment and confirmation is not considered complete until all outstanding DEs and OCFs have been completed, including all ICD-9-CM and ICD-O-2 coding. The expectation for these forms may have been triggered by information from a screening exam, an ASU, a death certificate, or another source. Further details regarding cancer ascertainment and confirmation are provided in [Chapter 8.0](#) of the MOOP.

After all DE and OCF forms have been completed, (and set to Final Complete (FCM) or Final Incomplete (FIC)) the "Cancer Confirmation" box should be completed on the DDS.

### 9.8 Determining Eligibility for DRC Review

All participant deaths will be reviewed by a computer algorithm program at the CC to determine eligibility for DRC review. The computer algorithm analyzes the causes of death on the participant's death certificate and other SMS data and selects participants for review by the DRC. The program will reject cases that have incomplete information. If a case is not selected for the DRC, it will be designated as 'certified' and no additional action is necessary. The procedures to determine the eligibility of a death for DRC review are described below.

#### 9.8.1 CC Review of Deaths

On a monthly basis, the CC reviews the recent shipment of death certificates for proper editing and legibility. The SC coordinator will be notified if there is a problem with a death certificate. Two CC nosologists will code all causes of death, and any discrepancies in coding will be arbitrated by a third nosologist as necessary. The agreed upon codes will be entered into a data file that will be merged with SMS information that is transmitted monthly from the SCs to the CC. A computer algorithm will be applied to all cases that have complete cancer information and complete cause of death information. For each PID submitted to the algorithm, the program reviews vital status and cancer status information to determine whether the case has the following information completed:

- Vital status is confirmed as deceased with a death certificate (vstatus = C).
- Cancer status is confirmed or closed because of an MDF (i.e. all cancers in cancers table have cstatus = C or P and there are no outstanding cancer suspicions).
- For cancer statuses of C (confirmed cancer), an ICD-O-2 code exists.
- For cancer statuses of N (confirmed as *not* cancer), an ICD-9-CM code exists.

If a case is missing any of the above information (e.g. the cancer status = S), the algorithm program will reject the participant and the SC will be sent a rejection report as described in [Section 9.8.2](#) below.

All valid (non-rejected) cases are run through the algorithm and only cases that meet criteria for review by the DRC, as described in [Section 9.8.2](#) below, are selected. If a case is selected for DRC review, it will be assigned a status of

"AR" for "Review." Cases that are valid but do not meet any of the death review criteria will be assigned a status of "AC" for "Certified."

### 9.8.2 The Algorithm Report

Once a month, the SC will receive by fax a report of the results of the CC review of deaths, the **Algorithm Results Report** ([Appendix B-9-6: Algorithm for Death Review](#)). The SC should carefully review the results of the algorithm. All cases selected for review are marked with an "AR" and the SC should begin record collection as described in [Section 9.9](#). All cases determined to be certified, are marked with a "AC" and require no additional action.

For participants who were rejected, "XX" the report indicates one or more reasons for the rejection as follows:

- 1 = Vital Status is not C
- 2 = Cancer Status is S
- 3 = Cancer Status of C or P, but no ICD-O-2 code
- 4 = Cancer Status of N but no ICD-9-CM code
- 5 = No Cancer Record with CSOURCE = "DCF"
- 6 = DC Data Not Yet Evaluated for Cancers

For rejected participants, the SC should review the participant's file and SMS record, collect any missing information and enter it into DEES and SMS. These participants will be automatically included in the next run of the algorithm. If the data are not available on the subsequent run, the PID will again be rejected by the algorithm. They will continue to be rejected by the algorithm until they are assigned a status of either "AR" or "AC."

For participants who were assigned "AR," the report indicates one or more reasons the "AR" status was assigned as follows:

- AR1
- AR2
- AR3
- AR4
- AR5

For more information, refer to the Algorithm Results Report ([Appendix B-9-6: Algorithm for Death Review](#)).

### 9.8.3 Death Review Selection Criteria

- A. death certificate diagnosis (from an immediate, underlying or contributing cause of death field) which specifies prostate, lung, colon-rectum or ovarian cancer, i.e., ICD-9:
  - 153-154, 235.2 malignant neoplasm of colon or rectum
  - 162, 235.7 malignant neoplasm of trachea, bronchus, and lung
  - 183, 236.2 malignant neoplasm of ovary and other uterine adnexa
  - 185, 236.5 malignant neoplasm of prostate

- B. A death certificate diagnosis (from an immediate, underlying, or contributing cause of death field) which suggests a primary bone, i.e., ICD-9:
- 170, 238.0 malignant neoplasm of bone and articular cartilage
- C. A death certificate diagnosis (from an immediate, underlying, or contributing cause of death field) which suggests uncertainty of the diagnosis of cancer, such that prostate, lung, colon-rectum, or ovarian cancer cannot be excluded, or a metastatic cancer with unknown primary, i.e., ICD-9:
- 158, 235.4 malignant neoplasm of retroperitoneum and peritoneum
  - 159, 235.5 malignant neoplasm of ill-defined sites within the digestive organs
  - 163, 235.8 malignant neoplasm of pleura
  - 165, 235.9 malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs
  - 184, 236.0, 236.3 malignant neoplasm of unspecified female genital organ
  - 187, 236.6 malignant neoplasm of male genital organ, site unspecified
  - 195. 1,2,3, 238.9 malignant neoplasm of other ill-defined sites (thorax, abdomen, or pelvis)
  - 196-199 secondary malignant neoplasm (with no mention of primary malignant neoplasm (ICD-9 140-195) on death certificate)
  - 239 neoplasm of unspecified nature
  - E870-876 Misadventures to patients during surgical and medical care
  - E878-879 Surgical or medical procedures as the cause of abnormal reaction of patient or later complication, without mention of misadventure at the time of procedure
  - E930-949 Drugs, medicinal and biological substances causing adverse effects in therapeutic use
  - 960-979 Poisoning by drugs, medicinals and biological substances
  - 997-999 Complications of surgical and medical care, not elsewhere classified
- D. A death certificate coded to an unknown underlying cause of death, i.e., ICD-9:
- 789 sudden death, cause unknown
  - 797 senility without mention of psychosis
  - 799 other ill-defined and unknown causes

- E. Death of a participant, from any cause, if the result of diagnostic evaluation field on a diagnostic evaluation form (DEP, DEL, DEC, or DEO) indicates prostate, lung, colon-rectum or ovarian cancer, i.e., ICD-9:
- 53-154, 235.2 malignant neoplasm of colon or rectum
  - 162, 235.7 malignant neoplasm of trachea, bronchus, and lung
  - 183, 236.2 malignant neoplasm of ovary and other uterine adnexa
  - 185, 236.5 malignant neoplasm of prostate
- F. Death of a participant, from any cause, if any Annual Study Update (ASU) form reports prostate, lung, colon-rectum or ovarian cancer, unless subsequent documentation show that the original report was incorrect. This occurrence should already have resulted in the completion of a DE form and therefore should be covered in the preceding section (E).
- G. Death of a participant, from any cause, if any ASU form suggests an interval diagnosis of a primary malignancy possibly representing misclassified or metastatic prostate, lung, colon-rectum, or ovarian cancer. This occurrence should have resulted in the completion of an OCF. Completion of an OCF with an ICD-O-2 topography code of any one of the following codes will trigger death review, i.e., ICD-O-2 topography:
- C480, 481, 482, 488 malignant neoplasm of retroperitoneum and peritoneum
  - C260, 268, 269, malignant neoplasm of ill-defined sites within the digestive organs
  - C381, 382, 383, 384 malignant neoplasm of pleura and mediastinum
  - C390, 398, 399 malignant neoplasm of other and ill-defined sites within the respiratory system
  - C400-419 malignant neoplasm of bone and articular cartilage
  - C570-574;C577-579 malignant neoplasm of unspecified female genital organ
  - C630-632;C637-639 malignant neoplasm of male genital organ, site unspecified
  - C761-3, 768 malignant neoplasm of other ill-defined sites (thorax, abdomen, or pelvis)
  - C809 secondary malignant neoplasm (with no mention of primary malignant neoplasm) on death certificate)

## 9.9 Collection and Preparation of Documents for the DRC

The SC will be responsible for preparing all documentation for the DRC. All documentation, which is collected for the DRP, should be placed in the DRP folder. Documentation should be collected, reviewed and edited, by a trained medical record abstractor with at least two years of job experience abstracting

medical records, and a demonstrated knowledge of medical record terminology, anatomy and physiology. The SC should attempt to collect the same types of information for all participants selected for death review. Obtaining all relevant documentation is critical for the determination of the underlying cause of death. If the SC is experiencing problems obtaining information from a physician's office or medical center assistance from the PI may be necessary. Procedures for collection and preparation of documents for the DRC review are given in the following sections.

### **9.9.1 Document Collection**

Any participant with a DRP status code of "AR," as designated by the algorithm, requires death review. The Death Review Committee will require all in/outpatient medical records including:

- Terminal events;
- Diagnosis documents;
- Treatment documents;
- Outpatient notes;
- Hospital admission history/physical;
- Operative procedures reports;
- Pathology reports;
- Chemotherapy notes;
- Radiotherapy notes;
- Management of co-existing cancers;
- Hospital discharge abstracts;
- Hospital discharge summary;
- Diagnostic procedure reports; and
- Diagnostic imaging reports.

Diagnostic documents will differ depending on the type of cancer. Some examples of diagnostic documents for PLCO cancers can be found in Appendix A-9-3. The Medical Documentation section (Part B) of the DDS should be updated as each document is collected.

Medical records needed for the DRP are those from the time of the initial precipitating cause of the terminal illness. The DRP does not require knowledge of the entire natural history of the underlying cause of death, but requires knowledge of disease status at the time of death. For example, the death review does not require knowledge of *extent* of cancer at the time of death or in a time frame encompassing the sequence of proximate events immediately leading to death.

For each case, screening centers must exercise informed judgement regarding the appropriate time frame for medical record collection. The time frame should be long enough to enable adequate characterization of cancer status at the time of death. In general, this time frame will encompass the last several weeks or months of life. Because of the long clinical duration associated with cancer, this time frame will often, but not always, exclude the time of initial cancer diagnosis.

The Death Review Committee should also be given information on cancers diagnosed prior to randomization. This information will simply be the fact of diagnosis, based on participant self-report on the Baseline Questionnaire. For all cases sent for review, the SC should consult the hardcopy Baseline Questionnaire, Item #30 (Personal cancer history). Any cancers listed in this item should be reported to the DRC by photocopying the page from the Baseline Questionnaire, and including it with the DRP package.

In some cases, the hospital or physician's office may not accept the PLCO Cancer Screening Trial consent form as sufficient for release of medical records. Additional authorization may need to be requested from the participant's next of kin. A sample Medical Authorization Release Form that may serve this purpose is provided in [Appendix C-8-1](#) of the MOOP, however some hospitals or insurance plans may require a release in a specific format.

If the death certificate stated the cause of death as 'Natural Causes', enough information needs to be collected for the DRC to determine the cause of death. In addition, the committee needs to confirm that there was no PLCO cancer.

### 9.9.2 Document Review

Once the SC Coordinator determines that all available information has been collected, all documents should be reviewed and edited. Documentation should be evaluated for completeness, placed in chronological order, and each of the following questions should be answered:

- Does each hospital discharge summary have a corresponding admission history and physical? (Exceptions may occur, if initial diagnosis and treatment were outpatient).
- Is there an operative and pathology report for all surgical procedures related to a malignancy or suspected malignancy?
- Is there a report for each diagnostic procedure performed?

If the answer to any of these questions is "no," then additional information should be collected. If the SC has attempted and is unable to obtain certain documentation this should be documented in Part B of the DDS.

### 9.9.3 Document Editing

Death Review Committee members will be blind as to participant allocation in the trial (intervention or control), and all information that could identify whether a cancer was screen-detected should be deleted. All identifiers should also be deleted to maintain participant confidentiality. Medical records for subjects in the screened group are more likely to contain direct or indirect mention of PLCO as an entity than in controls. Therefore, clinical records submitted to the DRC should also be edited to remove mention of PLCO, participation in research, or involvement in special cancer detection programs.

Medical records should be edited using the following guidelines:

- Editing should only be performed on *a copy* of the medical record. Original medical records should be photocopied and returned to the participant file or hospital (if on loan). **The SC should keep an unedited copy of the medical records in the file.**
- Any mention of the PLCO trial should be crossed out with a black magic marker or white out.

- All participant identifiers should be crossed out with a black magic marker or white out.
- Incorrect grammar and spelling should not be changed.
- Any mention as to the participant's randomization group should be removed.
- Any indication as to whether the cancer was screen detected or clinically detected should be deleted.
- WHEN IN DOUBT, DON'T WHITE IT OUT! The NCI consultant will help provide examples of information that should be deleted from the record. The DRP Coordinator will provide feedback to the SCs regarding information that should have been deleted.
- Edits should not be initialed, dated or highlighted in any way. This will minimize attention to the edits and thus prevent bias in the DRC members. If it becomes obvious that a participant file has many deletions, DRC members may be biased into assuming that this is a screened participant.
- Each page of documentation should be labeled with a PID number (PID label, or stamp). The PID should be placed anywhere on the front of the page (so that it will appear on the photocopies). This step is important in case a folder becomes disassembled at some point during the death review process. Do not hand write the PID number.
- All documentation that is required by the DRC should be included in the DRP folder, and if it is not available, this should be documented on the DDS.

After all documentation has been gathered and is complete, the DDS should be updated to indicate that medical record collection and editing is complete (Part C).

## 9.10 DRP Material Shipment

DRP materials should be shipped at the beginning of each quarter, by the 10<sup>th</sup> of the months of January, April, July and October. Once the SC Coordinator has verified that a participant's documentation is complete, one copy of the participant's DRP folder should be made. Folders should then be batched and shipped to the CC as follows:

- Verify that the DDS is included in the folder;
- Photocopy all documents in the participant's DRP folder; DO NOT STAPLE THE DOCUMENTS TOGETHER.
- Identify each document and folder with a PID label or stamp;
- Include a supply of 10 extra PID labels for each participant;
- Place a rubber band around each folder to ensure that all materials stay together;
- Complete a **DRP Material Transmittal Log** ([Appendix A-9-4](#)). The transmittal should list in PID order, the PID of each DRP folder included in the shipment.
- Compare the transmittal against the actual hard copy material. If any folders are lost or are not ready to be shipped, they should be crossed

off the transmittal. Delete any PIDs for which DRP materials are not being included in the shipment

- Include one copy of the transmittal with the shipment. FAX a copy to:

Joseph Eisen  
TB 268 - DRP Coordinator  
(301) 610-5516

- Keep one copy for the SC files.
- Assemble the folders in PID order. Package the folders in a box and send to the DRP Coordinator at the following location:

Joseph Eisen  
TB 268 - DRP Coordinator  
1650 Research Boulevard  
Rockville, MD 20850

- Send the death documentation material to the CC using Federal Express, UPS or another certified mail carrier. Keep a record of the package number.

## 9.11 CC Preparation of Materials for the DRC

The CC will receive and verify all shipments of documentation from the SC. Upon receipt of a shipment, the CC will check the transmittal log. If there is a discrepancy between the transmittal log and the contents of the shipment, the DRP Coordinator will contact the SC Coordinator by telephone or e-mail to resolve the discrepancy.

Once the contents of the shipment have been verified, the CC will ensure review of all of the material in order to ascertain that all editing has occurred and that the material is complete. When the CC review is complete, the folders will be forwarded to members of the DRC on a quarterly basis.

## 9.12 Requests for Additional Documentation from the SC

The CC, NCI and the members of the DRC will evaluate the adequacy of the information provided. If more information is needed, an **Additional Documentation Request Form (ADR)** ([Appendix A-9-5](#)) will be completed. NCI and DRC members will send this form to the CC DRP Coordinator who will forward it to the SC with a cover letter. The ADR will document exactly what additional data are needed. The SC will collect these data, delete identifiers and any other information, as stated above, and send a photocopy back to the CC in the same manner as the original DRP material, using the DRP Material Transmittal Log. The DRP coordinator will forward the documentation to the requestor. The SC should keep a copy of all information that is sent to the CC.

## 9.13 DRC Review

The Death Review Committee consists of six physician members, all of whom have no relationship to the PLCO study or to any of the SCs. After the review by the CC is performed, and it is determined that there is sufficient medical documentation provided to determine the underlying cause of death and that there is no information revealing the participant's group assignment, the folder

is sent to a randomly selected DRC reviewer. This folder will not contain the death certificate.

If the DRC member decides that more information is needed, he may request additional documentation as described in [Section 9.1.2](#) above.

Since the clinical record may contain conflicting or ambiguous information regarding the cancer diagnosis, DRC members may request acquisition and an external review of pathology slides by a designated pathologist(s). A Pathology Review Request (PRR) form ([Appendix A-9-6](#)) will be used to document this request. The SC coordinator will complete the Pathology Review Request Transmittal Log ([Appendix A-9-7](#)) when sending slides to the CC.

Once the DRC member has determined that the information is adequate, s/he will determine based on the evidence provided, whether s/he considers the death to be due to, probably due to, not due to, or probably not due to, prostate, lung, colorectum or ovarian cancer. The DRC member will also indicate whether or not other competing disease processes contributed to a participant's death. DRC members will complete a Cause of Death Questionnaire (CDQ). When a case review has been completed, the DRC member returns the CDQs to the DRP coordinator. The DRP coordinator runs a report to compare the results of each CDQ against the underlying cause of death on the death certificate and generates a concordance report for each case.

- If there is disagreement between reviewer one and the death certificate, then the folder is reviewed by one other DRC member. The results on the CDQ from the first reviewer and the second reviewer are compared. If there is agreement, then the case is finalized. If there is disagreement, the case is sent to a third reviewer. If there is disagreement among the three reviewers regarding the cause of death, the DRP coordinator schedules either a conference call or an ad hoc meeting with all members for case adjudication (see [Section 9.1](#))
- The DRP coordinator will notify the DRC members of the results.

# Part IV: Screening Tests, Diagnostic Pathology, Laboratory and Endpoint Assessment Protocols

## Introduction

Part IV of this manual presents the PLCO Screening Trial protocols for the screening examinations. These include:

- Blood Collection
- Chest X-Ray
- Digital Rectal Examination
- Flexible Sigmoidoscopy
- Ovarian Palpation Examination (Note: this exam was discontinued December 1998)
- Transvaginal Ultrasound

These protocols describe the aspects of the examinations that are standardized across all Screening Centers. They were developed and approved by the NCI and the PLCO Steering Committee.

In addition to the procedures for the examinations themselves, these protocols include examiner qualifications, examiner training and certification, and quality assurance. Each Screening Center is required to develop a plan which addresses these issues, using the guidelines presented in the protocols. These plans must be reviewed and approved by the NCI prior to the initiation of screening activities.

## 10.0 BLOOD SAMPLE PROTOCOL

### 10.1 Overview

Blood samples will be collected from each participant who is randomized to the intervention arm of the PLCO trial. Samples will be used for PSA and CA-125II analyses to be performed by the UCLA Tissue Typing Laboratory (UCLA) and for etiologic studies to be designated by NCI. Samples to be used for etiologic studies will be held in storage at the NCI Biorepository in Frederick, Maryland. A total of 43 ml of blood will be collected at the baseline visit (T0), 16 ml at the first annual follow-up visit (T1), 16 ml at the second annual follow-up visit (T2), 43 ml at the third annual follow-up visit (T3), 26 ml at the fourth annual follow-up visit (T4), and 36 ml at the fifth annual follow-up visit (T5).

Blood samples will be collected by SC staff during the screening visit. The SC will also be responsible for the blood processing, storage, and shipment to UCLA, the Biorepository, and the Processing Laboratory. The blood samples will be shipped as whole blood or processed to extract either serum, plasma, white cells (buffy coat), and/or red cells. The labeled cryovials containing the blood component samples will be frozen and shipped to UCLA (once a week) or to the Biorepository (at least once a month). Whole blood tubes will be shipped at ambient air temperature (20° - 28° C) to the Processing Laboratory daily. At some SCs, shipments of vials to the Biorepository may be made more frequently than once a month because of the volume of specimens to be shipped.

The blood tests performed by UCLA are the CA-125II for all female participants, except those who report ovarian cancer or bilateral oophorectomy, and the PSA for all male participants, except those who report prostate cancer or total prostatectomy. UCLA uses the CA-125II, a radioimmunoassay that utilizes a high affinity capture antibody that also tests for ovarian cancer, and the PSA, a microparticle enzyme immunoassay, that tests for prostate cancer. The Biorepository blood samples are collected for studies of cancer etiology and of molecular markers for early detection of cancer. Some of the tests to be performed on the Biorepository specimens include detection of trace metals and nutrient content. These tests will be performed at a later date.

Each SC will be responsible for making arrangements for the handling of samples collected at any satellite facility. The blood samples may either be processed and stored at each satellite facility until shipment to UCLA/Biorepository, or centralized at one facility for processing, storage and shipping. Whatever the arrangements, the SC should assume responsibility for maintaining quality control of any samples collected, processed and/or stored at satellite facilities.

The following sections of this chapter describe the study procedures for the collection, processing, storage, and shipment of blood samples. Also included in this chapter are discussions on labeling blood tubes, storage vials, and data forms.

### 10.2 Scheduling Blood Draws

Blood sample collection will be scheduled as part of the baseline or annual follow-up visit for each participant in the intervention arm of the trial. All intervention participants will have blood drawn for PSA or CA-125II at all study years (T0-T5) unless they meet certain conditions as described in [Section](#)

[10.3](#). All intervention participants who have completed an Etiologic Studies Consent (ESC) will have the Biorepository blood drawn for current and subsequent years through T5. Procedures for scheduling screening visits are discussed in [Chapter 6.0](#) (baseline visit) and [Chapter 7.0](#) (annual follow-up visits). Note that NCI has specified that the T5 PSA/CA-125II blood draw should be pursued for one year after the participant's activity window opens.

The PLCO protocol requires that the blood sample be collected from males prior to the digital rectal examination. There are no other restrictions on the order in which the blood collection takes place.

The blood sample for the PSA/CA-125II specimen will always be the first priority tube to be collected at each screening visit. If the PSA/CA-125II sample cannot be collected for any reason during a screening visit, the SC will make every attempt to reschedule the participant for a redraw. If possible, the visit should be rescheduled before the end of the participant's reporting period. *Redraws will be scheduled only when the PSA/CA-125II sample cannot be obtained at the screening visit, or if the UCLA sample was thawed, destroyed or lost before it was analyzed at UCLA.* If the UCLA blood was obtained at the screening visit, but the Biorepository blood was not obtained, then a repeat visit should *not* be scheduled; repeat visits should not be conducted for the purpose of drawing only Biorepository blood. If neither the UCLA nor the Biorepository blood was drawn at the initial screening visit, and a re-draw is scheduled, then Biorepository blood may be drawn in addition to the UCLA blood if the participant is willing and has signed an ESC.

Yellow-top tubes from T3 participants will be shipped to the Processing Laboratory on the same day they are drawn. Some SCs may need to arrange specific morning appointments for T3 participants in order to meet this goal. Holiday schedules at the SC, the Processing Laboratory, and the overnight courier service must also be taken into consideration when scheduling blood draws from T3 participants. Do not collect yellow-top tubes if the tubes will not be received at the Processing Laboratory within two days of collection. For example, if the Processing Laboratory will be closed on Thursday and Friday because of holidays, do not collect yellow-top tubes from T3 participants scheduled on Wednesday. However, in this example, the T3 green and lavender-top tubes would still be collected, processed, and frozen according to the protocol.

The T3 blood collection protocol was implemented in May 1998. T3 participants who were randomized on or before April 1, 1995 may have passed through their T3 screening window before the T3 protocol was put into the field. A special collection effort was fielded in October 1999 and concluded in September 2000 that attempted to obtain the T3 samples at the T5 visit from participants who were randomized between October 1994 and May 1995. Participants who had their T3 draw conducted belatedly at T5 were called the Vanguard group. For details on the Vanguard blood collection, see the Vanguard blood collection procedures memo ([Appendix A-10-8](#)).

### **10.3 Situations in Which the SC Should Not Draw Blood**

If a participant reports that he or she has been diagnosed with prostate or ovarian cancer, the PSA/CA-125II sample should not be collected. The SC is allowed to accept participant self-report of cancer. There is no need to confirm the cancer diagnosis before the cancellation of the PSA or CA-125II blood draws.

If a male participant has had his prostate or a female participant has had her ovaries either partially or completely removed, and the removal was not a follow-up to cancer of that organ, blood collection for the PSA and CA-125II screens will be performed according to the following guidelines:

1. Surgical removal of both ovaries: If both ovaries are completely removed, the CA-125II exam should not be performed. The status of the participant's ovaries will be based on spontaneous self-report only. The SC does not need to ask the participant if her ovaries are intact, nor to obtain written medical record documentation of bilateral oophorectomy. If a woman reports bilateral oophorectomy but requests the CA-125II test, the SC should not perform the test.

If a woman reports bilateral oophorectomy at randomization or at a screening visit, then reports at a subsequent visit that she does have one or both ovaries either partially or fully intact, then the SC should draw blood for the CA 125II test.

2. Surgical removal - one or partial ovary remaining: If a partial or entire ovary is remaining, the CA-125II should be performed at each screening visit from T0 through T5.
3. Men with a prostate gland (complete or partial) or who are unsure of whether or not they have a prostate will be offered the PSA test at each screening visit from T0 through T5.
4. Men who report radical prostatectomy after entrance into the study will not be offered the PSA test. The status of a participant's prostate will be based on spontaneous self-report only. The SC does not need to ask the participant if his prostate is intact, nor obtain written documentation of prostatectomy. If a man reports prostatectomy but requests the PSA test, the SC should not perform the test. If the SC becomes aware that a man, who previously reported prostatectomy, does have his prostate fully or partially intact, the SC should resume offering the PSA tests.

If a participant reports missing all or part of their prostate or ovaries, or has reported cancer of the prostate or ovaries and is therefore ineligible for the PSA/CA-125II draw, but is willing to have blood collected, then the appropriate Biorepository specimens should be collected.

**Note:** Individuals currently taking Proscar or Propecia should still have the UCLA and Biorepository blood samples collected. The SC is not required to ask about these medications prior to blood collection.

If a participant has not signed the ESC, Biorepository samples should not be collected. The ESC obtains permission to use blood already collected (prior to implementation of the consent) for research involving genetic studies. It also obtains permission for future collection of blood and use of those samples for research involving genetic studies. The ESC is not related to obtaining permission for collection of blood for PSA or CA-125II analyses.

If the participant did not have Biorepository blood drawn in the prior study year, but is willing to have blood drawn for the Biorepository in the current study year, the current study year protocol should be followed. For example, if the participant did not have Biorepository blood drawn in T0 and is now in his/her T1 study year, the T1 blood collection protocol should be followed, not the T0 protocol.

Participants in their T4 and T5 screening windows who are ineligible for the PSA/CA-125II draw because of missing organs or cancer are still eligible for the Biorepository draw, and should be scheduled to come in for these draws during their T4 and T5 activity windows.

### 10.4 Blood Sample ID Labels

Each SC will be supplied with a series of self-adhesive sample ID labels that will be used to label all blood samples, storage vials, and blood collection forms. A unique sample ID will be assigned for each blood draw. The sample ID number for blood samples will be a nine-digit number. The first six digits (two alpha and four numeric) are the unique draw ID and the last three digits (numeric) are the specimen ID (AA-NNNN-NNN). The specimen ID will identify the PSA and CA-125II samples; the Biorepository samples; and the Processing Laboratory samples. The sample ID labels will be bar-coded and eye readable, and will be freezer safe (-70°C). Sample ID labels will be specific to a study year as described below:

Study Year	Number of Labels per Unique Sample ID	Ink Color
T0	18	Black
T1 and T2	8	Black with "T1/T2 Only" in red
T3	18	Black with "T3 Only" in green
T4	12	Black with "T4 Only" in blue
T5	18	Black with "T5 Only" in lavender

An example of each type of sample ID labels follows:

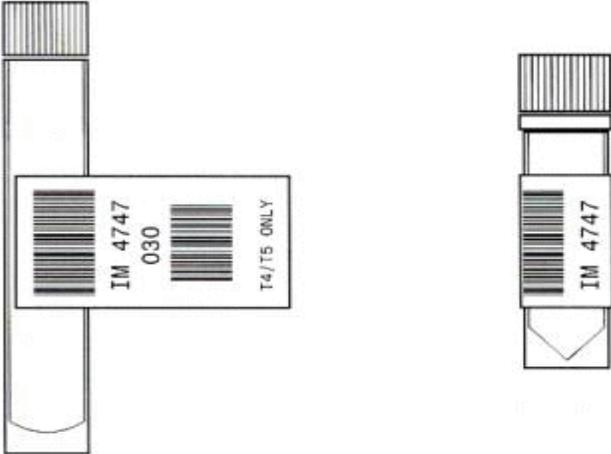


A sheet of sample ID labels will be provided for each participant for each blood draw procedure. The sheet of labels will include a set of sample ID labels for the Blood Collection Form, the blood draw procedure and transport of the blood samples (specimen ID = 000) and a set of labels for the processing of the PSA and CA-125II blood samples (specimen ID = 001 or 002). All study

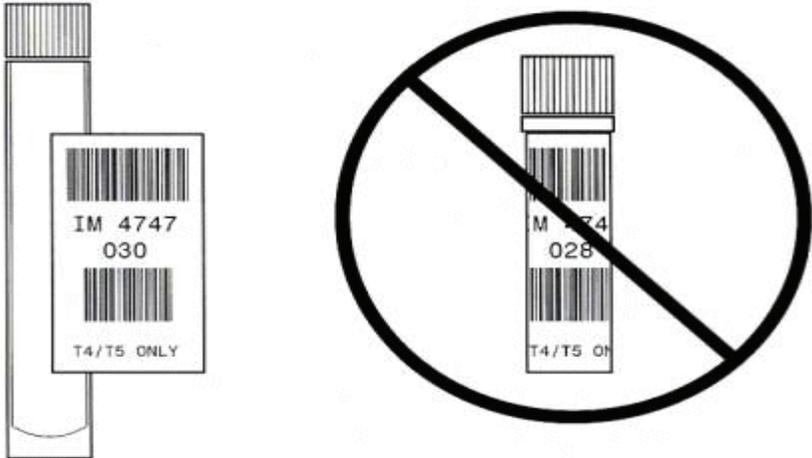
year labels are printed with "PSA" and "CA-125" on the "001" and "002" labels, respectively in each set of sample IDs. Each set of labels will also include Biorepository and Processing Laboratory (T3 only) labels appropriate to the study year as shown in the table below. Correct placement of the sample ID labels on the cryovials is shown in Exhibit 10-1.

### Exhibit 10-1 Sample ID Label Placement

#### Correct Label Placement:



#### Incorrect Label Placement:



**Exhibit 10-1.**  
Correct Label Placement

The following table depicts each specimen ID, how each specimen ID is to be assigned, and in which study years the specimen ID must be used:

### PLCO Blood Sample ID Label Assignments

Sample ID	Label Use	Study Year(s)
AA-NNNN-000	Blood collection form and collection tubes	T0, T1, T2, T3, T4 and T5
AA-NNNN-000	Extra label	T0, T1, T2, T3, T4 and T5
AA-NNNN-001	PSA vial	T0, T1, T2, T3, T4 and T5
AA-NNNN-002	CA-125II vial	T0, T1, T2, T3, T4 and T5
AA-NNNN-003	Biorepository – serum	T0, T1, and T2
AA-NNNN-004	Biorepository – serum	T0, T1, and T2
AA-NNNN-005	Biorepository – plasma	T0
AA-NNNN-006	Biorepository – plasma	T0
AA-NNNN-007	Biorepository – buffy coat	T0
AA-NNNN-008	Biorepository – RBC	T0
AA-NNNN-009	Biorepository – serum	T0
AA-NNNN-010	Biorepository – serum	T0
AA-NNNN-011	Biorepository – serum zinc	T0
AA-NNNN-012	Processing Laboratory – yellow-top tube #1	T3
AA-NNNN-013	Processing Laboratory – yellow-top tube #2	T3
AA-NNNN-014	Biorepository – plasma	T3
AA-NNNN-015	Biorepository – plasma	T3
AA-NNNN-016	Biorepository – buffy coat	T3
AA-NNNN-017	Biorepository – plasma	T3
AA-NNNN-018	Biorepository – plasma	T3
AA-NNNN-019	Biorepository – plasma	T3
AA-NNNN-020	Biorepository – plasma	T3
AA-NNNN-021	Biorepository – buffy coat	T3
AA-NNNN-022	Biorepository –Isocard	Not implemented
AA-NNNN-023	Biorepository – RBC	T3
AA-NNNN-028	Biorepository-serum	T4
AA-NNNN-029	Biorepository-serum	T4
AA-NNNN-030	Biorepository-plasma	T4
AA-NNNN-031	Biorepository-buffy coat and RBC	T4
AA-NNNN-038	Biorepository-serum	T5
AA-NNNN-039	Biorepository-serum	T5
AA-NNNN-040	Biorepository-plasma	T5
AA-NNNN-041	Biorepository-plasma	T5
AA-NNNN-042	Biorepository-buffy coat	T5
AA-NNNN-043	Biorepository-RBC	T5
AA-NNNN-044	Biorepository-plasma	T5

Sample ID	Label Use	Study Year(s)
AA-NNNN-045	Biorepository-plasma	T5
AA-NNNN-046	Biorepository-buffy coat	T5

For each blood draw, a sample ID is assigned to a participant and a sample ID label will be attached to the appropriate blood collection form, at baseline or follow-up as appropriate, to link the blood samples to the participant ID and the date of the blood draw. Sample IDs will be assigned in sequential order.

If the barcode labels are not available (because the SC's supply was depleted or they were destroyed), the SC should take the following steps to temporarily label blood samples until new bar-code labels are supplied by the CC:

- Blank self-stick labels should be used. Be sure that the labels will fit on the blood tubes and vials.
- Assign the next sequential Sample ID number. If the SC has run out of the bar-code labels, the SC should verify the next sequential Sample ID by immediately contacting their Westat Coordinator.
- Handwrite the assigned Sample ID on all the labels. As a reminder, the assigned Sample ID includes the unique draw ID (two alpha and four numeric) and the specimen ID (three numeric). One label should be placed on the Blood Collection Form and one label on each vial that is collected. Be sure to place the label with the appropriate specimen ID number on the corresponding vial. Also be sure that the handwriting is clear and legible and the ink is permanent.
- Attach the labels to the tubes and vials. If the labels are not freezer safe, secure the label to the vial with transparent tape. The tape should cover the label, completely surround the vial, and overlap itself.
- Since these temporary labels cannot be scanned, the SC must hand enter the Sample IDs into DEES.
- Once the SC receives the new bar-code labels, the SC should remove the temporary labels if the vials have not been frozen and replace them with the corresponding Sample ID bar-code labels. The temporary labels should not be removed once the vials have been frozen. In this case, only the bar-code label with specimen ID "000" should be used on the Blood Collection Form. All the other new bar-code labels (specimen IDs "001" through "046") should be discarded. The frozen vials will be shipped to UCLA and the Biorepository with the handwritten labels.
- Whenever vials with handwritten labels are being shipped to UCLA, the Biorepository or the Processing Laboratory (i.e., new bar-code labels have not arrived at the time of shipment or the vials were frozen prior to receiving the new labels), the SC must contact UCLA, the Biorepository and the Processing Laboratory to notify them that samples are being shipped with modified labels. The SC should remind UCLA, the Biorepository and the Processing Laboratory that they will have to hand enter the receipt data for these samples. Upon receipt of the handwritten labels, the recipient laboratory will contact the SC to confirm receipt of the samples with handwritten labels and verify that the SC was aware that handwritten labels were used.

In the rare situation where one or more labels of a unique Sample ID have been destroyed, the following procedures should be used for labeling these blood samples whose labels have been destroyed:

- Labels for all study years have at least one extra label with specimen ID “000” that may be used for replacing destroyed labels.
- When using an extra “000” specimen ID label for replacing a destroyed label, cross out the “000” and handwrite in the space above the appropriate specimen ID number for which the sample is being collected. Be sure that the handwriting is clear and legible and the ink is permanent.
- Attach the label to the appropriate tube or vial.
- The SC must contact both UCLA and the Biorepository to notify them that a sample is being shipped with a modified label. The SC should remind UCLA and the Biorepository that they will have to hand enter the receipt data for the sample.

## 10.5 The Blood Collection Forms

Two blood collection forms, the Blood Collection Form (BCF3) and the T4/T5 Blood Collection Form (BFF2) ([Appendix A-10-1](#) and [Appendix A-10-7](#)), are currently in use on the trial. These forms are used to document information pertaining to the participant’s ID number, sample ID number, SC visit, results of blood draw, and the processing, storage, and shipment of the blood samples. The BCF3 must be used for participants in study years T0, T1, T2 and T3. The BFF2 must be used for participants in study years T4 and T5.

Throughout this chapter, the term “blood collection form” refers to the appropriate form, either the BCF3 or the BFF2, to be used in accordance with the participant’s study year (BCF3 for T0-T3 and BFF2 for T4/T5). The term “blood collection form” does not apply solely to the BCF3.

Part A (Blood Draw) of the blood collection form will document the blood draw procedure, including time of blood draw, position of the participant, medical complications and any comments related to the blood draw. Part B (Blood Collection and Processing for PSA/CA-125II Samples) of the form will document information pertaining to the collection, processing, and storage for the PSA/CA-125II blood samples, while Part C (Blood Collection and Processing for Biorepository Samples) will document information pertaining to the collection, processing, and storage of the Biorepository samples and the Processing Laboratory samples. A new form should be completed each time a participant has blood drawn. If a participant does not have blood drawn (i.e., was not stuck with a needle), the blood collection form should not be completed. Refer to the specifications for completing the blood collection forms provided in [Appendix A-10-1](#) (BCF3) and [Appendix A-10-7](#) (BFF2).

The Blood Collection Form should be kept with the blood sample from the time that the blood was collected until after the sample has been processed and stored. The form will be scanned into the Data Entry and Editing System (DEES) and the form will be entered into the Study Management System (SMS) as described in [Chapter 17.0](#).

## **10.6 Phlebotomy Protocol**

The blood collection protocol for the PLCO Trial is provided in Exhibit 10-2. Required and recommended supplies for blood collection are listed in Exhibit 10-3. Specific instructions on participant preparation and phlebotomy procedures are presented in [Section 10.6.2](#) and [Section 10.6.3](#).

The blood samples must be collected according to the sequence specified in Exhibit 10-2. First priority will always be collecting the 6 ml SST tube for PSA and CA-125II blood samples. It should be noted that in several SCs up to 10 additional milliliters of blood are being collected for the Biorepository to increase serum yields. In these cases, some SCs an additional 10 ml red-top tube is collected. In others, the 10 ml red-top tube specified in the protocol is replaced by a 15 ml red-top tube.

**Exhibit 10-2**

**PLCO Blood Protocol  
Specimen Collection and Allocation**

**Baseline: T0**

<b>Tube</b>	<b>Size (mm)</b>	<b>Aliquot (#/amount)</b>	<b>Material</b>	<b>Cryovials (#/size)</b>	<b>Allocation</b>
SST 1 (6 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 UCLA*
Red-top #1 1 (10 ml draw)	16x100	2 x 2.0 ml	Serum	2 x 2.0 ml	2 Biorepository
Green-top 1 (10 ml draw)	16x100	2 x 2.0 ml 1 x 2.0 ml 1 x 2.0 ml	Plasma Buffy Coat RBC	2 x 2.0 ml 1 x 2.0 ml 1 x 2.0 ml	4 Biorepository
Red-top #2 1 (10 ml draw)	16x100	2 x 2.0 ml	Serum	2 x 2.0 ml	2 Biorepository
Royal blue-top 1 (7 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 Biorepository

**T1**

<b>Tube</b>	<b>Size (mm)</b>	<b>Aliquot (#/amount)</b>	<b>Material</b>	<b>Cryovials (#/size)</b>	<b>Allocation</b>
SST 1 (6 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 UCLA*
Red-top 1 (10 ml draw)	16x100	2 x 2.0 ml	Serum	2 x 2.0 ml	2 Biorepository

**T2**

<b>Tube</b>	<b>Size (mm)</b>	<b>Aliquot (#/amount)</b>	<b>Material</b>	<b>Cryovials (#/size)</b>	<b>Allocation</b>
SST 1 (6 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 UCLA*
Red-top 1 (10 ml draw)	16x100	2 x 2.0 ml	Serum	2 x 2.0 ml	2 Biorepository

\*UCLA-PSA/CA-125II

**Exhibit 10-2 (Contd.)  
PLCO Blood Protocol  
Specimen Collection and Allocation**

**T3**

Tube	Size (mm)	Aliquot (#/amount)	Material	Cryovials (#/size)	Allocation
SST 1 (6 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 UCLA*
Yellow-top 2 (8.5 ml draw)	16x100	N/A	Whole Blood	N/A	2 Processing Laboratory
Green-top 1 (10 ml draw)	16x100	2 x 2.0 ml 1 x 2.0 ml	Plasma Buffy coat	2 x 2.0 ml 1 x 2.0 ml	3 Biorepository
Lavender-top 1 (10 ml draw)	16x100	4 x 1.0 ml 1 x 2.0 ml 1 x 2.0 ml	Plasma Buffy coat RBC	4 x 1.2 ml 1 x 2.0 ml 1 x 2.0 ml	6 Biorepository

**T4**

Tube	Size (mm)	Aliquot (#/amount)	Material	Cryovials (#/size)	Allocation
SST 1 (6 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 UCLA*
Red-top 1 (10 ml draw)	16x100	2 x 2.0 ml	Serum	2 x 2.0 ml	2 Biorepository
Lavender-top 1 (10 ml draw)	16 X 100	1 x 3.6 ml 1 x 3.6 ml	Plasma Buffy Coat &RBC	1 x 4.0 ml 1 x 4.0 ml	2 Biorepository

**T5**

Tube	Size (mm)	Aliquot (#/amount)	Material	Cryovials (#/size)	Allocation
SST 1 (6 ml draw)	13x100	1 x 2.0 ml	Serum	1 x 2.0 ml	1 UCLA*
Red-top 1 (10 ml draw)	16x100	2 x 2.0 ml	Serum	2 x 2.0 ml	2 Biorepository
Lavender-top #1	16x100	2 x 2.0 ml 1x 2.0 ml 1x 2.0 ml	Plasma Buffy Coat RBC	2 x 2.0 ml 1x 2.0 ml 1 x 2.0 ml	4 Biorepository
Lavender-top #2	16x100	2 x 2.0 ml 1 x 2.0 ml	Plasma Buffy Coat	2 x 2.0 ml 1 x 2.0 ml	3 Biorepository

\*UCLA-PSA/CA-125II

**10.6.1 Recommended and Required Supplies**

A list of required and recommended supplies that should be assembled for each phlebotomy procedure is presented in Exhibit 10-3. The supplies listed are referenced in: the VWR Scientific Products Catalog, 2000-2001 Edition; the

Fisher Catalog 2000-2001; and the Becton Dickinson Catalog 2000. The CC will supply the Blood Collection Forms, the sample ID labels, and the royal blue-top tubes (T0 only). All other supplies must be purchased by each SC.

In 2000, Congress amended the Bloodborne Pathogens Act to require the use of needleless systems and safety devices, such as shielded needles, in health care settings to reduce the risk of needlestick injuries. This new law requires the screening centers to evaluate and select some sort of safety device, such as a shielded blood collection needle or a safety needle holder, for the PLCO blood collection at the T0 through T5 screening visits. One acceptable product is listed below. Additional acceptable products are available from other manufacturers.

**Exhibit 10-3  
Recommended Supplies for Blood Collection**

Item	Supplier	Quantity Required
Blood collection form (BCF3 or BFF2)	Will be supplied by CC	One BCF3 per participant at T0-T3 One BFF2 per participant at T4 and T5
* Sample ID labels	Will be supplied by CC	One set per participant per study year
* 6 ml draw (13x100) Vacutainer serum separator tube, silicon coated.	Becton Dickinson, p.1-5, 366511 VWR, p.1493, VT6511	One per person in all study years
* 10 ml draw (16x100) red-top Vacutainer tube, silicone coated	Becton Dickinson, p.1-6, 366430 VWR, p. 1493, VT6430	Two per person at T0 and one per person at T1, T2, T4 and T5
* 10 ml draw (16x100) green-top Vacutainer tube, with sodium heparin added	Becton Dickinson, p.1-7, 366480 VWR, p. 1493, VT6480	One per person at T0 and T3
* 7 ml draw (13x100) royal blue-top Vacutainer tube, trace element studies, silicone coated, no anticoagulant	Becton Dickinson, p.1-9, 369737  Will be supplied by CC	One per person at T0
* 10 ml draw (16x100) lavender-top Vacutainer tube, with liquid EDTA (K <sub>2</sub> ) added	Becton Dickinson, p.1-11, 366457, VWR, p. 1493, VT6457	One per person at T3 and T4 Two per person at T5
Blood collection needle and holder, 21 gauge	Becton Dickinson, 368607	As determined by SC
Tourniquet, latex	Fisher, p.1515, 15-235-2	As determined by SC
Alcohol wipes, individually wrapped	VWR, p.1373, 566-12-916	As determined by SC
BloodBloc Protective Pads, 2"x 2"	Fisher, p.1941, 06-670-37	As determined by SC
Adhesive bandage strips, ¾"x 3"	VWR, p.1374	As determined by SC
Test tube rack; Nalgene Brand Unwire	VWR, p.1681	As determined by SC
Needle disposal unit	VWR, p.1495	As determined by SC
Biohazard bags	VWR, pps.52-54	As determined by SC

Disposable gloves, latex, powder free; small, medium, large	VWR, pps.736-742	As determined by SC
Ammonia inhalants	Fisher, p.1516, 17-987-97E	As determined by SC

\* There should be no substitutions for these products without prior NCI approval

## 10.6.2 Participant Preparation

Participant suitability in accordance with the criteria specified in [Section 10.3](#) will be determined immediately prior to phlebotomy.

Several steps in the process of participant preparation will be standardized across all Screening Centers. The participant will be told that blood will be drawn for screening for prostate cancer (PSA, if male) or ovarian cancer (CA-125II, if female). In addition, the participant will be told that he/she will receive written documentation of the results of the PSA/CA-125II screening examinations within approximately three weeks. The SC will verify that the participant has signed an ESC and explain that blood is also being collected for future studies of cancer and other diseases.

## 10.6.3 Examination Steps

Before the blood samples are drawn, have the participant rest in a seated or reclining position for at least 5 minutes and remain in this position during the venipuncture. (Postural variation may elevate the lipid results by as much as 10 to 15 percent.) Clothing should not restrict the arm. If the blood draw is not successfully completed (all tubes filled to capacity) for all tubes, another draw should be attempted from the other arm. If attempts from both arms are unsuccessful, the participant should be scheduled for a repeat visit for the blood exam.

The participant will be asked to roll up a shirtsleeve to expose the middle portion of his/her arm. The phlebotomist will explain the procedure and position the participant with the arm in a dependent position. The phlebotomist will prepare the appropriate blood collection tubes, placing them in a test tube rack in the order in which they will be drawn. The phlebotomist will wash his/her hands and put on protective gloves. The phlebotomist will position the arm so that the veins are readily accessible and so the phlebotomist is able to work in a comfortable position. He/she will ensure that the arm is in a downward position with the elbow lower than the heart to prevent backflow. The phlebotomist will then inspect the arm to be used for the venipuncture. The veins of choice are those located in the antecubital area. Blood should not be drawn from any arm with an arterial access, such as a fistula or shunt, nor from any arm which has a rash or open sore or is swollen or edematous. A tourniquet will be applied 2 to 4 inches above the site with enough pressure to impede venous blood flow. The phlebotomist will select a vein that is palpable and well-fixed to surrounding tissue. The skin will be cleansed with alcohol in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleansed. The area will be dried using a sterile gauze pad and should be completely dried before the venipuncture is done in order to reduce the burning sensation caused by alcohol penetrating the skin.

The blood draw will be performed by inserting an appropriate needle into the arm, then inserting the SST tube, followed by the Biorepository tubes in sequence of priority. The SST tube for PSA/CA-125II will always be filled first.

The Biorepository samples will be collected at Baseline in the following order: a red-top tube, a green-top tube, a red-top tube, and a royal blue-top tube. At T1 and T2, only a red-top tube will be collected for the Biorepository. The Biorepository and Processing Laboratory samples will be collected at T3 in the following order: two yellow-top tubes, a green-top tube, and a lavender-top tube. At T4, the Biorepository tubes should be drawn in the following order: the red-top tube first, then the lavender-top tube. The Biorepository tubes for T5 should be drawn in the following order: the red-top first, then the two lavender-top tubes.

Immediately after the venipuncture, the phlebotomist will press a clean gauze square over the venipuncture site. After a few minutes, the venipuncture site should be checked and if clotting has occurred, an adhesive bandage will be applied over the gauze pad. If bleeding continues, direct pressure should be applied to the site for five minutes. Once the participant is feeling well enough, the phlebotomist will escort the participant to the appropriate SC staff.

## 10.7 Blood Processing and Storage Protocol for the PSA/CA-125II

The PLCO PSA/CA-125II blood processing protocol is summarized below.

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
16 ml SST	Serum	2.0 ml	2.0 ml	1

The following table lists equipment and supplies that will be needed for processing for the PSA/CA-125II blood specimens. The supplies listed are referenced in the VWR Scientific Products Catalog, 2000-2001 Edition; the Fisher Catalog 2000-2001; and the Becton Dickinson Catalog 2000.

Recommended Supplies for Processing the PSA/CA-125II Blood Specimens

Item	Supplier	Quantity Required
* Blood Collection Form (BCF3 or BFF2)	Will be supplied by the CC	One BCF3 per participant at T0-T3 One BFF2 per participant at T4 and T5
* Sample ID Labels	Will be supplied by the CC	One set per participant per study year
* Nalgene cryovial, 2.0 ml capacity, polypropylene, self-standing external threads, 13.5 mm x 48.3 mm	VWR, p.1878, 66008-728	One per participant per study year
* (Optional) Cryovial closure color-coders, (blue for PSA test, red for CA-125II test);	VWR, p. 431, 24270-060, blue closure; VWR, p. 431, 24270-064, red closure	One per participant per study year
Fisher/CMS transfer pipets, 5 ml, sterile, individually wrapped	Fisher/CMS, p. 1297,13-711-20	As determined by SC
Nalgene cryovial holder	WR, p.1895, 66008-783	As determined by SC

\* There should be no substitutions for these products without prior NCI approval.

[Section 10.7.1](#) through 10.7.3 describe the processing procedures immediately after the blood draw, the processing procedures for the serum component, and storage of the PSA and CA-125II blood samples. Please note that all blood handling and processing procedures should be followed as closely as possible. However, it is expected that some adjustments will have to be made to fit the unique situations that exist at each SC. If a SC would like to adjust a procedure, the adjustment must be documented and approved by NCI.

If an SC has difficulty obtaining the 2.0 ml Nalgene Cryovial (product no. 66006-728) as part of the blood processing protocol, then the SC may use the NCI-approved vial (Corning part no. 430659) as an acceptable substitute.

### **10.7.1 Processing Procedures Immediately After the Blood Draw for the PSA/CA-125II**

The following steps should be taken to process the blood sample immediately after the blood draw is complete:

1. After the blood sample tube is filled, invert it gently five times to mix, then stand it upright in the test tube rack. Allow the tube to stand at room temperature (22° to 25°C) for at least 30 to 45 minutes from the time of the draw to allow complete clotting retraction. If necessary, the tube may be transported during the clotting period as long as it remains in a stable, upright position. Once clot retraction is complete, maintain the tube at 2° to 8°C using either a refrigerator or an ice water bath. The sample may be allowed to stand longer than 45 minutes as long as it is maintained at 2° to 8°C after clot retraction is complete, centrifuged, and has the serum separated from the clot and frozen within 2 to 4 hours of blood collection.
2. Label the tube with the appropriate sample ID label.
3. Complete Part A (Blood Draw) and Part B, Items 1-2a (Blood Collection and Processing for PSA/CA-125II) of the Blood Collection Form.
4. If necessary, transport the blood sample with the Blood Collection Form to the SC processing laboratory. If the tube is transported during the clotting period, transport the tube at room temperature, 22° to 25°C. If the tube is transported after the clot retraction is complete, transport the tube at 2° to 8°C using an ice water bath or some type of refrigeration device. For ease of processing, the PSA/CA-125II and Biorepository samples may be centrifuged together.

### **10.7.2 Processing Procedures for Serum Separation for the PSA/CA-125II**

Follow the procedures given below to process the serum component of the blood sample:

1. Label one 2.0 ml cryovial with the sample ID label for PSA (001) or CA-125II (002), as appropriate. Sample ID labels will be provided by the CC.
2. Centrifuge the sample at 22° to 25°C at 1,200 x g for 15 minutes or 3900 x g for 6 minutes. A refrigerated centrifuge is not required. However, if the samples are not immediately aliquoted and frozen, transfer the samples to a refrigerator or an ice water bath within 5 minutes of finishing centrifugation.

3. Inspect the serum for hemolysis.
  - ▶ If the serum layer is red-tinged or pink, the blood sample is hemolyzed. Dispense the hemolyzed serum into the cryovial. Document the problem on the Blood Collection Form.
4. Check to see if the serum appears icteric.
  - ▶ Icteric (deep, yellow-green) samples may be processed after noting the condition on the Blood Collection Form.
5. Check to see if the serum appears turbid or lipemic.
  - ▶ If the serum is grossly turbid or lipemic, dispense the serum into the cryovial and document the problem on the Blood Collection Form.
6. Transfer the serum into a labeled storage cryovial.
  - ▶ Remove vial cap.
  - ▶ Using a graduated 5 ml transfer pipet, transfer 2.0 ml of serum into the 2.0 ml storage cryovial.
  - ▶ Recap the vial. If desired, use the blue closure cap for all PSA tests (male participants) and the red closure cap for all CA-125II tests (female participants). The SC may also use plain (i.e., non-colored) closure caps for both types of vials.
7. Record the results of the PSA/CA-125II blood processing in Part B of the Blood Collection Form.
8. Store specimens in storage boxes and freeze at -70°C.

### **10.7.3 Storage of PSA/CA-125II Samples**

All processed samples should be stored at -70°C until they are shipped to UCLA. They may be frozen on dry ice until they can be placed in a freezer. *The PSA and CA-125II cryovials will be stored separately (81 vials/box) in numbered storage (freezer) boxes.* Each freezer box will contain an inventory system. The inventory system and the organization of the vials in each box will be reflected on map cards, which must be completed for every box. (Exhibit 10-4 provides an example of the map card.) Each PSA/CA-125II storage box will be labeled with an ID box label, which will be generated by the SC (series number UP-xxxx or UC-xxxx). Three box labels will be generated for each unique storage box. One label will be placed on top part of the storage box, one label will be placed on the bottom part of the box, and one label will be placed on the side that is visible when the freezer door is opened. The storage boxes will be reusable for the PSA/CA-125II specimens; however, box numbers should be assigned sequentially and not reused. Instructions for generating box labels are provided in the *SMS User's Guide/SMS Upgrade Documentation*.

**Exhibit 10-4**

**Map Card**


The box labels will contain a six-character number. The first two characters will be either "UP" or "UC," which designates UCLA/PSA or UCLA/CA-125II blood samples, respectively. The next four characters will be a unique identifier number ranging from 0001 to 9999.

The supplies needed for storage of processed UCLA samples are listed below:

- 2" storage box (box dimensions 5 1/4"l x 5 1/4"w x 2"d) with 1-1/4" high 9 x 9 cell dividers; (Example: Bell Metal Specialty; telephone # 301-663-4522)
- Map Card (See Exhibit 10-4);
- Box labels; and
- -70°C freezer.

Follow the instructions given below to store processed samples.

1. Each vial for PSA/CA-125II is to be placed in the storage box, which is then stored in the freezer until shipment to UCLA.
2. Before adding samples to a storage box, be sure to label the box with a box number. There will be three labels provided for each box. Affix one label to the top part of the box, the second label to the bottom part of the box, and the third label to the side of the box.
3. Place each storage vial into the next available slot within the appropriate box, filling the box in serpentine order from the upper left corner to the lower right corner. Designate the upper left corner of the box with an "X".
4. Fill in the storage box map card with the sample ID of each vial added to the box.
5. Record the storage box number on the Blood Collection Form.
6. Immediately store the samples in the freezer at -70°C.
7. Do not remove a storage box from the freezer to add more vials. Small samples will quickly thaw. In the freezer environment, open the current

storage box, and place the new vial into the box. Take out the map card and let it stand in the air to defrost a few seconds. Then, write the sample ID of the new sample being added to correspond with the slot being filled. Replace the map card in the storage box.

## 10.8 The Blood Processing and Storage Protocol for the Biorepository

The Biorepository blood processing protocol is summarized below in order of processing priority:

### Baseline: T0

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
1 7 ml royal blue-top tube	Serum	2.0 ml	2.0 ml	1
1 10 ml green-top tube	Plasma Buffy coat RBC	2.0 ml 2.0 ml 2.0 ml	2.0 ml 2.0 ml 2.0 ml	2 plasma 1 buffy coat 1 RBC
1 10 ml red-top tube	Serum	2.0 ml	2.0 ml	2
1 10 ml red-top tube	Serum	2.0 ml	2.0 ml	2

### T1

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
1 10 ml red-top tube	Serum	2.0 ml	2.0 ml	2

### T2

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
1 10 ml red-top tube	Serum	2.0 ml	2.0 ml	2

### T3

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
2 8.5 ml yellow-top tubes	Whole blood	N/A	N/A	N/A
1 10 ml green-top tube	Plasma Buffy coat	2.0 ml 2.0 ml	2.0 ml 2.0 ml	2 plasma 1 buffy coat
1 10 ml lavender-top tube	Plasma Buffy coat RBC	1.2 ml 2.0 ml 2.0 ml	1.0 ml 2.0 ml 2.0 ml	4 plasma 1 buffy coat 1 RBC

#### T4

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
1 10 ml red-top tube	Serum	2.0 ml	2.0 ml	2
1 10 ml lavender-top tube	Plasma Buffy coat and RBC	4.0 ml 4.0 ml	3.6 ml 3.6 ml	1 plasma 1 buffy coat and RBC

#### T5

Collection Device	Specimen Type	Storage Vial	Volume per Vial	No. of Storage Vials
1 10 ml red-top tube	Serum	2.0 ml	2.0 ml	2
1 10 ml lavender-top tube	Plasma Buffy Coat RBC	2.0 ml 2.0 ml 2.0 ml	2.0 ml 2.0 ml 2.0 ml	2 1 1
1 10 ml lavender-top tube	Plasma Buffy coat	2.0 ml 2.0 ml	2.0 ml 2.0 ml	2 1

The following equipment and supplies will be needed for specimen processing.

- \*Appropriate Blood Collection Form (BCF3 for study years T0 through T3, BFF2 for study years T4 and T5);  
Provided by the CC
- \*Sample ID Labels;  
Provided by the CC
- \*Nalgene cryovials, 2.0 ml capacity, polypropylene, pre-capped, self-standing external threads, 13.5mm x 48.3mm. (Number per participant per draw: T0 = 9; T1 = 2; T2 = 2; T3 = 5; T4 = 2, T5 = 9); VWR, p.1983, 66008-728

**Approved Substitute:** Corning cryovial 2.0 ml capacity, polypropylene, pre-capped, self-standing, external threads. Corning product number 430659

- \*Wheaton cryovials, 1.2 ml capacity, polypropylene, pre-capped, self-standing internal threads, 12mm x 42mm  
(Number per participant per draw: T3 = 4);  
Wheaton Science Products Catalog product number 985745  
(Wheaton telephone 1-800-494-3286)  
Also available through VWR using product number 66008-955  
(VWR telephone 1-800-234-5227)
- \*Wheaton cryovial, 4.0 ml capacity, polypropylene; pre-capped, free-standing internal threads, 12 mm x 71 mm  
(Number per participant per draw: T4 = 2)  
Wheaton product number, 985747

**Approved Substitute:** Corning cryovial, 4.0 ml capacity, polypropylene, pre-capped, free standing, internal threads. Corning product number 430491.

- \* Porex Serum Sep IB, 13 mm diameter, 4" long, (trace metal free), (one per participant for T0); Fisher, Health Care Catalog, p. 405, 02-681-66
  - Fisher/CMS transfer pipets, 5 ml, sterile, individually wrapped; Fisher/CMS, p. 1297, 13-711-120
  - Nalgene cryovial holder; VWR, p. 2007, 66008-783
- [NOTE: The cryovials will be capped by the supplier prior to shipping. Precapping helps to eliminate contamination in the cryovial. This is especially important for the serum zinc specimen (cryovial 011).]
- Sharps containers and biohazard bags will also be needed for the proper disposal of contaminated waste.

### 10.8.1 Processing Procedures Immediately After the Blood Draw for Biorepository Specimens

Keep tubes away from sunlight or any other strong light source, which may degrade the Vitamin A content of the serum. If prolonged exposure to strong light is unavoidable, then tubes should be temporarily covered by aluminum foil for protection.

The following steps should be taken immediately after the blood draw.

#### Baseline (T0)

1. Label each of the following tubes with a Sample ID label (AA-NNNN-000):
  - 10 ml draw (16x100) red-top tube
  - 10 ml draw (16x100) green-top tube
  - 10 ml draw (16x100) red-top tube
  - 7 ml draw (13x100) royal blue-top tube
2. Immediately after the blood sample tubes are filled, invert the green-top tube gently several times and then stand upright in the test tube rack. After the green-top tube is inverted, maintain the green-top tube at 2° to 8°C using either a refrigerator or an ice water bath.
3. Allow the red-top tubes and the royal blue-top tube to remain at room temperature for a minimum of 60 minutes for complete blood coagulation. If necessary, the tubes may be transported during the clotting period if they remain in a stable, upright position. Once clot retraction is complete, maintain the red-top tubes and the royal blue-top tube at 2° to 8°C using either a refrigerator or an ice water bath.
4. Complete Part A (Blood Draw) and Part C (Blood Collection and Processing for Biorepository Samples), Items 1 through 3, of the Blood Collection Form.
5. If necessary, transport the blood samples with the Blood Collection Form to the SC processing laboratory. Transport the green-top tube at 2° to 8°C using an ice water bath or some type of refrigeration device. If the red-top tubes and the royal blue-top tubes are transported during the clotting period, transport the tubes at 22° to 25°C. If the red-top tubes and the royal blue-top tubes are transported after the clot retraction is complete, transport the tubes at 2° to 8°C using an ice water bath or some type of refrigeration device. The Biorepository samples

must be centrifuged, processed, and frozen within two hours of blood collection.

6. For ease of processing, the PSA/CA-125II and Biorepository samples may be centrifuged together.

### **T1 and T2**

1. Label the following tube with a Sample ID label (AA-NNNN-000):  
10 ml draw (16x100) red-top tube
2. Allow the red-top tube to remain at room temperature for a minimum of 60 minutes for complete blood coagulation. If necessary, the tube may be transported during the clotting period if they remain in a stable, upright position. Once clot retraction is complete, maintain the red-top tube at 2° to 8°C using either a refrigerator or an ice water bath.
3. Complete Part A (Blood Draw) and Part C (Blood Collection and Processing for Biorepository Samples), Items 1 through 3, of the Blood Collection Form.
4. If necessary, transport the blood sample with the Blood Collection Form to the SC processing laboratory. If the red-top tube is transported during the clotting period, transport the tube at 22° to 25°C. If the red-top tube is transported after the clot retraction is complete, transport the tube at 2° to 8°C using an ice water bath or some type of refrigeration device. The Biorepository samples must be centrifuged, processed, and frozen within two hours of blood collection.
5. For ease of processing, the PSA/CA-125II and Biorepository samples may be centrifuged together.

### **T3**

1. Label each of the following tubes with a Sample ID label (AA-NNNN-000):  
10 ml draw (16x100) green-top tube  
10 ml draw (16x100) lavender-top tube
2. Label each of the yellow-top tubes with a Sample ID Label (AA-NNNN-012 and AA-NNNN-013). Affix the sample ID label so that the longest side of the label wraps around the tube (in the same manner sample ID labels are placed on the cryovials).
3. Immediately after the blood sample tubes are filled, invert the yellow, green, and lavender-top tubes gently several times and then stand upright in the test tube rack. After the green and lavender-top tubes are inverted, maintain the green and lavender-top tubes at 2° to 8°C using either a refrigerator or an ice water bath. The yellow-top tubes will remain at ambient temperature.
4. Complete Part A (Blood Draw) and Part C (Blood Collection and Processing for Biorepository Samples), Items 1 through 3, of the Blood Collection Form.
5. If necessary, transport the blood samples with the Blood Collection Form to the SC processing laboratory. Transport the green and lavender-top tubes at 2° to 8°C using an ice water bath or some type of refrigeration device. The green and lavender-top tubes must be centrifuged, processed, and frozen within two hours of blood collection.

[**Note:** the two yellow-top tubes will not be processed by the SC, but instead will be shipped to the Processing Laboratory on the same day they are drawn. Please refer to [Section 10.10](#) for specific instructions on packaging and shipment of yellow-top tubes.]

6. For ease of processing, the PSA/CA-125II and green and lavender-top tubes may be centrifuged together.

#### **T4**

1. Label the following tubes with a Sample ID label (AA-NNNN-000):
  - 10 ml draw (16x100) red-top tube
  - 10 ml draw (16x100) lavender-top tube
2. Immediately after the lavender-top tube is filled, gently invert the tube several times and then stand it upright in the test tube rack. After the tube has been inverted, maintain it at 2°C to 8°C using either a refrigerator or an ice water bath.
3. Allow the red-top tube to remain at room temperature for a minimum of 60 minutes for complete blood coagulation. If necessary, the tube may be transported during the clotting period if it remains in a stable, upright position. Once clot retraction is complete, maintain the red-top tube at 2° to 8°C using either a refrigerator or an ice water bath.
4. Complete Part A (Blood Draw) and Part C (Blood Collection and Processing for Biorepository Samples), Items 1 through 3, of the Blood Collection Form.
5. If necessary, transport the blood sample with the Blood Collection Form to the SC processing laboratory. If the red-top tube is transported during the clotting period, transport the tube at 22° to 25°C. If the red-top tube is transported after the clot retraction is complete, transport the tube at 2° to 8°C using an ice water bath or some type of refrigeration device. Transport the lavender-top tube at 2° to 8°C using an ice water bath or some type of refrigeration device. The Biorepository samples must be centrifuged, processed, and frozen within two hours of blood collection.
6. For ease of processing, the PSA/CA-125II and Biorepository samples may be centrifuged together.

#### **T5**

1. Label the following tubes with a Sample ID label (AA-NNNN-000):
  - 10 ml draw (16x100) red-top tube
  - 10 ml draw (16x100) lavender-top tube #1
  - 10 ml draw (16x100) lavender-top tube #2
2. Immediately after the lavender-top tubes are filled, gently invert the tubes several times and then stand them upright in the test tube rack. After the tubes have been inverted, maintain them at 2°C to 8°C using either a refrigerator or an ice water bath.
3. Allow the red-top tube to remain at room temperature for a minimum of 60 minutes for complete blood coagulation. If necessary, the tube may be transported during the clotting period if it remains in a stable, upright position. Once clot retraction is complete, maintain the red-top tube at 2° to 8°C using either a refrigerator or an ice water bath.

4. Complete Part A (Blood Draw) and Part C (Blood Collection and Processing for Biorepository Samples), Items 1 through 3, of the Blood Collection Form.
5. If necessary, transport the blood sample with the Blood Collection Form to the SC processing laboratory. If the red-top tube is transported during the clotting period, transport the tube at 22° to 25°C. If the red-top tube is transported after the clot retraction is complete, transport the tube at 2° to 8°C using an ice water bath or some type of refrigeration device. Transport the lavender-top tubes at 2° to 8°C using an ice water bath or some type of refrigeration device. The Biorepository samples must be centrifuged, processed, and frozen within two hours of blood collection.
6. For ease of processing, the PSA/CA-125II and Biorepository samples may be centrifuged together.

### 10.8.2 Processing Procedures for Biorepository Samples

The following steps should be taken to process all components of the blood samples:

#### Baseline (T0)

1. Label the cryovials with the appropriate Sample ID labels. (See [Exhibit 10-1.](#)) The cryovials should be processed according to the following sequence:

- \*Vial 011serum from royal blue-top tube
- Vial 005plasma from green-top tube
- Vial 006plasma from green-top tube
- Vial 007buffy coat from green-top tube
- Vial 008RBC from green-top tube
- Vial 003serum from red-top tube
- Vial 004serum from red-top tube
- Vial 009serum from red-top tube
- Vial 010serum from red-top tube

[\***NOTE:** The cryovials will be precapped by the supplier, which helps eliminate contamination in the vial. This is especially critical for cryovial 011, serum from the royal blue-top tube. *Do not use uncapped vials for this specimen.* As an added precaution, do not remove the vials or the serum separators from their self-sealing bag until you are ready to process the centrifuged serum. Close the bag immediately thereafter to keep these supplies as clean as possible.]

2. Centrifuge all tubes for 15 minutes at 1,200 x g (or approximately 2400-3000 RPM for most counter-top centrifuges) or for 6 minutes at 3900 x g. Be sure to use balance tubes in the centrifuge, when necessary. Do not "rim" clot tubes prior to centrifugation. A refrigerated centrifuge is not required. However, the temperature should not exceed 25°C. If the samples are not immediately aliquoted and frozen, transfer the samples to a refrigerator or an ice water bath within 5 minutes of finishing centrifugation.
3. Inspect the blood tubes (serum) for hemolysis, icteric, turbid, or lipemic appearance. Document any problems on the Blood Collection Form.

4. Aliquot the serum from the royal blue-top Vacutainer tube first. After centrifugation, remove the stopper from the Vacutainer. Carefully and slowly push the Porex serum separator into the Vacutainer, white filter end down. Do not force it quickly; this could possibly create aerosol formation of the serum. The end of the serum separator should stop just short of the clot/serum interface. Red blood cells should not be forced into the serum; they contain very high amounts of zinc compared to the serum levels and a falsely elevated serum zinc level can result. Raise the serum separator approximately 25 mm. (1 inch) above the clot or cells until air space separates the serum separator and its contents from the clot or cells. Decant 2 ml of serum into cryovial 011. Recap the vial immediately after filling it with serum.

Do not use a pipet to transfer serum from the royal blue-top tube. Use only the Porex serum separator to decant the serum from the royal blue-top tube.

[**NOTE:** Any remaining serum can be placed into one of Vials 003, 004, 009, or 010.]

5. Aliquot the plasma from the green-top tube into cryovials 005 and 006 using a clean graduated 5 ml transfer pipet. Using the same pipet transfer the buffy coat into cryovial 007. Again using the same pipet, transfer 2 ml of RBC into cryovial 008. In order to maximize the buffy coat yield, when removing plasma leave a small amount of plasma above the buffy coat and when removing buffy coat include a small amount of RBC in the sample.
6. Aliquot the serum from the first red-top tube. Transfer 2 ml of serum into cryovials 003 and 004 using a graduated 5 ml transfer pipet. Aliquot serum from the second red-top tube. Transfer 2 ml of serum each into cryovials 009 and 010 using a graduated 5 ml pipet.

[**NOTE:** If the second red-top tube is not drawn, extra serum from the first red-top tube may be placed in vials 009 and 010; however extra serum from the SST tube for the PSA/CA-125II should *not* be used to fill Biorepository vials.]

7. Record the results of the Biorepository blood processing in Part C of the Blood Collection Form.  
[\***Note:** A partially filled vial should be marked with a problem code on the Blood Collection Form (refer to [Appendix A-10-1](#), Specifications for the Blood Collection Form)].
8. Place specimens in one of the numbered storage boxes for T0 participants' samples. Note that only samples from T0 participants should be placed in a T0 storage box. Freeze the samples at -70°C (refer to [Section 10.7.3](#) for specific storage box instructions) within two (2) hours of blood draw. Record the storage box number on the Blood Collection Form.

## T1 and T2

1. Label the cryovials with the appropriate Sample ID labels. (See [Exhibit 10-1](#).) The cryovials should be processed according to the following sequence:

Vial 003 - serum from red-top tube  
Vial 004 - serum from red-top tube

2. Centrifuge all tubes for 15 minutes at 1,200 x g (or approximately 2400-3000 RPM for most counter-top centrifuges) or for 6 minutes at 3900 x g. Be sure to use balance tubes in the centrifuge, when necessary. Do not "rim" clot tubes prior to centrifugation. A refrigerated centrifuge is not required. However, the temperature should not exceed 25°C. If the samples are not immediately aliquoted and frozen, transfer the samples to a refrigerator or an ice water bath within 5 minutes of finishing centrifugation.
3. Inspect the blood tubes (serum) for hemolysis, icteric, turbid, or lipemic appearance. Document any problems on the Blood Collection Form.
4. Aliquot the serum from the red-top tube. Transfer 2 ml of serum into cryovials 003 and 004 using a graduated 5 ml transfer pipet.
5. Record the results of the Biorepository blood processing in Part C of the Blood Collection Form.  
 [\***Note:** A partially filled vial should be marked with a problem code on the Blood Collection Form (refer to [Appendix A-10-1](#), Specifications for the Blood Collection Form).]
6. Place specimens in one of the numbered storage boxes for T1/T2 participants' samples. Note that only samples from T1/T2 participants should be placed in a T1/T2 storage box. Freeze the samples at -70°C (refer to [Section 10.7.3](#) for specific storage box instructions) within two (2) hours of blood draw. Record the storage box number on the Blood Collection Form.

### T3

1. Label the cryovials with the appropriate Sample ID labels. (See [Exhibit 10-1](#).) The cryovials should be processed according to the following sequence:
  - Vial 014plasma from green-top tube
  - Vial 015plasma from green-top tube
  - Vial 016buffy coat from green-top tube
  - Vial 017plasma from lavender-top tube
  - Vial 018plasma from lavender-top tube
  - Vial 019plasma from lavender-top tube
  - Vial 020plasma from lavender-top tube
  - Vial 021buffy coat from lavender-top tube
  - Vial 023RBC from lavender-top tube

[\***NOTE:** The cryovials will be precapped by the supplier, which helps eliminate contamination in the vial. This is especially critical for the T3 cryovials. *Do not use uncapped vials for these specimens.* As an added precaution, do not remove the vials from their self-sealing bag until you are ready to process the centrifuged sample. Close the bag immediately thereafter to keep the cryovials as clean as possible.]
2. Centrifuge the green-top and lavender-top tubes for 15 minutes at 1,200 x g (or approximately 2400-3000 RPM for most counter-top centrifuges) or for 6 minutes at 3900 x g. Be sure to use balance tubes in the centrifuge, when necessary. A refrigerated centrifuge is not required. However, the temperature should not exceed 25°C. If the samples are not immediately aliquoted and frozen, transfer the sam-

ples to a refrigerator or an ice water bath within 5 minutes of finishing centrifugation.

3. Inspect the blood tubes for hemolysis, icteric, turbid, or lipemic appearance. Document any problems on the Blood Collection Form.
4. Aliquot 2 ml of plasma from the green-top tube into two 2 ml cryovials (014 and 015) using a clean graduated 5 ml transfer pipet. Using the same pipet transfer the buffy coat (approximately 1.5-2.0 ml) into one 2 ml cryovial (016). In order to maximize the buffy coat yield, when removing plasma leave a small amount of plasma above the buffy coat and when removing buffy coat include a small amount of RBC in the sample.
5. Aliquot 1.0 ml of plasma from the lavender-top tube into four 1.2 ml cryovials (017, 018, 019, and 020) using a clean graduated 5 ml transfer pipet. Using the same pipet transfer the buffy coat (approximately 1.5-2.0 ml) into one 2 ml cryovial (021). Again using the same pipet, transfer 2 ml of RBC into one 2 ml cryovial (023). In order to maximize the buffy coat yield, when removing plasma leave a small amount of plasma above the buffy coat and when removing buffy coat include a small amount of RBC in the sample.
6. Record the results of the Biorepository blood processing in Part C of the Blood Collection Form.  
[\***Note:** A partially filled vial should be marked with a problem code on the Blood Collection Form (refer to [Appendix A-10-1](#), Specifications for the Blood Collection Form).]
7. Place cryovials in the appropriate numbered storage boxes for T3 participants' samples. Note that only vials from T3 participants should be placed in a T3 storage box. Freeze the samples at -70°C (refer to [Section 10.7.3](#) for specific storage box instructions) within two (2) hours of blood draw. Record the storage box numbers on the Blood Collection Form.

#### T4

1. Label the cryovials with the appropriate Sample ID labels. Exhibit 10-1 shows the correct placement for Sample ID labels. The cryovials should be processed according to the following sequence:
  - Vial 028serum from red-top tube
  - Vial 029serum from red-top tube
  - Vial 030plasma from lavender-top tube
  - Vial 031buffy coat and RBC from lavender-top tube
2. Centrifuge the red-top and the lavender-top tubes at for 15 minutes at 1,200 x g (or approximately 2400-3000 RPM for most counter-top centrifuges) or for 6 minutes at 3900 x g. Be sure to use balance tubes in the centrifuge, when necessary. A refrigerated centrifuge is not required. However, the temperature should not exceed 25°C. If the samples are not immediately aliquoted and frozen, transfer the samples to a refrigerator or an ice water bath within 5 minutes of finishing centrifugation.
3. Inspect the blood tubes for hemolysis, icteric, turbid or lipemic appearance. Document any problems on the blood collection form.

4. Aliquot the serum from the red-top tube. Transfer 2 ml of serum into cryovials 028 and 029 using a graduated 5 ml transfer pipet.
5. Aliquot 3.6 ml of plasma into one 4.0 ml cryovial (vial 030) using a graduated 5-ml transfer pipet. Using the same pipet, transfer the remaining material (includes buffy coat and substantial proportion of RBC) to about 3.6 ml into one 4.0 cryovial (vial 031). Collect the material by suctioning from the top of the buffy coat layer then gradually moving downward in a circular motion as the buffy coat and RBC are aspirated. Aliquot until the 3.6 ml line on the vial is reached. If more than 3.6 ml of material is available, discard extra RBC, but take care to retain the buffy coat.
6. Record the results of the Biorepository blood processing in Part C of the blood collection form.  
[\***Note:** A partially filled vial should be marked with a problem code.]
7. Place the cryovials in the appropriate numbered storage boxes for the T4 participants' samples. Note that only samples from T4 participants should be stored in a T4 storage box. Freeze the samples at  $-70^{\circ}\text{C}$  (refer to [Section 10.7.3](#) for specific storage box instructions) within two (2) hours of blood draw. Record the storage box numbers on the blood collection form.

## T5

1. Label the cryovials with the appropriate Sample ID labels. Exhibit 10-1 shows the correct placement for the Sample ID labels. The cryovials should be processed in the following order:
  - Vial 038serum from red-top tube
  - Vial 039serum from red-top tube
  - Vial 040plasma from lavender-top tube #1
  - Vial 041plasma from lavender-top tube #1
  - Vial 042buffy coat from lavender-top tube #1
  - Vial 043RBC from lavender-top tube #1
  - Vial 044plasma from lavender-top tube #2
  - Vial 045plasma from lavender-top tube #2
  - Vial 046buffy coat from lavender-top tube #2
2. Centrifuge the red-top and the lavender-top tubes at for 15 minutes at  $1,200 \times g$  (or approximately 2400-3000 RPM for most counter-top centrifuges) or for 6 minutes at  $3900 \times g$ . Be sure to use balance tubes in the centrifuge, when necessary. A refrigerated centrifuge is not required. However, the temperature should not exceed  $25^{\circ}\text{C}$ . If the samples are not immediately aliquoted and frozen, transfer the samples to a refrigerator or an ice water bath within 5 minutes of finishing centrifugation.
3. Inspect the blood tubes for hemolysis, icteric, turbid or lipemic appearance. Document any problems on the blood collection form.
4. Using a graduated 5-ml transfer pipet, aliquot 2.0 ml of serum from the red-top tube into the pre-labeled 2.0 ml cryovials, vials 038 and 039.
5. From lavender-top tube #1, aliquot 2.0 ml of plasma into two 2.0 ml cryovials, vials 040 and 041, using a graduated 5-ml transfer pipet. Using the same pipet, transfer the buffy coat (approximately 1.5-2.0 ml) into one 2.0 ml cryovial, vial 042. Then, transfer 2.0 ml of RBCs

into one 2.0 ml cryovial, vial 043. Collect the buffy coat and RBCs by suctioning from the top layer, then gradually moving downward in a circular motion. In order to maximize the buffy coat yield, when removing the plasma leave a small amount of plasma above the buffy coat and when removing the buffy coat, include a small amount of RBC in the sample.

**[NOTE:** If the second lavender-top tube is not drawn, extra plasma from the first lavender-top tube may be placed in vials 044 and 045.]

6. From lavender-top tube #2, aliquot 2.0 ml of plasma into two 2.0 ml cryovials, vials 044 and 045, using a graduated 5-ml transfer pipet. Using the same pipet, transfer the buffy coat (approximately 1.5-2.0 ml) into one 2.0 ml cryovial, vial 046. Collect the buffy coat by suctioning from the top layer then gradually moving downward in a circular motion. In order to maximize the buffy coat yield, when removing the plasma leave a small amount of plasma above the buffy coat and when removing the buffy coat, include a small amount of RBC in the sample.
7. Record the results of the Biorepository blood processing in Part C of the blood collection form. \*Note: A partially filled vial should have a problem code recorded on the blood collection form. (Refer to [Appendix A-10-7](#) Specifications for the BFF2)
8. Place the cryovials in the appropriate numbered storage boxes for the T5 participants' samples. Note that only samples from T5 participants should be included in a T5 storage box. Freeze the samples at  $-70^{\circ}\text{C}$  (refer to [Section 10.7.3](#) for specific storage box instructions) within two (2) hours of blood draw. Record the storage box numbers on the blood collection form.

### 10.8.3 Storage Box Assignment for Biorepository Samples

Each storage box will be labeled with a box label taken from a series of sequentially numbered labels generated by the SC. There will be two series of box labels: "B" series to be used for 2-inch and 3-inch Biorepository boxes and "Y" series to be used for yellow-top tube boxes shipped to the Processing Laboratory. The "T" box previously used for T3 vial 016 was discontinued in October 1999. All Biorepository vials for study years T0, T1, T2, T3, and T5, are stored in a 2-inch "B" box. Biorepository vials for T4 only are stored in a 3-inch "B" box. The box label has a five-character number. The first character of Biorepository box labels will be the letter "B." For Processing Laboratory box labels, the first character will be the letter "Y." The next four characters are the unique identifier number ranging from 0001 to 9999. Biorepository and Processing Laboratory samples must be assigned to storage boxes as follows:

Alpha Character	Storage Box Type	Used for Study Years	Used for Specimen Ids
B	2-inch Biorepository Box	T0 T1 and T2 T3 T5	003-011 003-004 014-021, and 023 038-046
B	3-inch Biorepository Box	T4	028-031

Y	Yellow-top Tube Box for Processing Laboratory	T3	012 and 013
---	---	----	-------------

Three box labels will be generated for each unique storage box. One label will be placed on top of the storage box, one label will be placed on the bottom of the box, and for frozen samples in "B" boxes, one label will be placed on the side, which is visible in the freezer. The storage boxes will be reusable for the Biorepository specimens; however, box labels should not be reused. In addition, do not use the same storage box number again within a 6-month period. Each SC will have the capability to generate new box labels if the storage box is lost or destroyed. Instructions for generating box labels are provided in the *SMS User's Guide/SMS Upgrade Documentation*.

#### 10.8.4 Storage of Biorepository Cryovials

All processed serum, plasma, buffy coat, and RBC cryovials will be stored at -70°C until they are shipped to the Biorepository. The cryovials will be placed into storage (freezer) boxes (81 vials/box). The inventory system and the organization of the cryovials in each storage box will be reflected on map cards, which must be completed for every cryovial storage box. ([Exhibit 10-4](#) provides an example of the map card.) The SC Coordinator should label the storage box with the SC name and address using a -70° label and a freezer-safe ink pen.

Supplies needed for storage of processed samples are listed below:

- 2" storage box (box dimensions 5 1/4"l x 5 1/4"w x 2"d) with 1-1/4"high 9 x 9 cell dividers; (Example: Bell Metal Specialty; telephone # 301-663-4522)
- 3" storage box (box dimensions 5 1/4"l x 5 1/4"w x 3"d) with 1-1/4" high 9 x 9 cell dividers; (Example: Bell Metal Specialty; telephone # 301-663-4522) (T4 only)
- Map Card (See [Exhibit 10-4](#));
- Box labels, laser labels, dimensions 2/3" x 3 7/16" (Example: Avery File Folder Laser Labels, Item #5366); and
- -70°C freezer.

Follow the instructions given below to store cryovials for the Biorepository.

1. Each cryovial is to be placed in the appropriate storage box. Cryovial storage boxes are then stored in the freezer until shipment to the Biorepository.
2. Before adding samples to a storage box, label the box with a unique box number. There will be three labels provided for each unique box number. Affix one label to the top part of the box, the second label to the bottom part of the box, and the third label to the side of the box.
3. **For the T0 visit**, each row of a storage box will be designated for a single T0 participant. Place the cryovials, in ascending specimen ID order (vials 003-011), into the slots next to each other in that row. Designate the upper left corner of the box with an "X". If all blood vials have been successfully filled, the participant will have nine cryovials and the row will be completely filled. However, if only some of the blood vials have been filled, then the row in the storage box for that partici-

part will only be partially filled. Start a new row for each participant. The 2-inch Biorepository storage box will hold the cryovials for nine T0 participants. Only vials for T0 participants should be stored in T0 storage boxes.

**For the T1 and T2 visits**, place each storage vial (with specimen IDs 003-004) into the next available slot within the appropriate box, filling the box in serpentine order from the upper left corner to the lower right corner. Designate the upper left corner of the box with an "X". The 2-inch Biorepository storage box will hold the cryovials for 40 participants with one empty slot remaining. T1 and T2 vials may be placed in the same storage box.

**For the T3 visit**, All cryovials will be placed in a 2-inch Biorepository storage box. Each row of a storage box will be designated for a single T3 participant. Place the cryovials, in ascending specimen ID order (vials 014-021, and 023), into the slots next to each other in that row. Designate the upper left corner of the box with an "X". If all blood vials have been successfully filled, the entire row will be full with no empty spots. However, if only some of the blood vials have been filled, then one or more slots in the row for that participant will be empty. Start a new row for each participant. The 2-inch Biorepository storage box will hold the cryovials for nine T3 participants. Only vials for T3 participants should be placed in a T3 storage box.

The 3-inch storage box used previously for T3 vial 016 was discontinued in October 1999. Vial 016 is now placed in a 2-inch box with the other T3 specimens.

**For the T4 visit:** All four (4) of the T4 Biorepository vials (028-031) should be stored and shipped in a **3-inch "B" box**. Place each storage vial (with specimen IDs 028-031) into the next available slot filling the box in serpentine order from the upper left corner to the lower right corner. Designate the upper left corner of the box with an "X". The **3-inch** Biorepository storage box will hold the cryovials for twenty participants with one empty slot remaining. Only vials from T4 participants should be placed in T4 storage boxes.

**For the T5 visit:** All nine (9) of the T5 Biorepository vials (038-046) should be stored and shipped in a 2-inch "B" box. Each row of a storage box will be designated for a single T5 participant. Designate the upper left corner of the box with an "X". Place the cryovials, in ascending vial ID order, into the slots next to each other in that row. If all blood vials have been successfully filled, the entire row will be full with no empty spots. However, if only some of the blood vials have been filled, then one or more slots in the row for that participant will be empty. Start a new row for each participant. One 2-inch T5 storage box will hold the vials for nine participants. Only vials for T5 participants should be placed in a T5 storage box.

4. Fill in the storage box map with the sample ID and specimen ID of each vial added to the box. (For example, IX 1234 003.)
5. Record the storage box numbers on the Blood Collection Form.
6. Immediately store the cryovials in the freezer at -70°C within five minutes of processing.

7. Do not remove a 2-inch or 3-inch storage box from the freezer to add more cryovials. Small samples will thaw quickly. In the freezer environment, open the current storage box and place the new cryovial into the box. Take out the map card and let it defrost for a few seconds. Then, write the sample ID of the new sample being that to correspond with the slot being filled. Replace the map card in the storage box.

## 10.9 UCLA and Biorepository Blood Sample Shipment

All frozen blood samples will be shipped to UCLA or the Biorepository via Federal Express\* overnight Priority 1 delivery. PSA and CA-125II blood samples will be shipped weekly on designated days for each SC, while Biorepository blood samples will be shipped at least monthly (once a month at some SCs, more than once a month at others). Blood samples shipped to UCLA or the Biorepository will be packed on dry ice for shipment. A Blood Sample Transmittal Log ([Appendix B-10-1: UCLA Transmittal Log](#) and [Appendix B-10-2: Biorepository Transmittal Log](#)) will be included with each shipment.

All PSA/CA-125II blood sample shipments will be processed by UCLA on the day received. Upon receipt, UCLA staff will check the shipment to identify missing, thawed, or damaged specimens. UCLA will contact the SC immediately by telephone and FAX to report any problems.

All Biorepository blood sample shipments will be receipted and stored by the Biorepository on the day received. Within two weeks of sample receipt, the Biorepository will inventory the samples and match the vials noted on the Transmittal Log to identify missing, thawed, or damaged vials. The Biorepository will contact the SC immediately by telephone and FAX to report any problems.

The following sections of this chapter discuss the procedures for packing and shipping blood samples. Included in this section are the following items:

- Scheduling shipments;
- Notifying UCLA and the Biorepository of shipments;
- Procedures to be completed the day of shipment;
- Preparing shipping transmittal logs;
- Packing specimens; and,
- Reporting problems with shipments.

\* Any Express Mail service that carries biologic samples may be used provided that overnight next morning delivery service is available and guaranteed.

### 10.9.1 Scheduling UCLA and Biorepository Shipments

PSA and CA-125II blood samples will be shipped to UCLA weekly; on Monday, Tuesday, or Wednesday. Biorepository blood samples will be shipped once a month, at a minimum, on the first Monday, Tuesday or Wednesday of each month. SCs wishing to ship to the Biorepository more than once a month must contact the Coordinating Center, who will then contact the Biorepository and request approval for a change in the shipping schedule. Each SC has been assigned a designated day of shipment on which it will regularly ship blood

samples to UCLA and the Biorepository. The SC schedule for weekly shipments of blood samples to UCLA and shipments to the Biorepository is as follows:

**Schedule for Weekly UCLA Shipments**

Day	Screening Center
Monday:	University of Minnesota
	Pacific Health Research Institute (Hawaii)
Tuesday:	Washington University - St. Louis
	University of Utah School of Medicine
	University of Alabama at Birmingham
	University of Colorado Health Sciences Center
Wednesday:	Georgetown University
	Pittsburgh Cancer Institute
	Washington University - St. Louis
	Henry Ford Hospital
	Marshfield Clinic

**Schedule for Biorepository Shipments**

Frequency	Screening Center	Shipment Day
Monthly:	Pacific Health Research Institute (Hawaii)	Monday
	University of Alabama at Birmingham	Tuesday
	Georgetown University	Wednesday
	Pittsburgh Cancer Institute	Wednesday
Twice Per Month: (First and Third Weeks)	Marshfield Clinic	Wednesday
	University of Colorado Health Sciences Center	Wednesday
	Washington University – St. Louis	Wednesday
Weekly:	University of Minnesota	Monday
	University of Utah School of Medicine	Tuesday
	Henry Ford Hospital	Wednesday

Blood samples should never be shipped to be received at either UCLA or the Biorepository on Fridays, holidays, or the day before a holiday. The SC will notify UCLA or the Biorepository, as appropriate, prior to making each shipment. If, on occasion, the SC cannot make the shipping date, they must call UCLA or the Biorepository in advance of the regular shipping date to reschedule. On the day of each Biorepository shipment, the SC will transmit the Biorepository transmittal file to the NIH Mainframe using standard File Transfer Protocol (FTP). Refer to the *SMS User's Guide/SMS Upgrade Documentation* for specifications on data transmission.

### **10.9.2 Tasks to be Completed the Day of UCLA and Biorepository Shipments**

The tasks that must be completed for a blood sample shipment to UCLA or the Biorepository are as follows:

- Contact Federal Express to arrange a pick-up time. (The Federal Express telephone number is 1-800-238-5355.)
- Fax or e-mail UCLA or the Biorepository the following information:
  - ▶ SC name and number;
  - ▶ Number of shipping boxes in shipment; and
  - ▶ Federal Express airbill number.
- The PLCO Shipment Notification fax sheet ([Appendix A-10-5](#)) may be used to fax the information listed above to either UCLA or the Biorepository.
- Generate the appropriate Blood Sample Transmittal Log. Make two copies of the log; one for shipment to UCLA or the Biorepository and one for the SC file.
- Generate a diskette that contains the transmittal log data for inclusion in the shipment to UCLA.
- Using the appropriate Blood Sample Transmittal Log, select the samples to be shipped. *Do not ship samples that are not listed on the transmittal.*
- Pack the shipping containers with the blood samples and cover with dry ice. Include the Blood Sample Transmittal Log and the appropriate diskette (UCLA shipments only). Place the diskette in a diskette mailer and tape to top of the styrofoam lid. Place the fiberboard lid on top of the styrofoam lid and tape the container to securely seal the fiberboard lid to the fiberboard base.
- Label the exterior of each shipping container with the appropriate Federal Express and IATA required warning labels.
- Confirm the Federal Express pick-up.
- File a copy of the Blood Sample Transmittal Log with a record of the Federal Express airbill number for each package shipped.
- On the day of each Biorepository shipment, the Biorepository transmittal file will be transmitted to the NIH mainframe using FTP.

### 10.9.3 The Blood Sample Transmittal Log for UCLA and Biorepository Shipments

A Blood Sample Transmittal Log must be generated for every shipment of blood samples sent either to UCLA or the Biorepository. The Blood Sample Transmittal Log will consist of a cover page and a computer generated log. The first page of the transmittal will be a standardized cover page for all SCs, while the remaining page(s) will be the computer generated log that will allow each SC to identify samples for each blood sample shipment. The central SC will generate the Blood Sample Transmittal Log and attach it to the cover page. If blood samples are shipped directly from the satellite centers to UCLA or the Biorepository, the central SC will generate the appropriate Blood Sample Transmittal Log for the satellite centers.

There are two versions of the Blood Sample Transmittal Log; one for shipment of PSA/CA-125II blood samples and one for shipment of the Biorepository blood samples. For the PSA/CA-125II blood sample shipments, the Blood Sample Transmittal Log will be generated separately for PSA samples and for CA-125II samples.

This log will include all relevant shipping and receipt control information for each sample ID. A copy of the Blood Sample Transmittal Log for PSA/CA-125II and the Biorepository is presented in Appendices B-10-1 and B-10-2, respectively. Instructions for generating the Blood Sample Transmittal Log are provided in the *SMS User's Guide/SMS Upgrade Documentation*.

In preparation for shipment of samples, the SC staff will perform the following steps:

1. Generate a Blood Sample Transmittal Log using the SMS.
  - ▶ All samples that were receipted (without problems that would prevent shipping) and have not been shipped will appear on the Blood Sample Transmittal Log as available/due for shipment.
  - ▶ It is strongly recommended that the SC run the SMS and DEES edits and comparison reports for Blood Collection Forms prior to generating a Blood Sample Transmittal. This will reduce or eliminate errors on the transmittal. (See [Chapter 17.0](#) for information on running edits.)
2. Locate and batch the specimen vials according to the transmittal log.

If a specimen cannot be located, has been destroyed, or other problems are identified that will prevent shipping, the SC staff member will cross the sample ID off the transmittal log, remove the shipping date from the SMS, and document that the vial was lost or destroyed according to the specifications for completion of the blood collection form. Then, regenerate the transmittal.

If a specimen is in the freezer but is not on the transmittal, the SC staff member will make a notation on the transmittal log and investigate to determine whether the sample should be listed on the transmittal log. If so, the SMS should be updated to indicate that it is available with no problems, and the transmittal should be regenerated. If necessary, correct the hard copies, rescan, and edit the forms in DEES.

The capacity of each storage box is 81 vials so *there should be no more than 81 vials listed on the transmittal for one box.*

3. If problems were found with the original transmittal log, regenerate a corrected transmittal log and verify that all problems have been resolved. Transmittal logs with handwritten notations will not be sent to UCLA or the Biorepository.
4. When the final, corrected transmittal is generated, retain one copy of the transmittal for the SC files, and include one copy with the specimens shipped to UCLA or the Biorepository.
5. Create the transmittal log file for UCLA and the Biorepository. For UCLA, save the transmittal log file on a diskette and include it with the shipment as described above in [Section 10.8.2](#). For the Biorepository, send the transmittal log file electronically to the Biorepository via the NIH Mainframe Computer as described in the *SMS User's Guide/SMS Upgrade Documentation*.

#### **10.9.4 The Blood Sample Pre-Transmittal Log for UCLA and Biorepository Shipments**

In order to resolve discrepancies between the sample storage boxes and the information in the SMS, it is strongly recommended that the SCs generate a Pre-Transmittal Log for all UCLA ([Appendix B-10-4: UCLA Pre-transmittal Log](#)) and Biorepository ([Appendix B-10-5: Biorepository Pre-transmittal Log](#)) shipments. The major advantage of the Pre-Transmittal is that ship dates are not assigned when the Pre-Transmittal is generated. This allows the SC to make modifications and/or corrections to the blood collection form SMS data as necessary without having to take additional steps to delete ship dates for those samples that require corrections. When this Pre-Transmittal is generated, only a hardcopy listing will be produced (an electronic file is *not* produced). There are no limits on the number of times a Pre-Transmittal can be generated. Once any discrepancies have been resolved, the SC should then generate the "official" transmittal log. The Biorepository and UCLA have been instructed not to accept Pre-Transmittal logs from the SCs. Instructions for generating the Pre-Transmittal Logs are provided in the *SMS User's Guide/SMS Upgrade Documentation*.

SCs using the Pre-Transmittal Log will perform the following steps in preparation for shipment of samples:

1. Generate a Pre-Transmittal Log using SMS.

All samples that were receipted (without problems that would prevent shipping) and have not been shipped will appear on the Blood Sample Pre-Transmittal Log as available/due for shipment.

It is strongly recommended that the SC run the SMS and DEES edits and comparison reports for Blood Collection Forms prior to generating a Pre-Transmittal Log. This will reduce or eliminate errors on the Pre-Transmittal. (See [Chapter 17.0](#) for information on running edits.)

2. Locate and batch the specimen vials according to the Pre-Transmittal log.

If a specimen cannot be located, has been destroyed, or other problems are identified that will prevent shipping, the SC staff member will cross the sample ID off the Pre-Transmittal log, and document that the vial was lost or destroyed according to the specifications for completion of the blood collection form. Then, regenerate the Pre-Transmittal.

If a specimen is in the freezer but is not on the Pre-Transmittal, the SC staff member will make a notation on the Pre-Transmittal log and investigate to determine whether the sample should be listed on the Pre-Transmittal log. If so, the SMS should be updated to indicate that it is available with no problems, and the Pre-Transmittal should be regenerated. If necessary, correct the hard copies of the blood collection form, rescan, and edit the forms in DEES to resolve any problems noted on the Pre-Transmittal.

The capacity of each storage box is 81 vials so there should be no more than 81 vials listed on the transmittal for one box.

3. If problems were found with the original Pre-Transmittal log, regenerate a corrected Pre-Transmittal log and verify that all problems have been resolved.
4. Once the Pre-Transmittal is correct, generate the "official" Transmittal Log and review the Transmittal. Then, retain one copy of the transmittal for the SC files, and include one copy with the specimens shipped to UCLA or the Biorepository. *Pre-Transmittal logs or transmittal logs with handwritten notations will not be sent to UCLA or the Biorepository.* SCs are cautioned that if blood collection forms are receipted after the Pre-Transmittal was reviewed, but prior to generation of the "official" transmittal log and transmittal file, these "new" samples will appear on the transmittal log and file.
5. Create the transmittal log file for UCLA and the Biorepository. For UCLA, save the transmittal log file on an empty/clean diskette and include it with the shipment as described above in [Section 10.8.2](#). For the Biorepository, send the transmittal log file electronically to the Biorepository via the NIH Mainframe Computer as described in the *SMS User's Guide/SMS Upgrade Documentation*.

### **10.9.5 Packing Containers for Frozen Blood Samples**

Each SC should maintain a sufficient supply of shipping supplies for making regularly scheduled frozen shipments to UCLA and the Biorepository that meet the shipping requirements specified in the current version of the International Air Transport Authority (IATA) Shipping Regulations for Dangerous Goods. The following is a list of recommended supplies that can be used for frozen blood shipments:

- SaftPak 710, 730 or 740 leakproof bag and envelope system as determined by size and number of freezer boxes included in the shipment (Telephone: 1-800-814-7484. Website [www.saftpak.com](http://www.saftpak.com));
- SaftPak 151 or 152 Absorbent Strips as determined by the volume of blood included in each leakproof bag and envelope system (see above);
- Polyfoam Packers Insulated Bio-Shippers; to be used as overpacks; (Telephone: 1-800-323-7442);
- Packing material;
- Self-sealing plastic bags to hold Transmittal Forms and UCLA transmittal diskette; and
- Dry ice.

Guidelines for the maximum number of freezer storage boxes and the minimum quantity of dry ice required for three different sizes of shipping overpacks are provided below.

<b>Dimensions of Shipping Overpack (inches)</b>	<b>Maximum Number of Freezer Storage Boxes</b>	<b>Minimum Suggested Quantity of Dry Ice (pounds)</b>	<b>Minimum Suggested Quantity of Dry Ice (kilograms)</b>
7x 10x 11.5	3	12	5.4
13x13x13	8	30	13.6
12.5x12x18.5	12	45	20.4

Frozen samples should always remain the freezer environment when they are being prepared for shipment. Thawing can occur within only a few minutes with small samples.

The procedure that should be followed to pack frozen samples is specified below.

1. Cover the bottom of the shipping overpack with crumpled packing material.
2. Lay dry ice on top of the packing material.
3. Remove the sample storage boxes from the freezer and secure each box with rubber bands.
4. Place the sample storage box into the leakproof plastic bag included with the SafTPak combination packaging (plastic bag and envelope). Note that the STP 730 can hold two 2-inch freezer boxes or one 3-inch freezer box. The STP 710 can hold one 2-inch freezer box, but is not large enough to accommodate the 3-inch box. The STP 730 must be used for shipping the 3-inch freezer box.
5. Place an absorbent strip sufficient to absorb the contents of the storage box(es) into the leakproof plastic bag. Normally, this will be the STP 152 which absorbs up to 250 ml. Note that a full 2-inch freezer box contains 160 ml of blood.
6. Seal the leakproof plastic bag in accordance with the printed instructions on the bag. Be careful to follow these directives as failure to do so will compromise the integrity of the packaging system.
7. Place the sealed leakproof plastic bag into the accompanying Tyvek envelope. Seal the envelope in accordance with the printed instructions found on the reverse side of the envelope. Only one leakproof plastic containing no more than two freezer boxes for the STP 730 and one freezer box for the STP 710 can be included in a single envelope.
8. Place the sealed Tyvek envelopes containing the sample storage box(es) in the leakproof plastic bags on top of the layer of dry ice.
9. Add dry ice to completely surround each envelope.
10. Fill the sides of the shipping overpack with dry ice.
11. Use crumpled packing material to fill in any holes or spaces and to keep the dry ice in place around the envelopes.

12. Place a final layer of dry ice on top of the envelopes.
13. Fill in any remaining space with crumpled packing material, and place the styrofoam lid on top of the shipping overpack.
14. Place the self-sealing bag containing the hardcopy Blood Sample Transmittal Log(s) and, for UCLA shipments, the transmittal diskette on top of the styrofoam lid.
15. Close the flaps on the fiberboard box and secure the exterior of the fiberboard box with strapping tape. Be sure to tape the box securely.

UCLA and the Biorepository will recycle both components of the overpacks, the Styrofoam liner and the outer fiberboard box to the appropriate SC. The SC will be responsible for covering the cost of the shipping of the storage boxes and shipping containers from UCLA and the Biorepository. The SC should include a mailing address label or a pre-addressed Federal Express airbill in the plastic bag with the Blood Sample Transmittal Log. Eight to ten working days should be allowed for return of the shippers. UCLA and the Biorepository will not return shipping containers that they consider to be too damaged or too worn to ensure safe transport of PLCO samples. The use of pelleted dry ice instead of block dry ice will result in less damage to the shipping container during transit and enable the shipper to be used for more shipments.

### **10.9.6 Labeling Shipping Containers for Frozen Samples**

As mentioned previously, all blood samples will be shipped to UCLA and the Biorepository via Federal Express\* overnight priority 1 delivery. All packages

\* Any Express Mail service that carries biologic samples may be used provided that overnight next morning delivery service is available and guaranteed.

containing frozen samples must be labeled as described in this section. Federal Express will supply airbills, plastic pouches for airbills, Class 9 (dry ice) labels, and multiple package service labels (if needed). Each SC will have the capability on the SMS to generate address labels and mailing labels for specimen shipment. The procedures given below meet Federal regulations, the International Air Transportation Association (IATA) Regulations for the Transport of Dangerous Goods, and Federal Express requirements for the labeling of biologic diagnostic specimens for shipment.

- Complete the Federal Express airbill, including: the date; the sender's name, telephone number, and address; and the recipient's name, telephone number, and address. Under express package service, mark the box for "Priority Overnight" delivery. Designate the type of packaging by marking the "Other Packaging" box. Under special handling: 1) check the box for "No" in response to "Does this shipment contain dangerous goods?" 2) check the box for "Dry Ice" and 3) record the number of packages and the number of kilograms of dry ice included in each package. (For example, "1x6 kg.") Complete the payment information section.
- Place the airbill in its self-stick plastic pouch, and attach the pouch to the top of the overpack.
- Place a Federal Express Class 9 label (for dry ice) on one side of the fiberboard box. The Federal Express Class 9 label (for dry ice) may be ordered, free-of-charge, through the local Federal Express Courier only. Request Logos #106426.

If Class 9 labels are obtained from another source, such as Labelmaster, verify that the following information is pre-printed on the Class 9 label:

UN 1845  
Dry Ice,  
\_\_\_kg.

- On the Class 9 label, record the weight (in kilograms) of dry ice included in the box. (The weight *must* be recorded in kilograms, not pounds. Calculate an approximation for kilograms as follows: kg = lb divided by 2.)

The following language must appear on the top of the overpack:

“Diagnostic Specimens

Packed in compliance with IATA Packing Instruction 650”

This language may be hand-written, or printed on labels which are then affixed to the top of the fiberboard box. Please note that pre-printed labels are preferred. IATA regulations specify that the exact language and punctuation listed above must be used.

- Attach a label with the SC name and address to the top of the overpack. Note that this is in addition to recording the information on the airbill.
- For shipment of PSA/CA-125II samples: attach a UCLA Tissue Typing Laboratory address label to the top of the fiberboard box. The specimen shipment address for UCLA is given below:

David Chia, Ph.D.  
UCLA Immunogenetics Center  
PLCO Study  
1000 Veterans Ave, Room A-549  
Los Angeles, CA 90095  
310-206-2062

- For shipment of Biorepository samples: attach a Biorepository address label to the top of the fiberboard box. The specimen shipment address for the Biorepository is:

McKesson BioServices - NCI Frederick  
1066 Boyles Street  
Ft. Detrick, MD 21702  
ATTN: Bldg. 1066 Repository  
Contact Person: Irma Flores  
Daytime Telephone: 301-846-5182  
After Hours Telephone: 301-846-1091  
FAX: 301-846-7069  
Email: iflores@ncifcrf.gov

- It is important that all labels are securely attached to the fiberboard box and that the labels do not overlap. If the box has pre-printed “up” arrows, avoid placing labels over the pre-printed markings.

## 10.10 Packaging and Shipment of Yellow-top Tubes

The yellow-top tubes for T3 participants will be placed directly into the shipping container and shipped at ambient temperature to the Processing Laboratory on the same day they are drawn. The yellow-top tubes will be shipped via Federal Express overnight Priority 1 delivery. A Processing Laboratory Transmittal Log ([Appendix A-10-4](#)) will be included with each shipment.

The Processing Laboratory will process all yellow-top tube shipments on the day received. Upon receipt of the samples, the Processing Laboratory will check the yellow-top tubes and match the tubes noted on the Processing Laboratory Transmittal Log to identify missing or damaged tubes. The Processing Laboratory will contact the SC immediately by telephone and FAX to report any problems.

The following sections of this chapter discuss the procedures for packing and shipping yellow-top tubes. Included in this section are the following items:

- Scheduling shipments;
- Notifying the Processing Laboratory of shipments;
- Procedures to be completed the day of shipment;
- Preparing shipping transmittal logs;
- Packing specimens; and,
- Reporting problems with shipments.

### 10.10.1 Scheduling Processing Laboratory Shipments

Yellow-top tubes from T3 participants will be shipped to the Processing Laboratory on the same day they are drawn. This is important to maintain cell viability. The Processing Laboratory will be able to receive shipments Mondays through and including Saturdays. However, the SC should not ship samples which would arrive at the Processing Laboratory on a holiday. If the SC is unable, under unusual circumstances, to ship samples on the same day they are drawn, then the yellow-top tubes may be shipped the next day. Yellow-top tubes not shipped on the same day or the next day after they are drawn should be destroyed. The reason the samples were not shipped within the required time frame must be noted on the Blood Collection Form under Part C (Blood Collection and Processing for Biorepository Samples) in Item C.16, Comments.

In addition to same day notification of yellow-top tube shipments, the SC will provide the Processing Laboratory with a projection of the SC's T3 participant load for the upcoming week. The projection should include the number of T3 participants scheduled each day, and may be sent to the Processing Laboratory via email or fax. The PLCO Weekly Projection for Processing Laboratory fax sheet ([Appendix A-10-5](#)) may be used for this purpose. The projection should be sent to the Processing Laboratory by the close of business on the Friday preceding the week the projection details.

### 10.10.2 Tasks to be Completed the Day of Processing Laboratory Shipments

The tasks that must be completed for a blood sample shipment to the Processing Laboratory are as follows:

1. Contact Federal Express to arrange a pick-up time.
2. Fax or e-mail the Processing Laboratory the following information:
  - ▶ SC name and number;
  - ▶ Number of samples in shipment;
  - ▶ Number of shipping boxes in shipment; and,
  - ▶ Federal Express airbill number.

The PLCO Shipment Notification fax sheet ([Appendix A-10-5](#)) may be used to fax the information listed above to the Processing Laboratory.

3. Complete the manual Processing Laboratory Transmittal Log ([Appendix A-10-4](#)).
4. Confirm the Processing Laboratory Transmittal Log reflects only yellow-top tubes included in this shipment and make any necessary corrections. Then, make one copy of the log for the SC file. Place the original log in a self-sealing bag.
5. Pack the shipping containers with the yellow-top tubes (as described in [Section 10.10.5](#)) and place the self-sealing bag containing the original Processing Laboratory Transmittal Log on the Tyvek envelope in the fiberboard shipping box. Close the flaps on the fiberboard box and secure the exterior of the fiberboard box with strapping tape. Since these samples are to be shipped at ambient temperature, neither dry ice nor cold packs are to be used.
6. Label the exterior of each shipping container with the appropriate Federal Express and IATA-required warning labels. If Saturday delivery is required, attach a Federal Express "Saturday Delivery" label. Note that unless a "Saturday Delivery" delivery label is used, any packages shipped on Friday will be held for normal Monday delivery.
7. Confirm the Federal Express pick-up.

File the copy of the Processing Laboratory Transmittal Log with a record of the Federal Express airbill number for each package shipped.

### **10.10.3 The Processing Laboratory Transmittal Log**

A Processing Laboratory Transmittal Log ([Appendix A-10-4](#)) must be completed for every shipment of blood samples sent to the Processing Laboratory. This log will be manually maintained and will contain only the information vital to processing the yellow-top tubes. The central SC and/or the satellite centers will complete the Processing Laboratory Transmittal Log.

This log will include the sample ID of each yellow-top tube contained in the shipment. A copy of the Processing Laboratory Transmittal Log and specifications for completing each item on the log are presented in [Appendix A-10-4](#)

In preparation for shipment of samples, the SC staff will perform the following steps:

1. Complete the Processing Laboratory Transmittal Log using the Blood Collection Form as an information source. List all yellow-top tubes (without problems that would prevent shipping) that were drawn that day.

2. Verify that the sample IDs listed on the transmittal log match the sample ID labels on the yellow-top tubes.
3. If a tube cannot be located, has been destroyed, or other problems are identified that will prevent shipping, cross the sample ID off the transmittal log. Make any necessary corrections on the Blood Collection Form including the entry of a problem code and removal of the shipping date. If the Blood Collection Form has been scanned prior to these corrections, rescan the Blood Collection Form and update the SMS.
4. If a yellow-top tube is available for shipment, but is not on the transmittal, investigate to determine why the sample was not listed on the transmittal log. If necessary, add the sample to the transmittal log and update the Blood Collection Form with the new shipment information. If the Blood Collection Form has been scanned prior to these corrections, rescan the Blood Collection Form and update the SMS.
5. Place the yellow-top tubes in the shipping container in the order they are listed on the transmittal log. The capacity of each shipping container will vary and a separate transmittal log should be completed for each shipping container. More than one page of a transmittal log may be required for a single shipment.
6. When the final, corrected transmittal is completed, make one copy of the transmittal for the SC files, and include the original transmittal with the shipment of yellow-top tubes to the Processing Laboratory.

#### **10.10.4 Packaging and Shipping Yellow-top Tubes to the Processing Laboratory**

Each SC should have adequate shipping containers available for making daily shipments of yellow-top tubes at ambient temperature that meet the shipping requirements specified in the current version of the International Air Transport Authority (IATA) Shipping Regulations for Dangerous Goods. Yellow-top tubes should always be shipped at ambient temperature. The following is a list of recommended supplies that can be used for fresh blood shipments:

- SaftPak STP 210 (includes leakproof plastic bag, Tyvek envelope and reusable fiberboard shipping box). Can hold up to six Vacutainer tubes.
- Saftpak STP 250 (includes leakproof plastic bag, Tyvek envelope and reusable fiberboard shipping box). Can hold up to thirty Vacutainer tubes.
- SaftPak STP 151 or 152 Absorbent strips; and
- Plastic self-sealing bags to hold Processing Laboratory Transmittal Form.

Note that while the outer fiberboard boxes included with the STP 210 or STP 250 can be re-used, a new leakproof plastic bag and Tyvek envelope must be used each time. These supplies can be ordered from SaftPak as STP 710 and ATP 730. The leakproof plastic bags and Tyvek envelopes used must be those obtained from SaftPak. Other plastic bags and envelope combinations will not meet the IATA regulations.

Follow the instructions given below to pack yellow-top tubes for shipment to the Processing Laboratory: .

1. Complete the Processing Laboratory Transmittal Log ([Section 10.9.3](#)).

2. Generate box labels and label the Tyvek envelope with a box number.
3. There will be three labels provided for each unique box number. Affix one label to each side of the Tyvek envelope. The third label may be discarded.
4. Record the storage box number on the Blood Collection Form and the Processing Laboratory Transmittal Log.
5. The Vacutainer tubes must be securely wrapped so that they do not break during shipment. The SCs may use bubble wrap, a tube holder or the Polyfoam Packers styrofoam shippers used to transport yellow top tubes prior to 2003. SafTPack sells both tube holders and self-adhesive bubble wrap that can be used for this purpose. Selection of cushioning material used is left to the SC's discretion.

The tubes must be wrapped with sufficient cushioning so that they do not break and in such a manner that the tubes do not touch each other.

6. Place the wrapped tubes in the leakproof plastic bag provided with the SafTPak shipper.
7. Place an absorbent strip, either the STP 151 or 152 depending upon the volume of blood included in the package, in the plastic bag.
8. Seal the plastic bag in accordance with the instructions printed on it.
9. Place the sealed plastic bag into the Tyvek envelope that has been labeled with a box number, and seal the envelope in accordance with the instructions printed on it.
10. Place the sealed Tyvek envelope in the fiberboard shipping box.
11. Seal the Processing Laboratory Transmittal Log in a self-sealing bag and place it on top of the Tyvek envelope.
12. Close the fiberboard shipper and secure the exterior with strapping tape.
13. Store the shipping container (with samples enclosed) at ambient temperature until shipment to the Processing Laboratory.

The Processing Laboratory will recycle the outer portion (the fiberboard box) of the yellow-top tube shipping containers to the appropriate SC. The SC will be responsible for covering the cost of shipping the shipping containers from the Processing Laboratory to the SC. For return of the shipping container, include a mailing address label or a pre-addressed airbill in the bag with the Processing Laboratory Transmittal Log. Ten to fourteen days should be allowed for return of the shippers. The Processing Laboratory will not return shipping containers that they consider to be too "damaged" or too "worn" to ensure safe transport of PLCO samples.

### **10.10.5 Labeling Shipping Containers for Yellow-top Tubes**

As mentioned previously, all blood samples will be shipped to the Processing Laboratory via Federal Express (Any express mail service may be used provided that overnight next morning delivery service is available and guaranteed) overnight priority 1 delivery. All packages containing yellow-top tubes must be labeled as described in this section. Federal Express will supply airbills, plastic pouches for airbills, and if needed, multiple package service labels. Each SC will have the capability on the SMS to generate address labels and mailing labels for specimen shipments. The procedures given below meet Fed-

eral regulations, IATA regulations, and Federal Express requirements for the labeling of biologic diagnostic specimens for shipment.

- Complete the Federal Express airbill, including: the date; the sender's name, telephone number, and address; and the recipient's name, telephone number, and address. Under express package service, mark the box for "Priority Overnight" delivery. Designate the type of packaging by marking the "Other Packaging" box. Under special handling mark the box for "No" in response to "Does this shipment contain dangerous goods?" Complete the payment information section.
- Place the airbill in its self-stick plastic pouch, and attach the pouch to the top of the fiberboard box.
- The following language must appear on the fiberboard box:

"Diagnostic Specimens

Packed in compliance with IATA Packing Instruction 650"

This language may be hand-written, or printed on labels which are then affixed to the fiberboard box. Note that pre-printed labels are preferred. IATA regulations specify that the exact language and punctuation listed above must be used.

- Attach a label with the SC name and address to the fiberboard box. (This is in addition to recording the information on the airbill.)
- Attach a Processing Laboratory address label to the fiberboard box. The specimen shipment address for the Processing Laboratory is given below:

Bill Kopp  
SAIC-Frederick  
Building 1050  
Boyles Street  
Frederick, MD 21702  
Telephone: 301-846-1491  
FAX: 301-846-6022  
Email: wkopp@mail.ncifcrf.gov

- If it is anticipated that the shipment will require Saturday delivery to the Processing Laboratory, affix a Federal Express Saturday Delivery label next to the Federal Express airbill. The Saturday delivery box must also be marked on the airbill. Packages shipped on Fridays without the Saturday delivery box checked on the airbill and without the Saturday delivery label will not be delivered until Monday.
- It is important that all labels are securely attached to the fiberboard box and that the labels do not overlap.

## 10.11 Resolving Problems with Shipments

If a shipment is not received at UCLA, the Biorepository, or the Processing Laboratory at the scheduled time, the respective laboratory will notify the SC immediately. The SC will be responsible for initiating tracking procedures. Each SC should keep a record of all Federal Express airbill numbers and certified tracking numbers.

Upon receipt of blood specimens, UCLA, the Biorepository, and the Processing Laboratory will reconcile the sample ID numbers listed on the Blood Sample Transmittal Log against samples actually received, and will notify the SC of any discrepancies. UCLA, the Biorepository, and the Processing Laboratory will also notify the SC of any other problems with the shipment such as broken vials or tubes, thawed samples (frozen shipments), or missing labels.

There are several types of discrepancies that can occur between the specimens that the lab received and the transmittal the SC sent to the lab:

1. A specimen that is in the shipment is not on the transmittal file (or log).
2. A specimen that is on the transmittal file (or log) is not in the shipment.
3. The box number on the transmittal does not match the number on the box that the lab received.
4. A PSA vial was shipped in a CA-125II box or a CA-125II vial was shipped in a PSA box (UCLA only).

### 10.11.1 Discrepancies in UCLA Shipments

When discrepancies occur in shipments to UCLA, UCLA personnel will fax the SC (and the CC) a "PLCO Discrepancy Notification" memo ([Appendix A-10-2](#)). The SC should investigate the error, make any necessary corrections in the SMS and DEES, and regenerate the transmittal file. ***The SC should not generate a new transmittal that only contains the corrected vial information. A complete, corrected transmittal must be generated for all vials in the storage box.*** The SC should then fax the hardcopy corrected transmittal to UCLA. It is not necessary for the SC to send UCLA a diskette with the corrected transmittal file. If the SC is not able to correct the error reported by UCLA, the SC should contact the UCLA lab supervisor for PLCO (Jean Reiss) and the CC to assist in the resolution of the error.

### 10.11.2 Discrepancies in Biorepository Shipments

When discrepancies occur in shipments to the Biorepository, Biorepository personnel will fax the SC a copy of the discrepancy report generated from the Biorepository Receipt System (BRS) with a cover memorandum (see example in [Appendix A-10-3](#)). The SC should investigate the error, make any necessary corrections in the SMS and DEES, and regenerate the transmittal file. The SC should *not* generate a new transmittal that only contains the corrected vial information. A complete, corrected transmittal must be generated for all vials in the storage box. The SC should then fax the corrected hardcopy transmittal to the Biorepository. The memo from the Biorepository will indicate whether or not the regenerated transmittal file should also be sent. If the SC is not able to correct the error reported by the Biorepository, the SC should contact the Biorepository contact person (Irma Flores) for PLCO and the CC to assist in the resolution of the error.

### 10.11.3 Discrepancies in Processing Laboratory Shipments

When discrepancies occur in shipments to the Processing Laboratory, Processing Laboratory personnel will fax the SC (and the CC) a "PLCO Discrepancy Notification" memo ([Appendix A-10-6](#)). The SC should investigate the error, make any necessary corrections in the SMS and DEES, and provide written clarification for resolution of the discrepancy to the Processing Laboratory (and the CC). If the SC is not able to correct the error reported by the Processing

Laboratory, the SC should contact the Processing Laboratory contact person for PLCO (Craig Smith) and the CC to assist in the resolution of the error.

## 10.12 Reporting Medical Complications of the Blood Draw Procedure

Medical complications of the blood draw procedure that occur while the participant is at the SC will be documented on the Blood Collection Form. Medical complications that occur prior to the participant's arrival at or after his/her departure from the SC will be documented on the Adverse Experience Report (AER), (see [Chapter 17.0](#)). The CC will provide information on medical complications to the NCI for monitoring purposes. The SC must also monitor medical complications so that appropriate action can be taken should any problems become apparent.

## 10.13 Documenting Non-Response for Blood Collection

There are a number of situations in which the SC will need to document non-response for the blood collection activity. In some cases, a participant may refuse to have his/her blood drawn. In other cases, the participant may be willing to participate in the blood collection, but blood cannot be obtained. As stated in [Section 10.5](#), one attempt from each arm should be made to obtain the PSA/CA-125II blood sample. If blood cannot be obtained from one arm and the participant is willing, an attempt should be made on the other arm. If attempts from both arms are unsuccessful, the participant should be scheduled for a repeat visit for the blood exam.

The following guidelines describe when to complete the blood collection form, when to assign a Sample ID number, and when to complete a Missing Data Form for cases in which blood is not collected:

1. If the participant is willing to participate in the blood exam, is stuck with a needle but a blood sample is *not* obtained, then a Sample ID is *not* assigned but the blood collection form is completed.
2. If the participant is willing to participate in the blood exam but is *not* stuck with a needle and, therefore, a blood sample is *not* obtained, then a Sample ID is *not* assigned, the blood collection form is *not* completed, and a Missing Data Form is completed instead. (Refer to [Chapter 17.0](#) for information on completion of the Missing Data Form.)
3. If the participant is *not* willing to participate in the blood exam, then a Sample ID is *not* assigned, the blood collection form is *not* completed, and a Missing Data Form is completed instead.

## 10.14 Editing and Data Entry

After the blood collection form is completed, the SC Coordinator will manually edit the form to make sure that all of the required data were collected. The blood collection form and the Participant Control Record will be receipted into the SMS and blood collection form will be scanned into the DEES. Form receipt may be performed through interactive data entry or via the DEES to SMS Update function. (See [Chapter 17.0](#)) It is recommended that the blood collection form be scanned in DEES, edited and then receipted via the DEES to SMS

Update as this method will reduce or eliminate errors on the blood sample transmittals.

The participant's signed ESC should be receipted prior to scanning or receipting a blood collection form. If a participant has not signed an ESC, the "No Biorepository Samples Expected" bubble must be marked on the blood collection form.

## **10.15 Resolving Blood Collection Form Discrepancies Between DEES and SMS**

Screening Centers should run the DEES-SMS Comparison Report periodically to identify and resolve any blood data discrepancies. Screening centers can help to prevent discrepancies by scanning, editing, and finalizing the blood data form and using Update SMS to transfer the data to the SMS. If possible, avoiding directly keying data into the SMS.

Once blood vials have been shipped, the system will not allow the SC to modify certain blood data fields in SMS. Note that if the ship date has been set in SMS, but the vials have not been physically shipped, the SC may remove the ship date, correct the discrepancies, and then reset the ship date. However, if the vials have been shipped and/or if the UCLA results associated with the blood form in question have been receipted into the SMS, then the SC will be unable to correct any data without assistance from the Coordinating Center.

If the SC requires assistance to resolve a blood data discrepancy they should contact either Karen Turk or User Support.

## **10.16 Interpreting Results of the PSA and CA-125II**

The following definitions of normal and abnormal findings are provided. These definitions will be used by the SC staff in entering the findings in the SMS.

### PSA Results

- Normal: less than or equal to 4.00 ng/ml
- Abnormal: greater than 4.00 ng/ml

### CA-125II Results<sup>1</sup>

- Normal: less than or equal to 34 units/ml
- Abnormal: 35 units/ml or greater

Normal and abnormal findings will be reported to the participant and his/her physician of choice. The SC will also report the name of the laboratory that performed the assay, the date the assay was performed, the brand name of the assay, and the normal limits for the assay.

A participant with abnormal findings will be told to consult with his or her own physician for evaluation of any symptoms and for routine medical care. Each SC will institute procedures for referring participants to appropriate physicians (see Chapters 6 and 7).

---

1. Prior to October 1, 1995, the CA-125 assay was in use and per UCLA, the normal range was 0-35 units/ml. Beginning October 1, 1995, the CA-125II assay was initiated and per UCLA the normal range is 0-34 units/ml.

## 10.17 Reporting Results

The UCLA Tissue Typing Laboratory will report assay results directly to the SC within seven calendar days of blood specimen receipt. Receipt of assay results may be as much as fourteen days from time of blood sample collection. UCLA will electronically transmit the assay results to the SC. One report form will be generated for each participant sample ID. When a test sample result is out-of-limits and must be repeated, UCLA will provide the SC with an average of both test sample results. A copy of the UCLA report forms for the CA-125II assay results and the PSA assay result are presented in [Appendix B-10-3](#)

UCLA will be responsible for transmitting assay result data in batches to the CC on a regular basis. Assay result data will be transmitted electronically. The CC will run quality control edit programs comparing the assay result data from UCLA and from the SCs, and if discrepancies exist, will contact UCLA or the SC, when appropriate, for data resolution.

To help the SC monitor UCLA assay results and discrepancies, the SMS will produce the following laboratory receipt and discrepancy reports. (See [Appendix B-10-3](#) for samples of these reports.)

- **All Original CA-125II/PSA Records Received from UCLA.** This report is generated for all samples that are contained in a specific UCLA file.
- **Errors on CA-125II/PSA Analysis File Results returned from UCLA with no corresponding vial or blood collection form record or with Blank Shipdate.** This report is generated if a UCLA result record is returned and there is no corresponding vial blood collection form record in the SMS, or a matching record exists in the SMS but the UCLA shipdate is blank.
- **Errors on CA-125II/PSA Analysis File Rejected:** blood collection form results already set. \*\*\*Contact Westat and Fax this report to User Support.\*\*\* This report is generated if the current SMS blood collection form's UCLA result is already AS, NG or IN for any of the Sample IDs on the UCLA records.
- **Rejected: Analysis Date is Blank.** This report is generated if the record from UCLA contains a blank analysis date.
- **Error: Problem plus Result – Notify Westat.** This report is generated if the UCLA Analysis record contains a CA-125II or PSA result but there is also a problem code (indicating a lost or damaged vial) present. The update for this Sample ID is rejected.
- **Unexpected Problem Code – Notify Westat.** This report is generated if the UCLA Analysis record contains an unexpected problem code. The update for this Sample ID is rejected.
- **Damaged Vials: Exam Result will be IN.** This report is generated if a UCLA vial was damaged, lost or destroyed after the vial was shipped from the Screening Center. The UCLA analysis record will contain a problem code indicating the type of problem incurred and the SMS will translate the code appropriately and update the blood collection form UCLA result to IN. This report will be used for the SC's information only and to assist the SC in contacting participants as necessary. The SC does not need to contact the Coordinating Center.

- **Errors on CA-125II/PSA Analysis File Results returned from UCLA with no corresponding PCR records.** This report is generated if a UCLA result is returned and there is no corresponding PCR record for the associated blood collection form and Sample ID.

To investigate a discrepancy reported on one of the above reports, the following steps should be taken:

1. Review SMS and DEES data and the original data collection forms (the appropriate blood collection form and the Participant Control Record) to identify any errors. If any errors are found, they should be corrected.
2. Document in a memo to the CC (to the Westat Coordinator and Westat User Support) the errors identified and the steps taken to correct them. A copy of the associated report or reports should be attached to the memo.
3. If upon investigating the SMS, DEES and the original forms, no errors can be identified, this information should also be included in a memo to the CC (to the Westat Coordinator and Westat User Support). A copy of the associated report or reports should be attached to the memo.
4. Upon receipt of the memo, Westat will contact UCLA to investigate and resolve any outstanding errors.

In cases where a specimen is lost or destroyed after the specimen has been shipped but prior to UCLA providing a result of the PSA/CA-125II, UCLA will download a special problem indicator with the other assay results. This indicator will cause the UCLA result for the blood collection form in the SMS to be changed to "inadequate." The blood collection form data should not be altered on hard copy, and the SC staff should not make any changes to the blood collection form data in the SMS or DEES. The information on the blood collection form should reflect the result of the blood draw, not the result of the analysis. The SC should contact the participant and give him/her the option of having an additional blood draw for PSA or CA-125II analysis. If the participant agrees to return for the blood draw, he/she must return to the SC by the end of his/her delinquency period. If Biorepository blood was successfully collected on the participant's previous visit for the current study year, collect only the PSA/CA-125II red-top SST tube. If Biorepository blood was not collected on the participant's previous visit for the current study year, both the PSA/CA-125II red-top SST tube and the Biorepository blood may be collected if the participant has signed an ESC. The SC should not use Biorepository blood to replace UCLA samples unless directed to do so by NCI. The SC will document the events related to both the lost or destroyed specimens and the outcome of contacting the participants and store this documentation in the participant's file.

## 10.18 Violations of the Blood Collection Protocol

If the SC violates the blood collection protocol in some way, a SC Report of Protocol Violation Form should be completed and sent to the Coordinating Center. (See [Chapter 17.0](#) for more information on Protocol Violations.) The following situations require submission of a protocol violation form:

- **Blood was drawn on a control participant.** If the participant is a control who was inadvertently screened, the blood should not be sent to the Biorepository or to UCLA. The SC will not be able to receipt a blood collection form for a control and therefore should not be able to

generate a transmittal to ship bloods. However, if in a rare situation, blood drawn from a control is shipped to the Biorepository, notification must go in writing to the Specimen Data Coordinator at the CC with copies to the CC Coordinator.

If blood drawn from a control is shipped to UCLA, the SC should send a notification letter to the CC Coordinator and User Support, with a copy to NCI. Upon receipt of this letter, the CC will write a memo to UCLA and request that the results of the CA-125II or the PSA be deleted from the UCLA data files.

The notification letter for both Biorepository and UCLA shipments must include:

- ▶ Participant ID;
  - ▶ Sample IDs and sequence number for each vial;
  - ▶ Date of Blood Draw; and
  - ▶ Ship Date.
- **PSA/CA 125-II red-top SST tube was drawn on a participant with a confirmed prostate or ovarian cancer or with a total prostatectomy or bilateral oophorectomy.** In these situations where blood was drawn in error, the PSA/CA-125II blood should be discarded, or if the participant so requests, it may be analyzed for PSA or CA-125II by an SC designated laboratory (cost to be incurred by the SC.) The decision of whether or not to analyze the blood and report the results of the blood test to the participant and/or to his or her physician is left to the SC.

If the blood has already been shipped to UCLA before the error is discovered, the SC must still notify the Coordinating Center in writing by the submission of a completed protocol violation. Note that the UCLA results incurred as a result of the inappropriate screen will not be removed from either the UCLA database or the SMS.

- **Biorepository blood was drawn on a participant without a signed ESC.** Biorepository blood samples should not be collected without a signed ESC.
- However, if this occurs, the data collection form should be receipted and Biorepository and Processing Laboratory samples should be shipped to the appropriate destination. The SC should not discard Biorepository or Processing Laboratory samples drawn without an ESC. The SMS is programmed to include an error message on the Interform Edits report so that the SC will be notified to obtain the appropriate consent (subsequent to the collection) and to complete a Protocol Violation form. If the consent is signed at a later date, this is still considered a protocol violation, since the blood was collected without a signed ESC. If the SC is unable to obtain the participant's consent, his/her specimens will be flagged at the Biorepository so that they can not be used for research involving genetic studies. An ESC data file will be matched to the PLCO specimen inventory at the Biorepository. Only matches, indicating a consent was obtained, will release a sample for research involving genetic studies. Any samples collected prior to the 4.1 systems upgrade date will be automatically flagged at the Biorepository. This flag will be removed once an ESC has been receipted.

- **Blood Drawn According To The Wrong Study Year Protocol.** If blood is drawn in accordance with the wrong study year protocol (e.g., a T3 participant receives a T2 draw), the UCLA blood should be shipped as usual. However, the Screening Center should not ship the Biorepository or Processing Laboratory samples that were drawn in error, and should destroy these specimens on site. Because the Processing Laboratory samples are shipped daily, a wrong protocol draw error is sometimes not discovered until after the yellow-top tubes have been shipped. If the Processing Laboratory samples are shipped before the wrong protocol draw is identified, notify the Processing Laboratory and the Coordinating Center so that corrective action can be taken.
  - ▶ Section C “No Biorepository Tubes Drawn” should be bubbled
  - ▶ Section C “Result of Blood Draw and Processing for Biorepository” = Inadequate
  - ▶ Section C “Reason for Partial or Inadequate” = Other Specify (wrong protocol draw)
  - ▶ Section C “Comments” = Yes. Provide a brief description of problem. (“T3 participant received T4 blood draw.”)

If the Screening Center discovers that a wrong protocol draw occurred after the Biorepository samples have been shipped, they should contact the Coordinating Center for assistance.

Note that these are only general instructions for wrong protocol draws and the Screening Center should contact the Coordinating Center for guidance if necessary for specific situations.

- **PSA/CA 125II red-top SST tube was drawn on a participant without a signed main study consent.** In these situations where blood was drawn in error, the PSA/CA-125II blood should be discarded.

## 10.19 Training Requirements for PLCO Shipments

Both the PLCO blood samples and the dry ice used to ship them are classified as dangerous goods by the International Air Transport Authority (IATA) Regulations for Shipping Dangerous Goods. These regulations require that individuals who ship dangerous goods must receive appropriate training to be IATA-certified to ship dangerous goods, including dry ice. Note that Federal Express requires compliance with IATA regulations for packing and labeling shipments of dangerous goods. Although the specific procedures detailed below for packing, labeling and shipping PLCO specimens meet the IATA regulations, they are not a substitute for IATA training. Screening Centers are required to be in compliance with these regulations. Screening Centers may contact the Coordinating Center if they need additional information on obtaining the required training.

## 10.20 Examiner Training

The blood collection procedure requires a trained examiner for the phlebotomy procedure (phlebotomist) and for the laboratory processing procedure (laboratory technologist). These procedures may be performed by one examiner or by two different examiners.

### **10.20.1 Minimum Qualifications for Examiners**

Phlebotomists will have documented experience in blood draw techniques. Individuals with an RN, nurse practitioner degree, or certification as a medical laboratory technician or medical technologist are assumed to have previous experience in phlebotomy, however they will be asked to verify this experience.

The laboratory technologist performing the laboratory processing of the blood samples must be certified by ASCP or NCA as a medical laboratory technician or medical technologist. Individuals with an RN or nurse practitioner degree who have prior experience in laboratory processing, particularly blood aliquoting, in a research environment will also be acceptable.

The SC must report the qualifications and licensure of each examiner by submitting to the NCI a completed Record of Experience, Credentials and Training (ECT) ([Appendix A-17-5](#)) with copies of relevant diplomas, certificates, and/or licenses. For any examiner who does not meet the PLCO qualifications listed above, the SC Principal Investigator must document and certify adequate training and experience. This information must be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of data collection activities.

### **10.20.2 Examiner Training Protocol**

Whenever a new blood collection protocol requiring centralized training is implemented, the SCs will be asked to send a qualified individual (phlebotomist, laboratory technician, or a nurse with laboratory experience) to a training session for blood drawing and processing. Ideally, the individual sent should be someone who is in a supervisory position and who will then train the examiner(s) on the blood collection and processing procedures.

### **10.20.3 Examiner Certification**

No additional certification will be necessary for the blood collection and processing procedures. Documentation of qualifications on the ECT form will suffice as documentation of certification.

## **10.21 Equipment Specifications**

The equipment required for the blood protocol includes a centrifuge with a swing out angle rotor and a -70°C freezer. The SC may opt to use a -20°C freezer for the storage of PSA/CA-125II specimens *only*. All equipment must meet FDA guidelines and institution and state licensure regulations.

Each SC must send equipment specification documentation to the NCI and the Coordinating Center. This should be done before data collection begins, and whenever equipment is replaced during the course of the trial.

## **10.22 Freezer Security**

Screening Centers will adhere to the following requirements to maintain security for biospecimen freezers:

- The temperature of each freezer used for PLCO specimens should be manually recorded in a freezer log each day.

- The freezer temperature should be recorded automatically by the freezer.
- Each freezer should have reliable back-up emergency power that can maintain the freezer temperature in case of a power outage.
- Each freezer should have an audible alarm system. The alarm system should have back-up power so that the alarm will sound in case of a power failure or freezer malfunction.
- The SC should develop written response plans to enact in case of a power outage, freezer malfunction or some other situation that would disable the primary freezer and require moving the samples to another freezer location. The SC should identify back-up emergency storage space where specimens can be stored for both the short-term and long term if the primary freezer becomes disabled. The response plan should specify where and how the samples will be moved and who will be available (during and after working hours) to supervise the transfer.
- Staff should be available 24 hours a day to respond to an alarm from any freezer at the Screening Center, including satellite centers. This may be accomplished by housing the freezer in an area in which staff are available at all times, such as laboratory within a hospital, or by installing an alarm system which is capable of calling one or more telephone or pager numbers to report a change in temperature.
- The SC should have maintenance service available for all freezers.

### **10.23 Specimen Collection Standardization and Quality Assurance**

It is the responsibility of the SC to develop a quality assurance plan for blood specimen collection, processing and storage. The SC's QA plan must be submitted to NCI for review prior to the initiation of screening and should be updated annually as necessary. The quality assurance plan should include the minimum qualifications of the phlebotomists, blood processors and shipping personnel, certification of completed training of examiners, quality control of the equipment and supplies and the SC's approach to monitoring phlebotomist, processor and shipping personnel performance. Quality assurance of the equipment will be guaranteed by each institution's compliance with a maintenance program as dictated by state and Federal regulations. Each SC laboratory must follow OSHA regulations for employee safety.

To facilitate the QA process so that minimum quality standards can be monitored and maintained for the blood specimen collection and processing, each phlebotomist must document the following information on the blood collection form: the time of the blood draw, the position of the participant, the number of tubes drawn, problems with the blood draw and any medical complications associated with the blood draw. In addition, the blood processor must document the blood processing procedures, including the time the sample was centrifuged, the vials filled, problems with the vial sample, the storage box number, and the time the sample was frozen.

As part of the quality assurance plan, the SC will monitor the number of successful, adequate, and repeat blood draws for the examiner performing blood draws. A successful draw is one where all tubes required to be drawn according to the study year protocol are filled to capacity. Note that the green-top

tube collected at T0 (baseline) and T3 for the Biorepository must be filled at to least fifty percent of capacity to allow effective mixing of the anticoagulant and be considered a successful draw. An adequate blood draw is one where only the PSA/CA-125II tube is filled. A repeat blood draw is a rescheduled draw that is done because the previous blood draw for the PSA/CA-125II tube was inadequate. The SC will report the results of quality assurance to the NCI on a semi-annual basis, and the report will include the number of adequate, successful, and repeated blood draws.

Upon receipt of the aliquoted specimens, UCLA, the Biorepository and the Processing Laboratory will check the condition and quality of the specimens. They will report any problems to the SC. The SC will document the problems and the resolutions and will include a log in their semi-annual report to NCI.

## **10.24 UCLA Laboratory Quality Control**

UCLA Laboratory will maintain strict quality control procedures for the PSA and CA-125II assays performed. The PSA and CA-125II assays will only be performed by licensed technologists who have satisfied the training requirements established by the Laboratory Supervisor and have demonstrated competence in performing these tests. Assay procedures will be performed as specified by the manufacturer. Quality control data for assay runs will be stored in the computer and control statistics may be generated monthly or as needed.

Each test run will include both a reagent kit control and a Bio-Rad tumor marker bi-level control, which are commercially prepared specifically for use in tumor marker testing. Also, to ensure accurate laboratory results, UCLA will retest a sample when a test result exceeds the normal range specified for the specific assay. The normal range for PSA is 0.00 to 4.00 ng/ml, and for CA-125II, 0 to 34 units/ml.

# 11.0 CHEST X-RAY PROCEDURES

## 11.1 Overview

A chest X-ray (one postero-anterior view) will be taken for each participant in the intervention arm at the T0-T2 screening visits. At the T3 visit, only participants classified as "smokers" will receive the X-ray screening examination. Screening Centers (SCs) are responsible for scheduling the participant for the X-ray, taking the X-ray, having the X-ray read and interpreted by a radiologist and documenting the performance and results of the X-ray. This chapter describes these procedures. It also provides the PLCO protocol for examiner training and certification and quality assurance procedures for this examination.

Smoking status is assigned based on responses to the Baseline Questionnaire (BQF/M) and is defined as Smoker, Non Smoker, or Unknown. The Participant Status Screen displays a smoking status that is derived from the Baseline Questionnaire for each participant. In addition, it also has an extra field where the SC can modify the smoking status, if necessary. For example, if the smoking status is "nonsmoker" but the participant insists that s/he is a smoker, the SC should change the smoking status on the Participant Status Screen, perform the T3 X-ray and receipt the exam. If the smoking status is unknown, the SC may either determine the smoking status or offer the participant the X-ray without ascertaining the smoking status. If the SC decides to determine the smoking status this should be done by asking the participant these questions from the Baseline Questionnaire: #10 (ever smoked cigarettes regularly), #16 (ever smoked a pipe), and #17 (ever smoked cigars). If the answer is yes to *any* of these, the participant should be classified as a smoker.

## 11.2 Scheduling Chest X-rays

The chest X-ray will be scheduled as part of the baseline or annual follow-up visit for each participant in the intervention arm of the trial. Procedures for scheduling screening visits are discussed in [Chapter 6.0](#) (baseline visit) and [Chapter 7.0](#) (annual follow-up visits).

If a participant has had a lung either partially or completely removed, and the removal was not a follow-up to lung cancer, the chest X-ray will be performed in all study years.

If a participant's responses on the Baseline Questionnaire classify him or her as a "never smoker" i.e., smoking status is equal to "non-smoker," the T3 X-ray will not be performed. If the smoking status has been changed, the modified smoking status will take precedence and this will be displayed on the Participant Overview Report.

If a "non-smoker" maintains that s/he has never smoked, but insists on having the T3 X-ray the SC should follow these steps:

- Perform the exam
- Do not receipt the exam in the system
- Report the results to the participant and his/her physician
- Keep the hardcopy exam forms in the participant's file with a note (initialed and dated) documenting the situation.

Smoking information on the Baseline Questionnaire is of particular importance, because the performance of the T3 XRY is dependent on the smoking status reported on the BQ. If a participant reports that s/he is a smoker on the BQ, an XRY will be performed at the T3 examination, regardless of the smoking status reported in data collection that is subsequent to the BQ. This examination is not to be performed on participants who report being non-smokers (i.e. have never smoked) on the BQ.

The timing and direction of a change in smoking status will determine whether BQ data can be changed and whether the T3 XRY will be performed. If it is discovered in the T0 year that a participant incorrectly reported his/her smoking status on the BQ, the BQ data can be changed. If the newly reported smoking status is "smoker", the T3 XRY should be performed. If the newly reported smoking status is "nonsmoker", the T3 XRY should not be performed. If such an error is discovered after the T0 year, the BQ data should not be changed. The participants smoking status should only be changed on the participants status screen if the participant reported on the BQ that s/he was a non-smoker and now reports that s/he is a smoker. Do not update the participant smoking status if the participant was originally reported being a smoker and now states s/he is a non-smoker. The T3 XRY should be performed regardless of the direction of the change in smoking status, effectively treating newly-reported nonsmokers as ex-smokers, and newly-reported smokers as longtime smokers – both being groups that should receive a chest XRY.

The SC staff will be responsible for determining when the chest X-ray is done during the screening visit. There are no protocol restrictions in regard to order for this procedure.

The PLCO protocol requires that every attempt be made to reschedule the examination if it is inadequate or cannot be done for some reason. It is anticipated that such problems should be minimal for the X-ray examination. If the X-ray technologist determines that the quality of the film is inadequate, it is expected that every attempt will be made to repeat the X-ray during the same visit. However, if the interpreting radiologist finds the X-ray to be inadequate, the participant should be asked to return for a repeat examination.

## **11.3 Chest X-ray Protocol**

This section presents the PLCO protocol for the chest X-ray. It discusses equipment, participant preparation, examination procedures and interpretation of results. This protocol was developed and approved by the NCI and the PLCO Steering Committee. In addition, experts in the field of radiology were consulted. Each SC is required to follow the protocol. Situations in which the SC cannot do so must be reported to the NCI. The Protocol for Chest X-Ray Examination is presented as [Appendix J-11-1](#)

### **11.3.1 Equipment Specifications**

The chest X-ray will be taken using dedicated high-kV equipment (approximately 110-140 kV). Film will be wide latitude type with a 12 to 1 standard grid or higher. The SC is required to send documentation of equipment specifications, including information on film type (e.g., symmetric or asymmetric film screen combination, etc.) to the NCI. This should be done before data collection begins and whenever equipment is replaced during the course of the trial.

### **11.3.2 Participant Preparation**

Several steps in the process of participant preparation will be standardized across all SCs. The participant will be told that the examination is a screening examination for lung cancer, not a routine examination, and that s/he should consult his/her own physician for evaluation of any symptoms and for routine medical care. In addition, the participant will be told that s/he will receive written documentation of the results of all screening examinations within approximately three weeks. If the SC plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.

### **11.3.3 Examination Procedures**

A postero-anterior X-ray will be taken at a tube-to-film distance of 6 to 10 feet. The participant will wear a hospital gown. The technologist will explain the procedure and position the participant. The participant will be instructed to inhale deeply and to hold his/her breath while the X-ray is being taken.

Note: If a participant has a condition such as severe kyphosis and cannot assume the correct position for a PA view of the lung, it is acceptable to do an AP view of the lung. The fact that an AP film was taken and the reason for it must be recorded in the Comments section of the data collection form.

The technologist will initially evaluate the X-ray for quality before the participant has left the SC. The quality will be such that the lung vessels are clearly visible and the mediastinal structures are sufficiently penetrated to allow for adequate visualization. If the X-ray is determined to be inadequate it will be repeated. Reasons for inadequacy may include participant refusal, poor film quality, or equipment malfunction. Poor film quality may be due to:

- Excessive rotation;
- Inadequate inspiration;
- Motion or processing artifact;
- Over or under penetration; and
- Entire lung and mediastinal structures not included on the film.

The SCs will do their best to ensure that when a repeat X-ray is necessary, it is taken during the same visit. No more than two X-ray attempts will be made in one visit. Note: If an X-ray is initially determined to be adequate but upon quality assurance review it is found to be inadequate, a second X-ray should not be performed.

X-rays determined by the technologist to be adequate will be sent to the study radiologist for interpretation. The radiologist may, at this point, determine the X-ray examination to be inadequate due to poor film quality, because the X-ray film has been lost, or for some other reason. In such cases, the participant will be asked to return for a repeat examination. If the X-ray is judged to be adequate, it should be read by the study radiologist in a timely manner such that the results can be reported to the participant within approximately three weeks of the visit, as dictated by the protocol.

### 11.3.4 Interpretation of Findings

The examination result should be an interpretation of the examination findings only. The participant's prior medical history, prior chest X-rays, or prior PLCO examination findings should not be considered when assigning an examination result. The following definitions of negative and abnormal findings are provided. These definitions will be used by the radiologist in recording his/her findings on the **Chest X-ray Screening Examination Form**.

- **Negative Screen, No Abnormalities (formerly Negative):**

Evaluation reveals midline structure and heart to be of normal size and not displaced or enlarged. Pulmonary parenchyma reveals no suspicious abnormality for cancer.

- **Positive Screen (formerly Abnormal, Suspicious for Lung Cancer):**

Evaluation reveals any of the following pulmonary abnormalities:

- ▶ nodule (circular opacity  $\leq$  3.0 cm in diameter);
- ▶ mass (any discrete opacity  $>$  3.0 cm in diameter without regard to contour, homogeneity, or border characteristics);
- ▶ hilar or mediastinal lymph node enlargement (exclude calcified nodes);
- ▶ major atelectasis/lobar collapse;
- ▶ infiltrate/consolidation/alveolar opacity; or
- ▶ pleural mass.

- **Negative Screen, Other Abnormalities (formerly Abnormal, Not Suspicious for Lung Cancer):**

Evaluation reveals any of the following pulmonary abnormalities:

- ▶ pneumonia
- ▶ marked cardiac enlargement
- ▶ pulmonary edema
- ▶ congestive heart failure (CHF)
- ▶ pericardial effusion
- ▶ pleural effusion
- ▶ valvular heart disease
- ▶ shunt vascularity
- ▶ thoracic aortic aneurysm, dissection

- ▶ pneumothorax
- ▶ pneumomediastinum
- ▶ unexplained foreign body (catheter fragment in heart, etc.)
- ▶ granuloma
- ▶ rib/spine/shoulder girdle metastases
- ▶ plasmacytomas
- ▶ acute fractures
- ▶ hepatomegaly
- ▶ splenomegaly
- ▶ old rib fractures
- ▶ compression fractures of the spine
- ▶ shoulder fractures
- ▶ scoliosis
- ▶ pleural calcification, pleural thickening, plaques
- ▶ previous mastectomies, breast implants
- ▶ COPD, emphysema, bullae
- ▶ old granulomatous disease, parenchymal calcification, calcified nodes
- ▶ pneumoconiosis
- ▶ mild to moderate cardiac enlargement
- ▶ pulmonary vascular congestion
- ▶ interstitial fibrosis, honeycombing, small scars
- ▶ pulmonary fibrosis with hilar retraction,
- ▶ radiation fibrosis
- ▶ previous lung surgery
- ▶ biopsy sites
- ▶ changes related to old trauma, retained shrapnel, etc.
- ▶ previous cardiac surgery (CABG, valve replacements)
- ▶ vascular anomalies (right aortic arch, etc.)
- ▶ vascular calcification
- ▶ bronchiectasis
- ▶ hiatal hernia, gallstones
- ▶ linear or plate atelectasis
- ▶ enlarging tracheal nodule

### **11.3.5 Referral of Participants for Abnormal Results**

Negative and abnormal results will be reported to the participant. Abnormal results that are suspicious for cancer will also result in the participant being referred to a physician of his/her choice. The examiner will determine whether or not a referral is needed for abnormal findings that are not suspicious for

cancer, according to standard practice at the SC. Each SC will institute procedures for referring participants to appropriate physicians (see [Chapter 6.0](#) and [Chapter 7.0](#)).

All screening examinations with a result of “Positive Screen” must be referred for follow-up. Screening examinations with a result of “Negative Screen, Other Abnormalities” should be referred according to standard practice at the SC. The SC may choose to obtain prior radiographs and compare them to the screening chest X-ray before referring the participant externally to reduce the number of referrals to outside physicians for conditions that can be determined to be stable based on a comparison with prior radiographs. Prior radiographs may include radiographs taken prior to the participant’s enrollment in the study, or prior PLCO films. The comparison must be performed by a board-certified radiologist and should not be documented on the PLCO Chest X-Ray Examination Form. Such comparisons are “internal” referrals and are considered part of the diagnostic evaluation process. Refer to Chapters 6 and 7 for a discussion of “internal” referrals.

## 11.4 Documenting Performance and Results of the Chest X-ray

Information documenting that the X-ray was taken and the interpretation by the radiologist will be recorded on the **Chest X-ray Screening Examination Form** ([Appendix A-11-1](#)). The **Participant Control Record** (see [Chapter 6.0](#)) will also be used to summarize information about the examination. Since the radiologist’s reading of the X-ray will usually not occur during the participant’s visit, the exam status recorded on the Participant Control Record at the end of his/her visit will likely be “Result Pending” (RP). This means that the X-ray has been taken but has not yet been read by the radiologist. This status will not be able to be updated to a final status (Positive Screen, Negative Screen-No Abnormalities, Negative Screen, Other Abnormalities, or Inadequate) until the Chest X-ray Screening Examination Form is received back from the radiologist.

In addition to the examination result, the radiologist will assign a level of referral for the exam indicating the severity of the abnormality, if any, and whether or not the SC recommends follow-up for this examination.

### 11.4.1 The Chest X-ray Screening Examination Form

The **Chest X-ray Screening Examination Form** will be used to document the results and findings of the examination. The form provides documentation of the fact that the examination was carried out, whether the results were negative or abnormal and a description of abnormal findings. The information in the administrative section at the top of the first page of the form will be completed by the SC Coordinator. Part A will be completed by the X-ray technologist. If adequate films are obtained, Parts B and C of the form will be completed by the interpreting radiologist. If adequate films are not obtained by the technologist, Part B will be left blank and Part C will be completed by the technologist. Specifications for the Chest X-ray Screening Examination Form are provided in [Appendix A-11-1](#). It is the responsibility of the SC Coordinator to train the technologists and radiologists in the use of the form.

### 11.4.2 Editing and Data Entry

After completion, the examination form will be manually edited by the SC Coordinator. Any data retrieval with the examiner will be performed as expedi-

tiously as possible. The form will be receipted into the SMS and scanned into DEES. SMS receipt may be performed interactively or via the DEES to SMS Update function. Editing and data entry procedures are discussed in [Chapter 17.0](#).

### **11.4.3 Reporting Results of the Chest X-ray Examination**

As described in [Chapter 6.0](#) and [Chapter 7.0](#), within three weeks of the screening visit, the SC will send the participant and the participant's physician of choice the results of the chest X-ray examination. This reporting will be accomplished using the Screening Test Results Report (STRR) or the SC's version of the STRR. The SC may, if desired, report the detailed findings from the examination using the Screening Examination Report for the Chest X-Ray Examination ([Appendix B-11-1: Screening Examination Report - Chest X-Ray](#)). This report is generated from DEES and is a decoded or "English" version of the opscan form. The SC may also design its own materials for reporting detailed findings. All such materials must be approved by the NCI prior to implementation at the SC. Refer to Chapters 6 and 7 for a detailed discussion of results reporting activities.

### **11.4.4 Storage of PLCO Images**

The SC is responsible for storing the films for each of the participant's annual chest X-ray screening examinations. Inadequate films should be retained at the SC until adequate films are obtained. Upon collection of an adequate film, inadequate films may be discarded. PLCO films should be stored in a way that is consistent with the confidentiality agreement for the trial. It is not recommended that a participant's films be stored with the participant's medical record or with other films that are not related to the PLCO trial, but if an SC wishes to store PLCO data in the regular medical record, it must submit to NCI documentation of the methods that will be used to maintain confidentiality of the data (see [APPENDIX L](#)).

While images on radiographic film are the usual method of storage, digital images are also acceptable. This method of storage should meet the requirements for 20-year storage with no decrease in image quality, and the image must be retrievable at any time during the 20-year period. If digital images are the chosen method of storage, it is required that a backup file of each image be maintained.

## **11.5 Examiner Qualifications, Training, and Certification**

The chest X-ray examination requires two examiners: the X-ray technologist and the radiologist. The minimum qualifications for these persons and the PLCO training protocol are discussed in this section.

### **11.5.1 Minimum Qualifications for Examiners**

Technicians will be American Registry of Radiologic Technologists certified (ARRT) radiologic technicians. The radiologists (interpreters and QA examiners) will be American Board of Radiology (ABR) board certified or board eligible. The SC must report the qualifications and licensure of each examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) [Appendix A-17-5](#), to the NCI. For any technician who is not ARRT certified or any radiologist/interpreter/QA examiner who is not ABR

board certified or board eligible, the SC Principal Investigator must document and certify adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of data collection activities.

### **11.5.2 Training Protocol**

Because of the qualifications required of the technologist and radiologist, training requirements are minimal. The SC Coordinator will be responsible for training the technologist and the radiologist on the use of the study forms and SC administrative procedures. The training plan must be submitted to the NCI.

## **11.6 Examiner Certification**

No special certification of the technologist or radiologist is required for this examination. The qualifications of these individuals will serve as certification of their technical expertise.

## **11.7 Examination Standardization and Quality Control**

For the chest X-ray, there are several aspects of the procedure that will be part of the quality assurance plan. These include quality control of the equipment, quality control of the X-ray film produced by the technologist, and quality control of the interpretation of the findings by the radiologist.

Quality control of the equipment will be assured by each institution's compliance with a maintenance program as dictated by state licensure regulations. Quality control will generally include sensitometric testing at least three times a week, and yearly documentation of kV calibration within 5 percent, radiation output assessed by use of an anatomic phantom, documentation of film-screen contact, and demonstration that the X-ray spectrum is free of low energy contaminants through use of half-value layer, collimation, dose exposure and function of automatic exposure control. The SC will send the NCI a record of maintenance and quality checks of the X-ray equipment.

Quality control of the X-ray will be maintained through maintenance of the equipment and through the radiologist's reading of each X-ray. The number of X-rays which the radiologist determines to be inadequate and types of problems noted must be carefully monitored. In addition, the number of X-rays which the technologist has to repeat during the same visit should be monitored. Remedial action must be taken if problems resulting from the competency of the technologist are encountered.

Each month, the X-ray results from 9 participants will be reinterpreted by a second designated qualified radiologist (QA examiner). Second radiologists are blinded to the results of the initial interpretation. If circumstances are such that examiners review their own film, a letter should be submitted to NCI explaining this system and justifying the level of blinding. The number of X-rays to be reinterpreted as well as the method for their selection are determined by NCI through consultation with each screening center (see [APPENDIX L](#): PLCO Quality Assurance Plan). If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams. If upon QA review of an "adequate"

exam, the QA examiner determines that it was actually inadequate, the X-ray procedure should not be repeated, that is, a new X-ray should not be obtained.

To assist the QA process, a form is provided on which the second radiologist will record his/her findings. This form is the same as the Chest X-ray Screening Examination Form, except that it is titled **Chest X-ray Screening Examination Form Quality Assurance** ([Appendix A-11-2](#)) and is printed in another color to help distinguish it from the original report form. The SMS allows for the receipt of the quality assurance form, and the data from the quality assurance form is scanned into the DEES.

It should be noted that referral of the participant will be based on the “worst case” result when two radiologists have reviewed the X-ray. The following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner interprets the X-ray as negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

Because reporting to the participant is required within three weeks of the visit, it is important that review by a second radiologist be completed in a timely manner so that reporting can take place within the designated time period.

As outlined in the PLCO Quality Assurance Plan (see [APPENDIX L](#)), it is the responsibility of the SC to develop an SC-specific plan for the performance of duplicate chest X-rays for quality assurance purposes. The plan must be submitted to the NCI for review prior to the initiation of screening. In addition, each SC will report the results of quality assurance of the technologists and radiologists to the NCI on a semi-annual basis. Information to be reported includes the number of X-rays repeated due to poor film quality, the number of X-rays (negative and abnormal) read by a QA radiologist and the level of agreement between the two radiologists.

# 12.0 DIGITAL RECTAL EXAMINATION PROCEDURES

## 12.1 Overview

A digital rectal examination of the prostate (DRE) will be performed on all male participants in the intervention arm at each screening visit (T0-T3). Screening Centers (SCs) are responsible for scheduling the participant for the examination, performing the examination, and documenting the performance and results of the examination. This chapter describes these procedures. It also provides the PLCO protocol for examiner training and certification, and quality assurance procedures for this examination.

## 12.2 Scheduling Digital Rectal Examinations

The DRE will be scheduled as part of the baseline and annual follow-up visit for each male participant in the intervention arm of the trial. Procedures for scheduling screening visits are discussed in [Chapter 6.0](#) (baseline visit) and [Chapter 7.0](#) (annual follow-up visits).

The PLCO protocol requires that the DRE be performed after the blood has been drawn for the PSA test. There are no other protocol restrictions in regard to order for this procedure.

If a participant has had his prostate either partially or completely removed, and the removal was not a follow-up to prostate cancer, the DRE will be performed according to the following guidelines:

- Men with a prostate gland (complete or partial) or who are unsure of whether or not they have a prostate will be offered the DRE in each of the four years of screening.
- Men who report radical prostatectomy after entrance into the study will not be offered the DRE in the current study year (if the exam has not already been performed) or in any subsequent study years.

The status of the participant's prostate will be based on spontaneous self-report only. The SC does not need to ask the participant if his prostate is intact nor obtain written medical record documentation of radical prostatectomy. In the case of a participant who reports radical prostatectomy but requests a DRE, the SC should not perform the exam.

If the SC becomes aware that a man who previously reported radical prostatectomy does have the prostate partially or fully intact, the SC should resume offering the DRE.

The PLCO protocol requires that every attempt be made to reschedule the examination if it is inadequate or cannot be performed for some reason (other than prostate cancer or prostate removal). If possible, the visit should be rescheduled before the end of the participant's activity window.

## 12.3 Digital Rectal Examination Protocol

This section presents the PLCO protocol for the DRE. It discusses participant preparation, examination procedures, interpretation of results, and reporting of medical complications. This protocol was developed and approved by the NCI and the PLCO Steering Committee. Each SC is required to follow the pro-

tolcol. Situations in which the SC does not do so must be reported to the NCI on the SC Report of Protocol Violation form (See [Chapter 17.0](#)). The **Protocol for Digital Rectal Examination of the Prostate** is presented as [Appendix J-12-1](#).

### **12.3.1 Participant Preparation**

Several steps in the process of participant preparation will be standardized across all SCs. The participant will be given written information about the DRE. This written information will be developed and/or provided by the SC. The examiner will describe the complete procedure, including the preferred positioning and the discomfort associated with the examination. The participant will be asked whether he has ever had a prostate examination. The participant will be told that the examination is a screening examination for prostate cancer, not a routine examination, and that he should consult his own physician for evaluation of any symptoms and routine medical care. When appropriate, the participant will also be told that a second examiner may repeat the examination for quality control purposes. Finally, the participant will be told that he will receive written documentation of the results of all screening examinations within approximately three weeks. If the SC plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.

### **12.3.2 Examination Procedures**

The participant will enter the examination room and will remove his clothes from the waist down. The examiner will explain the procedure and will position the participant. The participant may either be bent at the waist over the end of the examination table, in the kneeling knees to chest position, or in the lateral decubitus position with knees pulled up to chest.

The examiner will visualize the anal area and may request the participant to bear down or perform a valsalva maneuver. The examiner will apply a lubricated gloved index finger at the 6 o'clock position to relax the sphincter, and will then introduce it into the anal area to palpate the prostate. The examiner will examine the anterior portion of the rectal vault, i.e. the base, apex, and lateral lobes of the prostate, and the seminal vesicles. The examiner will then remove the gloved examining finger.

If a non-physician examiner requires assistance in performing an adequate examination, a physician consultant will be called to perform the examination. The results of the physician's examination, not the examiner's, will be documented on the screening examination report form.

An examination will be judged inadequate if:

- ▶ the participant is unwilling to allow the examination;
- ▶ the participant is unable to tolerate the discomfort of the examination;
- ▶ the examiner is unable to palpate the prostate due to participant obesity;
- ▶ the examiner is unable to palpate the apex, base and lateral lobes of the prostate, and seminal vesicles, and no abnormality suspicious for cancer is found in the area palpated; or

- ▶ the prostate has been previously removed and no abnormalities are identified.

When appropriate, the SC should make every attempt to reschedule inadequate examinations. However, duplicate exams performed for QA purposes should not be repeated even if they are inadequate.

### 12.3.3 Interpretation of Findings

The examination result should be an interpretation of the examination findings only. The participant's prior medical history or prior PLCO examination findings should not be considered when assigning an examination result.

The following definitions of negative and abnormal results are provided. These definitions will be used by the examiner in recording his/her findings on the examination form.

- Negative Screen - No Abnormalities:
  - ▶ Symmetric, soft, non-nodular prostate.
- Positive Screen (Referral Required):
  - ▶ Nodularity or induration of the prostate gland;
  - ▶ Examiner judges the prostate to be suspicious for cancer, in the absence of nodularity or induration.

**Note:** In the event that that examiner judges the prostate to be suspicious for cancer (i.e., a positive screen) but there is no nodularity or induration, the examiner is required to describe the basis of this judgement in the comments section.

- Negative Screen-Other Abnormalities (Referral Optional):
  - ▶ Enlargement;
  - ▶ Tenderness;
  - ▶ Bogginess with no other abnormal findings;
  - ▶ Asymmetry in a prostate of normal consistency and of normal size or slightly enlarged;
  - ▶ Prostate has been previously removed and abnormalities not indicative of a positive screen are identified.

### 12.3.4 Referral of Participants for Abnormal Results

Negative and abnormal findings will be reported to the participant. Abnormal findings that are suspicious for cancer will also result in the participant being referred to a physician of his choice for follow-up. The examiner will determine whether or not a referral is needed for abnormal findings that are not suspicious for cancer, according to standard practice at the SC. Each SC will institute procedures for referring participants to appropriate physicians (see [Chapter 6.0](#) and [Chapter 7.0](#)).

### 12.3.5 Reporting Medical Complications

Medical complications of the procedure that occur while the participant is at the SC will be documented on the examination form. Serious medical complications that occur prior to the participant's arrival at or after his departure from the SC will be documented on the Report of Adverse Events for NIH-

Sponsored Clinical Trials (RAE) ([Appendix A-17-11](#)). The CC will provide information on medical complications to the NCI for monitoring purposes. The SC must also monitor medical complications so that appropriate action can be taken should any problems become apparent.

## **12.4 Documenting Performance and Results of the Digital Rectal Examination**

The performance and results of the DRE will be reported on the **Digital Rectal Screening Examination of the Prostate Form** ([Appendix A-12-1](#)). The **Participant Control Record** (see [Chapter 6.0](#)) will also be used to summarize information about the examination, including the examination result and the level of referral (i.e., the severity of the abnormality if any, and whether or not the SC recommends follow-up for the examination).

### **12.4.1 The Digital Rectal Screening Examination of the Prostate Form**

The Digital Rectal Screening Examination of the Prostate Form will be used to document the results of the examination. The form provides documentation of the fact that the examination was performed, whether the examination was adequate or inadequate, whether the results were negative or abnormal, and a description of abnormal findings. The administrative section on the top of the first page of the form will be completed by the SC Coordinator. Parts A and B of the form will be completed by the examiner. Specifications for the Digital Rectal Screening Examination of the Prostate Form are provided in [Appendix A-12-1](#). It is the responsibility of the SC Coordinator to train the examiner in the use of the form.

### **12.4.2 Editing and Data Entry**

After the examination form is completed, the SC Coordinator will manually edit it to make sure that all of the required data were collected. Any data retrieval with the examiner will be performed as expeditiously as possible. The examination form and the Participant Control Record will be receipted into the SMS and the examination form will be scanned into the DEES (See [Chapter 17.0](#)).

### **12.4.3 Reporting Results of the Digital Rectal Examination**

As described in [Chapter 6.0](#) and [Chapter 7.0](#), within three weeks of the screening visit, the SC will send the participant and the participant's physician of choice the results of the digital rectal examination. This reporting will be accomplished using the Screening Test Results Report (STRR) or the SC's version of the STRR. The SC may, if desired, report the detailed findings from the examination using the Screening Examination Report for the digital rectal examination ([Appendix B-12-1: Screening Examination Report - Digital Rectal Examination](#)). This report is generated from DEES and is a decoded or "English" version of the opscan form. The SC may also design its own materials for reporting detailed findings. All such materials must be approved by the NCI prior to implementation at the SC. Refer to [Chapter 6.0](#) and [Chapter 7.0](#) for a detailed discussion of results reporting activities.

## **12.5 Examiner Qualifications, Training, and Certification**

The digital rectal examination requires a trained examiner. The minimum qualifications for the examiner and the PLCO training protocol are discussed in this section.

### **12.5.1 Minimum Qualifications for Examiners**

The examiner performing the digital rectal examination of the prostate must be a Registered Nurse, Certified Physician's Assistant, Nurse Practitioner, Physician, or equivalent. Equivalency is to be determined by the SC Principal Investigator and documented in a letter to be submitted with a completed Record of Experience, Credentials and Training (ECT - [Appendix A-17-5](#)) to NCI. The SC must report the qualifications and licensure of each examiner by submitting to the NCI a completed ECT with copies of relevant diplomas, certificates, and/or licenses. The ECT must be approved by the NCI prior to the initiation of data collection activities.

### **12.5.2 Minimum Qualifications for QA Examiners**

The QA examiner will be a licensed physician who is adequately trained and experienced in the DRE or a certified PLCO DRE examiner. For any individual who is not a PLCO DRE examiner or a board certified urologist, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The screening center must report the qualifications of each QA Examiner to the NCI by submitting a completed ECT with copies of the appropriate board certification. The ECT must be approved by the NCI prior to the initiation of QA activities.

### **12.5.3 Minimum Qualifications for Trainers**

A non-physician examiner will be taught the correct examination procedure by a board certified urologist (trainer). The Screening Center will report the qualifications and board certification of each trainer to the NCI by submitting a completed ECT with copies of the appropriate board certificate. For any individual who is not a board certified urologist, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of training.

## **12.6 Examiner Training and Certification**

A non-physician examiner must successfully perform at least 15 of 30 examinations, including 10 examinations with abnormal findings, under the supervision of a trainer (PLCO MOOP, Appendix J, Protocol for Digital Rectal Examination of the Prostate, Item 1.H).

The SC Coordinator will be responsible for training the examiner and the trainer in the use of study forms and SC administrative procedures.

The SC must report the results of examiner training certification to the NCI on the Record of Experience, Credentials and Training (ECT).

## 12.7 Examination Standardization and Quality Control

For minimum quality standards to be maintained for the DRE of the prostate, the examiner must note the texture of each portion of the prostate and must document the palpation of the entire prostate and seminal vesicles, the estimated size of the prostate, the overall consistency of the gland, the number of areas of induration, and the size, location, type, grade and extent of the three largest areas of induration. The procedures for quality control are described below.

Each month, the digital rectal exam of 7 participants will be repeated by the QA examiner or trainer. The number of repeat exams as well as the method for their selection are determined by NCI through consultation with each screening center (see [APPENDIX L](#): PLCO Quality Assurance Plan). If in the process of selecting exams for QA repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

To assist the QA process, a form is provided on which the trainer will record his/her findings. This form is the same as the Digital Rectal Screening Examination of the Prostate Form, except that it is titled **Digital Rectal Screening Examination of the Prostate Quality Assurance** ([Appendix A-12-2](#)), and is printed in a different color to help distinguish it from the original report form. The SMS allows for the receipt of the QA form and the data from the QA form can be scanned into the DEES to facilitate comparison.

If the repeat examination does not have the same findings as the first examination, referral will be made based on the "worst case" abnormal findings, regardless of whether the original examiner or the QA examiner found the abnormal result. The following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the exam negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

Because reporting to the participant is required within three weeks of the visit, it is important that the QA examination be completed in a timely manner so that reporting can take place within the designated time period.

As outlined in the PLCO Quality Assurance Plan (see [APPENDIX L](#)), it is the responsibility of the SC to develop an SC-specific plan for repeat of DRE exams for quality assurance purposes. The plan must be submitted to the NCI for review prior to the initiation of screening. In addition, each SC will report the results of quality assurance of the examiners to the NCI on a semi-annual basis. Information to be reported includes the number of examinations (negative and abnormal) repeated by the QA examiner and the level of agreement between the examiner and the QA examiner.

# 13.0 FLEXIBLE SIGMOIDOSCOPY EXAMINATION PROCEDURES

## 13.1 Overview

A flexible sigmoidoscopy (FSG) examination will be performed on all participants in the intervention arm at the baseline screening visit (T0) and the fifth annual follow-up screening visit (T5). Screening Centers (SCs) are responsible for scheduling the participant for the examination, performing the examination, and documenting the performance and results of the examination. This chapter describes these procedures. It also provides the PLCO protocol for examiner training and certification, and quality assurance procedures for this examination.

## 13.2 Scheduling Flexible Sigmoidoscopy Examinations

The FSG examination will be scheduled as part of the baseline (T0) and the fifth (T5) annual follow-up visit for each participant in the intervention arm of the trial. Procedures for scheduling screening visits are discussed in [Chapter 6.0](#) (baseline visit) and [Chapter 7.0](#) (annual follow-up visits).

If a participant has had his/her colon either partially or completely removed, and the removal was not a follow-up to colon cancer, the FSG will be performed according to the following guidelines:

- If the total colon is removed, the FSG examination should not be performed.
- If a partial colon is remaining, the FSG examination should be performed at T0 and T5.

Prior to December 1998 the FSG exam was offered in the T3 year, not T5. Those participants who had an FSG exam at T3 will not be offered the exam again at T5. Participants who did not receive the T3 FSG for any reason other than organ removed or confirmed colorectal cancer are eligible for the T5 FSG. If the participant, in the T3 study year, insists that s/he receive the T3 FSG exam rather than the T5 FSG exam, since the original consent form stated that participants would receive the second FSG exam at the T3 study year, perform the exam during his T3 screening visit. The SC should inform the participant that if he receives the FSG exam during the T3 screening visit, s/he will not receive the T5 FSG exam.

Due to lower than desired compliance rates, the T5 FSGs should be pursued for one year after the anniversary of the participant's date of randomization. After this period, an MDF should be receipted with the appropriate code and subcode.

If a participant was not screened in his or her T5 study year and requests the T5 FSG during the T6 study year, you may perform the exam. The SC may perform T5 screening exams during the T6 year only for participants who have requested the exam. The T5 FSG exams may be performed up until the end of the T6 year.

For female participants, the PLCO protocol requires that the FSG examination be performed after the transvaginal ultrasound examination. In the rare event that the FSG examination and TVU are performed on different days, the FSG

examination may be performed either before or after the TVU. There are no restrictions for male participants in regard to order for this procedure.

The PLCO protocol requires that every attempt be made to reschedule the examination if it is inadequate or cannot be performed for some reason. If possible, the visit should be rescheduled before the end of the participant's activity window.

### **13.2.1 Scheduling T5 Participants with Identified Adenoma**

Some participants may have an adenoma diagnosed following a positive T0 FSG. Other participants may have had an adenoma diagnosed by their personal physician in the period between T0 and T5. If the participant had a colonoscopy within 1 year of T0 and it was normal, then the T5 FSG should be performed. If an adenoma was found, i.e. the colonoscopy was not normal, then the T5 FSG should not be performed. If the colonoscopy was performed beyond 1 year of the T0 FSG do not offer the T5 FSG regardless of the results. The following steps should be taken at the SC to identify all participants with diagnosed adenomas before offering the T5 FSG:

1. Identify those participants who had an adenoma resected during the one-year period following the T0 FSG or had a colonoscopy during the period from T1 to the opening of the T5 activity window. This may be done in several ways:
  - ▶ Review information on adenomas found during the T0 year on the Participant Overview Report. Please note that a DEC form must be completed for all Positive (AS) T0 FSG exams prior to the opening of the T5 activity window so that information on adenomas identified during the T0 FSG will be available in the system.
  - ▶ Obtain information on adenomas and follow-up colonoscopies during the scheduling process. It will be necessary for the SCs to question each participant regarding history of colonoscopy prior to scheduling a T5 exam.
2. Obtain information on adenomas and follow-up colonoscopies during the scheduling process. It will be necessary for the SCs to question each participant regarding history of colonoscopy prior to scheduling a T5 exam. Prior to the T5 visit, the SC should explain to the participants with T0 adenomas or follow-up colonoscopies why they will not be receiving the T5 FSG. This may be done verbally or in writing. Any written participant materials that address this protocol change will need to be approved by the NCI.
3. If the T5 FSG is not offered because a follow-up colonoscopy is indicated and planned or has been performed, the SC should complete a Missing Data Form (MDF) for T5. The participant must be reminded that s/he is still in the PLCO Trial and will be contacted for blood collection/questionnaire completion. The participant must be contacted when his/her T5 window opens to schedule a screening visit for the T5 blood collection.
4. If a participant has a history of adenoma between T0 and T1 and has not undergone follow-up colonoscopy, s/he should be encouraged to follow the standard of care at the institution with which the SC is affiliated. If s/he does not plan to undergo the follow-up colonoscopy and requests the FSG at T5, the T5 FSG should be performed.

### 13.2.2 Monitoring Reports

When scheduling participants for the T5 FSG, the SCs will be able to use the following SMS reports to monitor the number of participants who refused the FSG at T3:

- **Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report will show all delinquent or outstanding forms, by individual PID. It can be used to identify those participants who have an outstanding expectation for the T5 FSG.
- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#)): This report gives a summary of the study information for a participant such as PID, Randomization Date, Randomization Group, Participant Name, Gender, Date of Birth, address, and scheduling notes. Other vital status and cancer information are also presented as well as forms that are outstanding or receipted. This report can be run for selected PIDs or for a block of participants according to their randomization date. It can be used to identify participants who did not have a T3 FSG or who reported an adenoma/colonoscopy (if the adenoma/colonoscopy comments are recorded in the scheduling notes.)
- **User-defined Report**: This option will allow you to generate a report of all the T3 MDF-FSG forms receipted with reason codes, and other-specific reasons.

## 13.3 Flexible Sigmoidoscopy Examination Protocol

This section presents the PLCO protocol for the FSG. It discusses equipment, participant preparation, examination procedures, interpretation of results, and reporting of medical complications. This protocol was developed and approved by the NCI and the PLCO Steering Committee. Each SC is required to follow the protocol. Situations in which the SC cannot do so must be reported to the NCI.

The PLCO study is designed as a screening trial, and the study protocol refers to screening examinations only. If circumstances require, a biopsy may be performed during the screening sigmoidoscopy. This is acceptable only if the examiner is a physician and if a separate informed consent is obtained for the biopsy. The separate informed consent will specify that biopsy is not part of the PLCO trial and that the costs of the biopsy will be charged to the participant.

### 13.3.1 Equipment Specifications

The FSG will be performed using a flexible endoscope with capability to 60 centimeters, and a light source. The SC may optionally use camera or video equipment to record examinations for quality control purposes. In emergency situations, a colonoscope may be substituted for a flexible sigmoidoscope but it should not be inserted beyond 60 cm. It is expected that instrument cleaning and disinfection procedures will be performed according to standard medical practice and pertinent federal and local regulations. Leak testing of the instrument will be done daily. The SC must send the NCI documentation of the type of equipment used for flexible sigmoidoscopy.

### 13.3.2 Participant Preparation

Several steps in the process of participant preparation will be standardized across all SCs. Prior to the visit, the SC will advise participants who are constipated to take a laxative the night before the examination. The bowel preparation will include one Fleet enema administered by the participant, at home, on the morning of the examination. If the bowel is not adequately prepared, an additional Fleet enema will be administered at the SC.

[**Note:** In SCs where physicians may be performing a biopsy during the flexible sigmoidoscopy procedure, the participant should be instructed about what to do if s/he is taking aspirin, warfarin, non-steroidal anti-inflammatory drugs, or if s/he has conditions that require prophylactic antibiotic therapy.]

The participant will be given written information about the examination and will be informed of the risks and complications of sigmoidoscopy. The participant will be told that a physician, physician's assistant or trained nurse will be performing the examination, as appropriate. The participant will also be told that the examination is a screening examination for colorectal cancer, not a routine examination, and s/he should consult his or her physician for evaluation of any symptoms and for routine medical care. If the SC's plan for quality assurance includes direct observation by a gastroenterologist, the participant will be told that such an observation may take place. The participant will be told that s/he will receive written documentation of the results of all screening examinations within approximately three weeks. If the SC plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.

### 13.3.3 Examination Procedures

Standard medical practice requires that a brief medical history be obtained before sigmoidoscopy. The SCs will determine the content of this medical history. In addition, vital signs will be measured before and after the sigmoidoscopy. It is recommended that in the presence of certain medical conditions, clearance be obtained from a study physician before the sigmoidoscopy examination can be allowed to proceed. Significant conditions include:

- the presence of heart rhythm irregularity;
- pulse rate below 60/minute or above 100/minute;
- systolic blood pressure below 100 mm Hg or above 180 mm Hg;
- diastolic blood pressure below 60 mm Hg or above 95 mm Hg;
- myocardial infarction or cerebrovascular accident within six months;
- recent fainting spells;
- chest pain within 24 hours; or
- increased shortness of breath.

If the participant has not administered an enema at home prior to coming to the SC or the first enema was insufficient, s/he will be prepared with a disposable enema kit until it appears the rectum has had all stool evacuated.

When the preparation has been judged adequate, the examiner will explain the procedure to the participant and the participant will then lie on his/her left side with the anal/rectal area exposed. Upon agreement of the participant, the examiner will do a digital rectal examination to exclude any low rectal lesion and to determine the path of the rectum. The examiner will introduce a lubri-

cated flexible scope with capability to 60 centimeters of examination. The examiner will visualize the rectum and the colon as the scope is advanced. Air for inflation or exposure will be used at the discretion of the examiner.

The goal of the examination is full insertion of the 60-centimeter scope unless one or more of the following occur:

- Undue participant discomfort;
- Vasovagal response;
- Palpitations with tachycardia;
- Severe diverticulosis with unclear lumen;
- Severe ulcerative colitis;
- Inadequate preparation with unclear lumen.

Once the scope is advanced to the full length or to a distance maximally tolerated by the participant, the examiner will withdraw the scope and visualize the colon and the rectum as the scope is withdrawn. Once the examination is completed, the participant will be asked to sit briefly.

If a non-physician examiner requires assistance in performing an adequate examination, a physician consultant will be called to perform the examination. The results of the physician's examination, not the examiner's, will be documented on the screening examination report form.

An examination will be judged inadequate if the scope is not advanced to at least 50 centimeters (unless an obstructing lesion is encountered) or less than 90 percent of the mucosa is identified due to one or more of the following:

- Participant discomfort;
- Participant refusal;
- Equipment malfunction;
- Inadequate preparation with unclear lumen;
- Vasovagal response;
- Palpitations with tachycardia;
- Severe diverticulosis with unclear lumen;
- Severe ulcerative colitis.

If the examiner cannot insert the scope to at least 50 centimeters, the on-call gastroenterologist should be notified and, if possible, s/he will come and perform the procedure on that individual participant. If the examination is inadequate due to inadequate preparation, then one additional Fleet enema should be administered and the procedure repeated during the participant's visit. If this is not possible, the FSG should be rescheduled. However, duplicate exams performed for QA purposes should not be repeated if they are inadequate.

#### **13.3.4 Interpretation of Findings**

The examination result should be an interpretation of the examination findings only. The participant's prior medical history or prior PLCO examination findings should not be considered when assigning an examination result.

The following definitions of negative and abnormal results are provided. These definitions will be used by the examiner in recording his findings on the examination form.

- Positive Screen (Referral Required):
  - ▶ Visible or palpable evidence of a mucosal abnormality:
    - rectal nodule(s);
    - rectal and colon mass(es); and
    - rectal and colon polyp(s).
- Negative Screen-No Abnormalities: Examiner able to advance scope to full or desired length and give a description of negative findings (i.e., no abnormalities are detected).
- Negative Screen-Other Abnormalities (Referral Optional):
  - ▶ External hemorrhoids;
  - ▶ Rectal tenderness;
  - ▶ Blood;
  - ▶ Stricture;
  - ▶ Fistulas;
  - ▶ Fissures;
  - ▶ Diverticulosis;
  - ▶ Diverticulitis;
  - ▶ Colitis;
  - ▶ Vascular lesions;
  - ▶ Ulcers;
  - ▶ Melanosis coli;
  - ▶ Internal hemorrhoids; and
  - ▶ Anal warts.

### **13.3.5 Referral of Participants for Abnormal Results**

Negative and abnormal findings will be reported to the participant. Abnormal findings will also result in the participant being referred to a physician of his/her choice for follow-up. Each SC will institute procedures for referring participants to appropriate physicians (see [Chapter 6.0](#) and [Chapter 7.0](#)).

### **13.3.6 Reporting Medical Complications**

Medical complications of the procedure that occur while the participant is at the SC will be documented on the examination form. Serious medical complications that occur prior to the participant's arrival at or after his departure from the SC will be documented on the Report of Adverse Events for NIH-Sponsored Clinical Trials (RAE) ([Appendix A-17-11](#)). The CC will provide information on medical complications to the NCI for monitoring purposes. The SC must also monitor medical complications so that appropriate action can be taken should any problems become apparent.

## 13.4 Documenting Performance and Results of the Flexible Sigmoidoscopy Examination

The performance and results of the FSG examination will be reported on the **Flexible Sigmoidoscopy Screening Examination Form** ([Appendix A-13-1](#)). The **Participant Control Record** (see [Chapter 6.0](#)) will also be used to summarize information about the examination, including the examination result, and the level of referral (i.e., the severity of the abnormality if any, and whether or not the SC recommends follow-up for this examination).

### 13.4.1 The Flexible Sigmoidoscopy Screening Examination Form

The Flexible Sigmoidoscopy Screening Examination Form will be used to document the results of the examination. The form provides documentation of the fact that the examination was performed, whether the examination was adequate or inadequate, whether the results were negative or abnormal, and a description of abnormal findings. The administrative section on the top of the first page of the form will be completed by the SC Coordinator. Parts A, B, and C of the form will be completed by the examiner. Specifications for the Flexible Sigmoidoscopy Screening Examination Form are provided in [Appendix A-13-1](#). It is the responsibility of the SC Coordinator to train the examiner in the use of the form.

### 13.4.2 Data Entry

After the examination form is completed, the SC Coordinator will manually edit it to make sure that all of the required data were collected. Any data retrieval with the examiner should be performed as expeditiously as possible. The examination form and the Participant Control Record will be receipted into the SMS, and the examination form will be scanned into the DEES (see [Chapter 17.0](#)).

### 13.4.3 Reporting Results of the Flexible Sigmoidoscopy Examination

As described in Chapters 6 and 7, within three weeks of the screening visit, the SC will send the participant and the participant's physician of choice the results of the FSG examination. This reporting will be accomplished using the Screening Test Results Report (STRR) or the SC's version of the STRR. The SC may, if desired, report the detailed findings from the examination using the Screening Examination Report for the FSG examination ([Appendix B-13-1: Screening Examination Report - Flexible Sigmoidoscopy](#)). This report is generated from DEES and is a decoded or "English" version of the opscan form. The SC may also design its own materials for reporting detailed findings. All such materials must be approved by the NCI prior to implementation at the SC. Refer to Chapters 6 and 7 for a detailed discussion of results reporting activities.

## 13.5 Examiner Qualifications, Training, and Certification

The FSG examination requires a trained and certified examiner. The minimum qualifications for examiners and the PLCO training protocol are discussed in this section.

### **13.5.1 Minimum Qualifications for Examiners**

The examiner performing the FSG examination must be a Registered Nurse, Certified Physician's Assistant, Nurse Practitioner, Physician or equivalent. Equivalency is to be determined by the SC Principal Investigator and documented in a letter to be submitted with a completed Record of Experience, Credentials and Training (ECT - [Appendix A-17-5](#)) to NCI. The SC must report the qualifications and licensure of each examiner to the NCI by submitting a completed ECT with copies of relevant diplomas, certificates and/or licenses. The ECT must be approved by the NCI prior to the initiation of data collection activities.

### **13.5.2 Minimum Qualifications for QA Examiners**

The QA examiner will be either a PLCO FSG trainer (see below) or a PLCO FSG examiner who has performed at least 240 PLCO FSG examinations in the prior 12 months (average 20 per month) and achieved 50+cm insertion depth in at least 85 percent of cases with adequate bowel preparation. The Screening Center will report the qualifications and board certification of each QA examiner to NCI by submitting a completed ECT ([Appendix A-17-5](#)) with copies of the appropriate board certification. For any individual who is not a board certified gastroenterologist, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of quality assurance activities. FSG QA examiner status must be renewed at annual intervals.

### **13.5.3 Minimum Qualifications for Trainers**

A non-physician examiner will be taught the correct examination procedure by a board certified gastroenterologist (trainer). The Screening Center will report the qualifications and board certification of each trainer to the NCI by submitting a completed ECT ([Appendix A-17-5](#)) with copies of the appropriate board certificate. For any individual who is not a board certified gastroenterologist, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of training.

## **13.6 Examiner Training and Certification**

A non-physician examiner must successfully perform 25 examinations according to the trainer in order to be certified to perform flexible sigmoidoscopies for the PLCO trial.

The SC Coordinator will train the examiner, QA examiner, and the trainer in the use of study forms and SC administrative procedures. The SC will report the results of examiner training and certification to the NCI on the Record of Experience, Credentials and Training (ECT).

## **13.7 Examination Standardization and Quality Control**

The quality assurance plan for the flexible sigmoidoscopy examination will include quality control of the equipment and quality control of the examination itself. Quality control of the equipment will be assured by each institution's

compliance with a maintenance program as dictated by state licensure regulations. Quality control will include daily leak testing.

For minimum quality standards to be maintained for the examination itself, the participant's bowel must be adequately prepared, such that greater than 90 percent of the mucosa is visible per examiner estimation. In addition, an insertion of at least 50 centimeters is required unless a specific lesion is found (for example, an obstructing carcinoma).

In SCs with the appropriate video equipment, each month the sigmoidoscopies of 4 participants will be selected for videotaping and reviewed by QA examiner or trainer. In those SCs that do not have the appropriate video equipment, the exams may be repeated. Although they may be ideal, repeat FSGs are not practical within the context of the study. Review of videotape and real-time observation have potential biases, but either method will be an acceptable option for FSG QA. The number of exams to be reviewed as well as the method of their selection are determined by NCI through consultation with each Screening Center (see [APPENDIX L](#): PLCO Quality Assurance Plan). If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

In cases where the QA examiner repeats an examination or reviews the videotape of an examination, a form will be provided on which s/he will record his/her findings. This form is the same as the Flexible Sigmoidoscopy Screening Examination Form, except that it is titled **Flexible Sigmoidoscopy Screening Examination for Quality Assurance** ([Appendix A-13-2](#)), and is printed on a different colored paper to help distinguish it from the original report form. The SMS allows for the receipt of the QA form and the data from the QA form can be scanned into the DEES to facilitate comparison between the examiner and QA examiner findings.

If the repeat examination does not have the same findings as the first examination, referral will be made based on the "worst case" abnormal findings, regardless of whether the original examiner or QA examiner found the abnormal result. The following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the exam negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

Because reporting to the participant is required within three weeks of the visit, it is important that the QA examination be completed in a timely manner so that reporting can take place within the designated time period.

As outlined in the PLCO Quality Assurance Plan (see [APPENDIX L](#)), it is the responsibility of the SC to develop an SC-specific plan for repeat of FSG exams for quality assurance purposes. The plan must be submitted to the NCI for review prior to the initiation of screening. In addition, each SC will report the results of quality assurance of the examiners to the NCI on a semi-annual basis. Information to be reported includes the number of examinations (negative and abnormal) repeated or reviewed by the QA examiner and the level of agreement between the examiner and the QA examiner.

## 14.0 OVARIAN PALPATION EXAMINATION PROCEDURES

### 14.1 Overview

An ovarian palpation examination (OVR) will be performed on all female participants in the intervention arm at each screening visit (T0-T3). Screening Centers (SCs) are responsible for scheduling the participant for the examination, performing the examination, and documenting the performance and results of the examination. This chapter describes these procedures. It also provides the PLCO protocol for examiner training and certification and quality assurance procedures for the ovarian palpation exam.

### 14.2 Scheduling Ovarian Palpation Examinations

The ovarian palpation examination will be scheduled as part of the baseline and annual follow-up visit for each female participant in the intervention arm of the trial. Procedures for scheduling screening visits are discussed in [Chapter 6.0](#) (baseline visit) and [Chapter 7.0](#) (annual follow-up visits).

If a participant has had one or both ovaries either partially or completely removed, and the removal was not a follow-up to ovarian cancer, the ovarian palpation examination will be performed according to the following guidelines:

- Women with ovaries or who are unsure of whether or not they have ovaries will be offered the OVR examination in each of the four years of screening.
- Women who report bilateral oophorectomy before entrance into the study will not be offered the OVR examination in any study year.
- Women who report bilateral oophorectomy after entrance into the study will no longer be offered the OVR examination in the current study year (if the exam has not already been performed) or in any subsequent study years.

The status of the participant's ovaries will be based on spontaneous self-report only. The SC does not need to ask the participant if her ovaries are intact, nor to obtain written medical record documentation of bilateral oophorectomy. In the case of a woman who reports bilateral oophorectomy but requests a OVR examination, the SC should not perform the exam.

If the SC becomes aware that a woman who previously reported bilateral oophorectomy, does have one or both ovaries partially or fully intact, the SC should resume offering the OVR examination.

The SC staff will be responsible for determining when the ovarian palpation is performed during the screening visit. The protocol requires that the examiner who performs the ovarian palpation be blinded to the results of the transvaginal ultrasound examination and the sonographer blinded to the results of the ovarian palpation exam. Since it is likely that these examinations will be performed back-to-back, the SC coordinator must establish procedures to assure that the examiners remain blinded until both exams have been completed.

The PLCO protocol requires that every attempt be made to reschedule the examination if it is inadequate or cannot be performed for some reason other

than ovarian cancer or bilateral oophorectomy. If possible, the visit should be rescheduled before the end of the participant's activity window.

## **14.3 Ovarian Palpation Protocol**

This section presents the PLCO protocol for the ovarian palpation examination. It discusses participant preparation, examination procedures, interpretation of results and reporting of medical complications. This protocol was developed and approved by the NCI and the PLCO Steering Committee. Each SC is required to follow the protocol. Situations in which the SC cannot do so must be reported to the NCI. The **Protocol for Ovarian Palpation Examination** is presented as [J-14-1](#).

### **14.3.1 Participant Preparation**

Several steps in the process of participant preparation will be standardized across all SCs. The participant will be told that the examination is a screening examination for ovarian cancer, not a routine examination, and that she should consult her physician for evaluation of any symptoms and for routine medical care. When appropriate, the participant will also be told that a second examiner may repeat the examination for quality control purposes. The participant will be instructed to empty her bladder within 30 minutes of the examination.

The participant will be informed that the ovarian palpation examination is not a substitute for a gynecologic examination, and will not include a Pap smear. The Screening Center may offer the participant a Pap smear and charge the participant or her insurance carrier for the cost of the procedure. The Pap smear is considered outside the scope of the PLCO Screening Trial and will not be covered by the PLCO consent form.

Finally, the participant will be told that she will receive written documentation of the results of all her screening examinations within approximately three weeks. If the SC plans to report preliminary results to the participant, the participant will also be told this in advance of the examination. However, these results will not be provided until after the transvaginal ultrasound since examiners (and participants) are to remain blinded to the results of these exams until after both are completed.

### **14.3.2 Examination Procedures**

The participant will be asked to remove clothing from the waist down. The examination will be performed with the participant in the dorsal recumbent position, in stirrups and draped. The examiner will explain the procedure to the participant step-by-step as it is being performed.

The examiner will note right and left ovaries separately. The cervix will not be visualized. A rectovaginal examination will be included. The examiner will note if there is gross blood on the glove after the examination.

If a non-physician examiner requires assistance in performing an adequate examination, a physician consultant will be called to perform the examination. The results of the physician's examination, not the examiner's, will be documented on the screening examination report form.

An examination will be judged inadequate if:

- the examination was not completed (including the rectovaginal exam) (due to participant discomfort, participant refusal, or some other reason), and no abnormalities indicative of a positive screen are identified;
- both ovaries are reported by the participant as removed and no abnormalities indicative of a positive screen are identified; or
- the participant is so obese that the examiner is unable to adequately examine the ovaries.

When appropriate, the SC should make every attempt to reschedule inadequate examinations.

### **14.3.3 Interpretation of Findings**

The examination result should be an interpretation of the examination findings only. The participant's prior medical history or prior PLCO examination findings should not be considered when assigning an examination result.

The following definitions of negative and abnormal results are provided. These definitions will be used by the examiner in recording the findings on the examination form.

- Positive Screen (Referral Required):
  - ▶ Palpable adnexal mass (may include a palpable ovary); or
  - ▶ Cul-de-sac nodularity.
- Negative Screen - No Abnormalities:
  - ▶ Adequate examination fully completed and no adnexal masses or other abnormalities detected.
  - ▶ For non-obese participants with non-palpable ovaries, the examination will be considered negative.
- Negative Screen - Other Abnormalities (Referral Optional): An adequate exam, fully completed and one or more of the following abnormalities detected:
  - ▶ Abdominal pain or tenderness on examination;
  - ▶ Vaginal bleeding;
  - ▶ Other significant clinical findings noted incidentally while doing the examination. (For example: lesions on external genitalia, enlarged uterus, or other non-ovarian pelvic masses).

Negative and abnormal findings will be reported to the participant. Abnormal findings that are suspicious for cancer will also result in the participant being referred to a physician of her choice. The examiner will determine whether or not a referral is needed for abnormal findings that are not suspicious for cancer, according to standard practice at the SC. Each SC will institute procedures for referring participants to appropriate physicians (see [Chapter 6.0](#) and [Chapter 7.0](#)).

### **14.3.4 Reporting Medical Complications**

Medical complications of the procedure that occur while the participant is at the SC will be documented on the examination form. Medical complications that occur prior to the participant's arrival at or after her departure from the

SC will be documented on the Adverse Experience Report (AER). The CC will provide information on medical complications to the NCI for monitoring purposes. The SC must also monitor medical complications so that appropriate action can be taken should any problems become apparent.

## **14.4 Documenting Performance and Results of the Ovarian Palpation Examination**

The performance and results of the ovarian palpation examination will be reported on the **Ovarian Palpation Screening Examination Form** ([Appendix A-14-1](#)). The **Participant Control Record** (see [Chapter 6.0](#)) will also be used to summarize information about the examination, including the examination result, and the level of referral (i.e., the severity of the abnormality, if any, and whether or not the SC recommends follow-up for this examination).

### **14.4.1 The Ovarian Palpation Examination Form**

The Ovarian Palpation Screening Examination Form will be used to document the results of the examination. The form provides documentation of the fact that the examination was performed, whether the examination was adequate or inadequate, whether the results were negative or abnormal, and a description of abnormal findings. The administrative section on the top of the first page of the form will be completed by the SC Coordinator. Parts A, B, and C of the form will be completed by the examiner. Specifications for the Ovarian Palpation Examination Form are provided in [Appendix J-14-1](#). It is the responsibility of the SC Coordinator to train the examiner in the use of this form.

### **14.4.2 Data Entry**

After the examination form is completed, the SC coordinator will manually edit it to make sure that all of the required data were collected. Any data retrieval with the examiner will be performed as expeditiously as possible. The examination form and the Participant Control Record will be receipted into the SMS, and the examination form will be scanned into the DEES (see [Chapter 17.0](#)).

### **14.4.3 Reporting Results of the Ovarian Palpation Examination**

As described in [Chapter 6.0](#) and [Chapter 7.0](#), within three weeks of the screening visit, the SC will send the participant and the participant's physician of choice the results of the ovarian palpation examination. This reporting will be accomplished using the Screening Test Results Report (STRR) or the SC's version of the STRR. The SC may, if desired, report the detailed findings from the examination using the Screening Examination Report for the ovarian palpation examination ([Appendix B-14-1: Screening Examination Report - Ovarian Palpation](#)). This report is generated from DEES and is a decoded or "English" version of the opscan form. The SC may also design its own materials for reporting detailed findings. All such materials must be approved by the NCI prior to implementation at the SC. Refer to [Chapter 6.0](#) and [Chapter 7.0](#) for a detailed discussion of results reporting activities.

## 14.5 Examiner Qualifications, Training, and Certification

The ovarian palpation examination requires a trained examiner. The minimum qualifications for the examiner and the PLCO training protocol are discussed in this section.

### 14.5.1 Minimum Qualifications for Examiners

The examiner performing the ovarian palpation examination must be a Clinical Nurse Specialist, Registered Nurse, Certified Physician's Assistant or equivalent. Equivalency is to be determined by the SC Principal Investigator and documented in a letter to be submitted with a completed Record of Experience, Credentials and Training (ECT - [Appendix A-17-5](#)) to NCI. The SC must report the qualifications and licensure of each examiner by submitting to the NCI a completed ECT with copies of relevant diplomas certificates and/or licenses. The ECT must be approved by the NCI prior to the initiation of data collection activities.

### 14.5.2 Minimum Qualifications for QA Examiners

The QA examiner will be any licensed physician with adequate training and experience in the ovarian palpation examination as determined by the Principal Investigator or a certified PLCO OVR examiner. The Screening Center will report the qualifications and board certification of each QA examiner to the NCI by submitting a completed ECT ([Appendix A-17-5](#)). For any individual who is not a board certified gynecologist or gynecologic oncologist, or a certified PLCO OVR examiner, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of QA activities.

### 14.5.3 Minimum Qualifications for Trainers

A non-physician examiner will be taught the correct examination procedure by a board certified gynecologist or gynecologic oncologist (trainer). The Screening Center will report the qualifications and board certification of each trainer to the NCI by submitting a completed ECT ([Appendix A-17-5](#)) with copies of the appropriate board certificate. For any individual who is not a board certified gynecologist or gynecologic oncologist, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of training.

## 14.6 Examiner Training and Certification

A non-physician must spend at least two full work days with a trainer and must successfully perform at least 40 examinations in post-menopausal women, including 10 examinations with abnormal findings. The trainer will document that the examiner successfully performed the examinations and that, in the judgment of the trainer, the examiner is considered certified.

The SC Coordinator will be responsible for training the examiner and the trainer in the use of the study forms and SC administrative procedures.

The SC must report the results of examiner training and certification to the NCI using the **Record of Experience, Credentials and Training (ECT)**.

## 14.7 Examination Standardization and Quality Control

For minimum quality standards to be maintained for the ovarian palpation examination, the examiner must document the palpation of the right and left ovaries, the symmetry of the right and left ovaries and the characteristics of palpable adnexal masses, including number, location, size, shape, nodularity, consistency, tenderness and mobility. Cul-de-sac nodularity observed during the rectovaginal examination will also be noted.

Each month, 14 screening tests will be repeated by the QA examiner or trainer. To assist the QA process, a form is provided on which the QA examiner will record his/her findings. This form is the same as the Ovarian Palpation Screening Examination Form, except that it is titled **Ovarian Palpation Screening Examination Form Quality Assurance** ([Appendix A-14-2](#)), and is printed in orange to help distinguish it from the original report form (printed in red). The SMS allows for the receipt of the QA form and the data from the QA form can be scanned into the DEES to facilitate comparison. If the repeat examination does not have the same findings as the first examination, referral will be made based on the “worst case” abnormal findings, regardless of whether the original examiner or QA examiner found the abnormal result. Because reporting to the participant is required within three weeks of the visit, it is important that the QA examination be completed in a timely manner so that reporting can take place within the designated time period. The number of tests to be repeated as well as the method of their selection are determined by NCI through consultation with each Screening Center (see [APPENDIX L](#): PLCO Quality Assurance Plan).

As outlined in the PLCO Quality Assurance Plan ([APPENDIX L](#)), it is the responsibility of the SC to develop an SC-specific plan for repeat of ovarian palpation examinations for quality assurance purposes. The plan must be submitted to the NCI for review prior to the initiation of screening. In addition, each SC will report the results of quality assurance of the examiners to the NCI on a semi-annual basis. Information to be reported includes the number of examinations (negative and abnormal) repeated by the QA examiner and the level of agreement between the examiner and the QA examiner.

# 15.0 TRANSVAGINAL ULTRASOUND EXAMINATION PROCEDURES

## 15.1 Overview

A transvaginal ultrasound (TVU) examination will be performed on all female participants in the intervention arm at each screening visit (T0-T3). Screening Centers (SCs) are responsible for scheduling the participant for the examination, performing the examination, and documenting the performance and results of the examination. This chapter describes these procedures. It also provides the PLCO protocol for examiner training and certification and quality assurance procedures for the TVU exam.

## 15.2 Scheduling Transvaginal Ultrasound Examinations

The TVU examination will be scheduled as part of the baseline and annual follow-up visit for each female participant in the intervention arm of the trial. Procedures for scheduling screening visits are discussed in [Chapter 6.0](#) (baseline visit) and [Chapter 7.0](#) (annual follow-up visits).

If a participant has had one or both ovaries either partially or completely removed, and the removal was not a follow-up to ovarian cancer, the TVU examination will be performed according to the following guidelines:

- Women with ovaries or who are unsure of whether or not they have ovaries will be offered the TVU examination in each of the four years of screening.
- Women who report bilateral oophorectomy before entrance into the study will not be offered the TVU examination in any study year.
- Women who report bilateral oophorectomy after entrance into the study will no longer be offered the TVU examination in the current study year (if the exam has not already been performed) or in any subsequent study years.

The status of the participant's ovaries will be based on spontaneous self-report only. The SC does not need to ask the participant if her ovaries are intact, nor to obtain written medical record documentation of bilateral oophorectomy. In the case of a woman who reports bilateral oophorectomy but requests a TVU examination, the SC should not perform the exam.

If the SC becomes aware that a woman who previously reported bilateral oophorectomy, does have one or both ovaries partially or fully intact, the SC should resume offering the TVU examination.

The protocol for the TVU requires that this examination be performed prior to the flexible sigmoidoscopy (applies to the T0 screening visit only). In the rare event that the FSG and TVU are performed on different days, the TVU may be performed either before or after the FSG.

The PLCO protocol requires that every attempt be made to reschedule the examination if it is inadequate or cannot be performed for some reason other than ovarian cancer or bilateral oophorectomy. If possible, the visit should be rescheduled before the end of the participant's activity window. However,

duplicate exams performed for QA purposes should not be repeated even if they are inadequate.

## 15.3 Transvaginal Ultrasound Protocol

This section presents the PLCO protocol for the TVU examination. It discusses equipment specifications, participant preparation, examination procedures, interpretation of results and reporting of medical complications. This protocol was developed and approved by the NCI and the PLCO Steering Committee. Each SC is required to follow the protocol. Situations in which the SC cannot do so must be reported to the NCI. The **Protocol for Transvaginal Ultrasound Examination** is presented as [Appendix J-15-1](#).

### 15.3.1 Equipment Specifications

The TVU will be performed using a 5-7.5 MHz transvaginal probe. Doppler color imaging should not be used during a PLCO TVU examination. TVU equipment must meet FDA guidelines and institution and state licensure regulations. Photo documentation capability is also required. A photograph or thermal print of each adnexal area in transverse and lateral planes will need to be obtained for documentation and will be retained as part of the permanent record. Photo documentation should be obtained regardless of whether or not the ovaries were visualized. It is acceptable to store transvaginal ultrasound images on thermal paper and radiographic film. Digital storage is also acceptable but a back-up copy should also be maintained. The storage method should meet requirements of 20-year storage with no decrease in the quality of the image and with capability to retrieve a film or paper image at any time during the 20-year storage period. The SC must send documentation of equipment specifications to the NCI. This should be done before data collection begins and whenever equipment is replaced during the course of the trial.

### 15.3.2 Participant Preparation

Several steps in the process of participant preparation will be standardized across all SCs. The participant will be told that the examination is a screening examination for ovarian cancer, not a routine examination, and that she should consult her physician for evaluation of any symptoms and for routine medical care. When appropriate, the participant will also be told that a second examiner may repeat the examination for quality control purposes.

Finally, the participant will be told that she will receive written documentation of the results of all her screening examinations within approximately three weeks. If the SC plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.

The participant will be instructed to empty her bladder prior to the examination and the procedure will be briefly explained by the sonographer.

A sample script to present the information discussed above follows:

*Your bladder should be empty. The exam involves the insertion of a small probe, which is covered with a protective sheath, into the vagina. The probe lets me see your pelvic organs. The sensations from the probe and the speculum used for a Pap smear are very similar. Sometimes, participants experience some discomfort during this part of the test. To make sure that the test results are correct, a second sonogra-*

*pher or doctor may ask your permission to repeat the exam. Your test results will be sent to your home within three weeks.*

### **15.3.3 Examination Procedures**

The examiner will image both the left and right adnexal area in two planes and will record the transverse, longitudinal, and anteroposterior diameters for both the left and right ovary. The examiner will search no less than five minutes per ovary for each ovary to ensure an adequate search for the ovaries; however, if the iliac vessels are visualized and no ovaries are visualized, the examiner may conclude the search for the ovaries. The examiner will photograph both ovaries in two perpendicular planes (four images total).

If the examiner (sonographer) requires assistance in performing an adequate examination, a physician consultant will be called to perform the examination. The results of the physician's examination, not the examiner's, will be documented on the screening examination report form.

An examination will be judged inadequate if it cannot be carried out due to:

- participant discomfort or pain;
- participant refusal;
- inability to insert the probe;
- equipment malfunction;
- bowel interference; or
- some other condition.

When appropriate, the SC should make every attempt to reschedule inadequate examinations. If possible, the examination should be rescheduled before the end of the participant's reporting window. A QA exam with an inadequate result should not be repeated as a PLCO screening exam or as a PLCO QA exam.

### **15.3.4 Interpretation of Findings**

The examination result should be an interpretation of the examination findings only. The participant's prior medical history or prior PLCO examination findings should not be considered when assigning an examination result.

The following definitions of negative and abnormal results are provided. These definitions will be used by the examiner in recording the findings on the examination form.

- Positive Screen (Referral Required): The prolate ellipsoid formula (width x height x thickness x 0.523) will be used to calculate the volume of each ovary and/or cyst. For cysts, the maximum diameter will be used in volume calculations  $[(\text{max. diameter})^3 \times 0.523]$ . An abnormal (positive) transvaginal ultrasound will consist of one or more of the following features:
  - ▶ any ovary or cyst greater than 10 cubic cm in volume;
  - ▶ any solid area or papillary projection extending into the cavity of a cystic ovarian tumor of any size;
  - ▶ any mixed (solid/cystic) component within a cystic ovarian tumor.

- Negative Screen-No Abnormalities: An examination in which no abnormalities of any kind are found (regardless of whether or not the ovaries are visualized).
- Negative Screen-Other Abnormalities (Referral Optional): An examination which reveals one or more abnormalities that do not satisfy the criteria for a positive screening examination.

**Note:** If the examiner notes a nabothian cyst, defined as a cyst of the nabothian gland (located in the cervix), the examiner can make the decision whether or not to code the result as either Negative Screen - No Abnormalities or Negative Screen - Other Abnormalities.

### 15.3.5 Referral of Participants for Abnormal Results

Negative and abnormal findings will be reported to the participant. Abnormal findings that are suspicious for cancer will also result in the participant being referred to a physician of her choice. The examiner will determine whether or not a referral is needed for abnormal findings that are not suspicious for cancer. Each SC will institute procedures for referring participants to appropriate physicians (see [Chapter 6.0](#)).

### 15.3.6 Reporting Medical Complications

Medical complications of the procedure that occur while the participant is at the SC will be documented on the examination form. Serious medical complications that occur prior to the participant's arrival at or after his departure from the SC will be documented on the Report of Adverse Events for NIH-Sponsored Clinical Trials (RAE) ([Appendix A-17-11](#)). The CC will provide information on medical complications to the NCI for monitoring purposes. The SC must also monitor medical complications so that appropriate action can be taken should any problems become apparent.

## 15.4 Documenting Performance and Results of the Transvaginal Ultrasound Examination

The performance and results of the TVU examination will be reported on the **Transvaginal Ultrasound Screening Examination Form** ([Appendix A-15-1](#)). A photograph or thermal print out of each ovary or adnexal area in transverse and longitudinal planes will be made and retained as part of the permanent record. The **Participant Control Record** (see [Chapter 6.0](#)) will also be used to summarize information about the examination, including the examination result and the level of referral (i.e., the severity of the abnormality, if any, and whether or not the SC recommends follow-up for this examination).

### 15.4.1 The Transvaginal Ultrasound Screening Examination Form

The TVU Screening Examination Form will be used to document the results of the examination. The form provides documentation of the fact that the examination was performed, whether the examination was adequate or inadequate, whether the results were negative or abnormal, and a description of abnormal findings. The administrative section on the top of the first page of the form will be completed by the SC coordinator. Parts A, B, and C of the form will be completed by the examiner. In some SCs another examiner (such as a radiologist)

will interpret the findings. In such cases, the sonographer will complete Parts A and B, and the second examiner will complete Part C.

Specifications for the TVU Screening Examination Form are provided in [Appendix A-15-1](#). It is the responsibility of the SC Coordinator to train the examiner and the trainer in the use of this form.

### **15.4.2 Data Entry**

After the examination form is completed, the SC Coordinator will manually edit it. Any data retrieval with the examiner will be performed as expeditiously as possible. The examination form and the Participant Control Record will be receipted into the SMS, and the examination form will be scanned in its entirety into the DEES. SMS receipt may be performed interactively or via the DEES to SMS update function (see [Chapter 17.0](#)).

### **15.4.3 Reporting Results of the Transvaginal Ultrasound Examination**

As described in [Chapter 6.0](#) and [Chapter 7.0](#), within three weeks of the screening visit, the SC will send the participant and the participant's physician of choice the results of the TVU examination. This reporting will be accomplished using the Screening Test Results Report (STRR) or the SC's version of the STRR. The SC may, if desired, report the detailed findings from the examination using the Screening Examination Report for the Transvaginal Ultrasound Examination ([Appendix B-15-1: Screening Examination Report - Transvaginal Ultrasound](#)). This report is generated from DEES and is a decoded or "English" version of the opscan form. The SC may also design its own materials for reporting detailed findings. All such materials must be approved by the NCI prior to implementation at the SC. Refer to [Chapter 6.0](#) and [Chapter 7.0](#) for a detailed discussion of results reporting activities.

## **15.5 Examiner Qualifications, Training, and Certification**

The TVU examination requires a trained examiner. The minimum qualifications for the examiner and the PLCO training protocol are discussed in this section.

### **15.5.1 Minimum Qualifications for Examiners**

The TVU examiner for the PLCO Screening Trial must be a sonographer who is registered by the American Registry of Diagnostic Medical Sonographers (ARDMS), has passed the OB/Gyn section of the ARDMS certification examination, and has performed 50-100 prior transvaginal ultrasound examinations. If the examiner is a physician, s/he must be adequately trained in transvaginal ultrasonography as determined by the Principal Investigator. The SC must report the qualifications and licensure of each examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT - [Appendix A-17-5](#)). The ECT must be approved by the NCI prior to the initiation of data collection activities. For any individual who is not a sonographer registered by the ARDMS, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.

### **15.5.2 Minimum Qualifications for QA Examiners**

The QA examiner will be either a PLCO TVU trainer (see below) or a PLCO TVU examiner who has performed at least 240 PLCO TVU exams in the prior 12

months (average 20 per month) and detected one or both ovaries in at least 60 percent of those examinations deemed adequate. The Screening Center will report the qualifications and licensure or board certification of each QA examiner by submitting a completed Record of Experience, Credentials and Training (ECT - [Appendix A-17-5](#)) with copies of the appropriate diplomas, certificates and/or licenses. For any individual who is not a board certified radiologist with specific training in ultrasonography, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of QA activities. The TVU QA examiner status should be renewed at annual intervals.

### **15.5.3 Minimum Qualifications for Trainers**

The sonographer will be trained by a board certified radiologist with specific training in ultrasonography (trainer). The Screening Center will report the qualifications and licensure or board certification of each trainer to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT - [Appendix A-17-5](#)) with copies of the appropriate diplomas, certificates and/or licenses. For any individual who is not a board certified radiologist, the SC Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The ECT must be approved by the NCI prior to the initiation of training.

## **15.6 Examiner Training and Certification**

Sonographers must be registered by the American Registry of Diagnostic Medical Sonographers must have performed 50-100 TVU exams and must be adequately trained in transvaginal ultrasonography as determined by the Principal Investigator. No other certification will be required. Examiners will display competence by successfully performing examinations accurately during training.

The SC Coordinator will be responsible for training the examiner and the trainer in the use of the study forms and SC administrative procedures. The SC must report the results of examiner training and certification to the NCI using the Record of Experience, Credentials and Training (ECT).

## **15.7 Examination Standardization and Quality Control**

For minimum quality standards to be maintained for the TVU, every reasonable attempt will be made to image and photograph both ovaries in two perpendicular planes, (four images total). The examiner must provide documentation of ovarian dimensions (if ovaries are successfully visualized). In those participants who have previously had an ovary removed, a complete examination will include visualization of the remaining structures. Inability to visualize the ovaries, after every reasonable attempt, will be considered an adequate examination with negative findings. In some examinations, the examiner can only visualize some or part of one ovary, therefore s/he cannot calculate ovarian volume. Such examinations should be considered inadequate unless morphologic abnormalities that are considered "abnormal suspicious" are visualized. In such cases, the result of "AS" should take precedent. If no abnormalities are visualized, or if abnormalities that are not suspicious of cancer are visualized, then the examination should be considered inadequate.

Quality control of the equipment will be assured by each institution's compliance with a maintenance program as dictated by state licensure regulations.

Each month, 14 screening tests will be repeated by QA examiner or trainer. The number of exams to be repeated or reviewed as well as the method for their selection are determined by NCI through consultation with each Screening Center (see [APPENDIX L](#): PLCO Quality Assurance Plan). If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

To assist the QA process, a form is provided on which the QA examiner will record his/her findings. This form is the same as the TVU Screening Examination Form, except that it is titled **Transvaginal Ultrasound Screening Examination Form Quality Assurance** ([Appendix A-15-2](#)), and is printed in orange to help distinguish it from the original exam form. The SMS allows for the receipt of the QA form and the data from the QA form can be scanned into the DEES to facilitate comparison.

If the repeat examination/review does not have the same findings as the first examination, referral will be made based on "worst case" abnormal findings, regardless of whether the original examiner or the QA examiner found the abnormal result. The following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the exam negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

Because reporting to the participant is required within three weeks of the visit, it is important that the QA examination be completed in a timely manner so that reporting can take place within the designated time period.

As outlined in the PLCO Quality Assurance Plan ([APPENDIX L](#)), it is the responsibility of the SC to develop an SC-specific plan for repeat of TVU exams for quality assurance purposes. The plan must be submitted to the NCI for review prior to the initiation of screening. In addition, each SC will report the results of quality assurance of the examiners to the NCI on a semi-annual basis. Information to be reported includes the number of examinations (negative and abnormal) repeated or the number of films reviewed by the QA examiner and the level of agreement between the examiner and the QA examiner.

## 16.0 COLLECTION OF PATHOLOGY MATERIAL AND PATHOLOGY DATA REVIEW

### 16.1 Central Review of Pathology Slides

The pathology slides will be stored at the Central Repository and will be examined periodically throughout the year by the central Pathology Data Review Committee, a team of NCI designated pathologists. The central committee will histopathologically review all slides for confirmation of a PLCO cancer. If significant discrepancies are found between the central committee results and the local pathologist results, the central committee will review both the pathology report and the original cut slide that confirmed the cancer diagnosis. The central committee will attempt to resolve all discordant cases.

When cases are discordant and the pathology report and original slide are necessary for review by the central committee, the Central Repository Coordinator will contact the SC Coordinator to request a copy of the pathology report and the original cut slide. Original cut slides will be returned to the local pathologist, if required.

### 16.2 Obtaining Pathology Slides from Local Pathologists

It will be the responsibility of the SC Coordinator to arrange with the local pathologists to obtain pathology slides. The steps to be followed include:

- Pathology slides of all confirmed PLCO cancers found during the course of the trial will be obtained from appropriate pathologists/hospital pathology department (here referred to as the "local" pathologist).
- The SC Coordinator will contact the local pathologist to request permission to obtain one stained slide prepared by the local pathologist for routine examination and determination of histology. The SC Coordinator will request a representative slide that supports the diagnosis of cancer and can be permanently retained for the trial. It is expected that the slide will be a recut, since the local pathologist will likely not release the original slide for permanent retention.
- The SC Coordinator will request that the slide be marked to indicate that it is a recut slide. (If the original slide is later needed for review (on loan) it will be necessary to indicate that it is an original slide.)
- The slide will be assigned a sample ID number and receipted into the SMS (see [Section 16.4](#)).
- The slide will be labeled and stored in a storage box until shipped to the Central Repository (see [Section 16.5](#)).
- Slides will be shipped quarterly to the Central Repository (see [Section 16.6](#)).
- If the results are discordant between the Central Pathology Data Review Committee and the local pathologist, the SC Coordinator will be asked to obtain the original slide for central review.
- Original slides which need to be returned to the local pathologist will *not* be labeled with a sample ID. These slides will be receipted by the identification number assigned to them by the local pathologist. Only

slides for permanent retention will be assigned a sample ID number. The Central Repository Coordinator will return original slides to the SC after the review is completed. The SC Coordinator will receipt all returned original slides in the SMS. (**Note:** Receipt of slides and related information is not available from the SMS.)

### 16.3 Labeling and Receipting Pathology Slides

Each SC will use the SMS to generate a series of self-stick bar code labels that will be used to label all pathology slides. A unique sample ID will be assigned to each slide obtained for permanent retention. The sample ID will be a nine character ID number. The format will be two alpha characters, followed by four numeric characters (unique sequential sample identifier), followed by three numeric characters (type of cancer). A representation of the sample ID labels is presented below:

AA-NNNN-001 = Prostate Cancer Slide

AA-NNNN-002 = Lung Cancer Slide

AA-NNNN-003 = Colorectal Cancer Slide

AA-NNNN-004 = Ovarian Cancer Slide

In addition to attaching a sample ID label to the slide itself, a copy of the label should be attached to the letter/form which was received from the local pathologist accompanying the slide. A Participant ID label should also be placed on this form. This step will provide hard copy documentation of the link between the two identification numbers.

To avoid wasting labels, a sheet of labels will be generated for each type of cancer at one time. Each sheet will contain enough labels for 144 slides. Whenever a new slide for the particular type of cancer is received, the next sequential label from the appropriate sheet of labels should be used.

As stated above, when review committee results are discordant, the original slide will be requested, on loan. Original slides will not be labeled with a sample ID since they will not become part of the slide repository. These slides will be receipted by the slide identification number assigned to them by the local pathologist.

After the slide is properly identified and labeled, the SC Coordinator will receipt the slide into the SMS. Items of information to be entered include the sample ID number assigned (or local pathologist ID number if the slide is an original which needs to be returned), the date of receipt, and whether the slide is an original which needs to be returned to the local pathologist. (**Note:** Receipt of slides and related information is not available from the SMS.)

### 16.4 Storing Pathology Slides

Pathology slides will be stored at room temperature until they are shipped to the Central Repository. Procedures to be followed for storing slides are discussed below:

- After the pathology slide is receipted in the SMS, the SC Coordinator will store the slide in sequential order in a slide box. Slide boxes should hold approximately 25 slides with all slides separated. The recommended storage box is:

- ▶ Plastic Hinged box with 25 slide capacity
- ▶ Baxter Scientific Catalog # M6299.
- The slide boxes should be filled as much as possible before shipment.
- Each slide box will be labeled with box labels taken from the series of self-stick sequentially numbered labels (series number S-xxxx) generated by the SMS (see *SMS User's Guide/SMS Upgrade Documentation*). The "S" identifies these boxes as containing pathology slides. The next four characters are the unique identifier number ranging from 0001 to 9999. These labels should be used in sequence.
- Duplicate labels will be generated for each box number. One label will be placed on the top of the box. The second label will be placed on the right side of the box as the box opening is facing the labeler.

## 16.5 Shipment of Slides to the Central Repository

Pathology slides will be shipped quarterly via certified mail to the Central Repository. A Pathology Slide Transmittal Log will be included for every slide box in the shipment. All shipments will be confirmed with the Central Repository the day of the shipment.

Upon receipt of the pathology slides, the Central Repository Coordinator will check the shipment to identify missing or damaged slides. The Central Repository Coordinator will contact the SC Coordinator to resolve any problems.

The following sections describe the procedures to be followed for pathology slide shipment.

### 16.5.1 Preparing Pathology Slides for Shipment

The tasks to be completed by the SC in preparing pathology slides for shipment are as follows:

- Pathology slide shipments will be scheduled for Monday, Tuesday or Wednesday. Slides should never be shipped to be received at the Central Repository on a weekend or a holiday.
- On the day before a scheduled shipment the SC Coordinator will call the Central Repository SC Coordinator to notify him/her of the upcoming shipment and to give him/her an estimated date of arrival.
- The SC Coordinator will select the slide boxes to be shipped, then access the SMS to print the **Pathology Slide Transmittal Log** ([Appendix B-16-1: Pathology Slide Transmittal Log](#)) and a mailing label. The Pathology Slide Transmittal Log will list all receipted pathology slides which have not yet been sent to the Central Repository. The SC Coordinator will use the transmittal log to inventory the slides for shipment. If a slide cannot be located or cannot be shipped for some reason, the SC Coordinator will access the SMS to update the status for that slide ID number by deleting the shipping date and adding the appropriate problem code. A modified transmittal will then be generated. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for further information on generating the transmittal form and updating the SMS.

### **16.5.2 Packing Shipping Containers**

The SC Coordinator will pack the pathology slides for shipment. The packing procedures to be followed are described below:

- Pack the slide box(es) in a shipping container such as a corrugated fiberboard box.
- Place several paper towels or some other padding inside the slide box(es), on top of the slides to cushion the movement of the slides inside the slide box(es).
- Securely tape the slide box(es) closed.
- Wrap the slide box(es) with bubble or other padded material.
- Place the slide box(es) in the shipping container.
- Fill the space around the box(es) with crumpled paper or other material so the box(es) will not shift during transport.
- Place a copy of the Pathology Slide Transmittal Log(s) in the shipping container.
- Seal the shipping container with strapping tape.
- Label the pathology slide shipping container with the following information:
  - ▶ The SC (return) address;
  - ▶ The address of the Central Repository;
  - ▶ "Fragile -- Glass -- Handle with Care;" and
  - ▶ "Clinical Specimens for Diagnostic Use."
- File a copy of the Pathology Slide Shipping Transmittal Log(s) in the SC files.
- The SC Coordinator will send the slides by certified mail to the Central Repository.
- The SC Coordinator will record the certified mail tracking number for each shipping container on the SC file copy of the Pathology Slide Transmittal Log(s) produced for that container.

### **16.5.3 Shipping Address and Contact Information**

- The address of the Central Repository is as follows:  
*(address to be determined)*
- The name and telephone number of the Central Repository Coordinator is:  
*(name and phone number to be determined)*

## **16.6 Receipt of Pathology Slides at the Central Repository**

Upon receipt of the pathology slides at the Central Repository, the Central Repository Coordinator will complete the "Date of Receipt," "Time of Receipt," and "Number of Slides Received" items on the Pathology Slide Transmittal Log. The Central Repository Coordinator will also check to ensure that all slides have been delivered intact and that all slides are labeled.

If the shipment is not received on schedule, or if there are any problems such as discrepancy between transmittal and slide box or broken slides, the Central Repository Coordinator will complete the "Problem with Slides" item on the transmittal and will call the SC Coordinator to resolve the problem. If necessary, the SC Coordinator will contact the local pathologist to obtain a replacement slide.

## **16.7 Monitoring Pathology Slide Procurement Activities**

The SC Coordinator can monitor the procurement of pathology slides through the SMS. The following report will provide relevant information:

**Open Forms Report** ([Appendix B-17-8: Open Forms/Specimens Report](#)): This report lists delinquent or outstanding forms by Participant ID. Although not technically forms, pathology slides will be included on this report.

## **16.8 Reporting the Results of Slide Procurement**

The results of slide procurement activities will be sent to the Coordinating Center through the transmission options in the Network Administration module of the PLCO computer system. (See the *Network User's Guide/Network Upgrade Documentation* for more information.)

# 17.0 GUIDELINES FOR SCREENING CENTER MANAGEMENT

## 17.1 Overview

The Screening Center (SC) Coordinator has overall responsibility for the management of the Screening Center. These management tasks include staffing, scheduling and documenting data collection activities, record keeping, requesting information, processing study data, shipping, transmitting data to the Coordinating Center (CC), coordinating activities with satellite centers, monitoring SC activities, and quality assurance.

This chapter describes the SC management activities and the tools provided to perform these activities.

## 17.2 Staffing the Screening Center

Each SC is responsible for providing staff to recruit and screen participants, process forms and specimens, perform cancer and vital status confirmation, perform quality assurance measures, and manage SC activities. While each Investigator may hire staff as s/he sees fit, it is suggested that the following personnel be available at each SC:

- SC Coordinator;
- Examiners [physician or non-physician];
- Phlebotomist/Laboratory Technologist;
- Data Manager;
- Data Entry Clerk;
- General Office Staff;
- Lead Medical Record Abstractor;
- Medical Record Abstractor;
- Medical Coder (Nosologist); and
- Physician Consultants in Gynecology, Urology, Gastroenterology, and Radiology.

### 17.2.1 Screening Center Staff Responsibilities

The following is an overview of the responsibilities of the SC staff, presented by functional title. The responsibilities described under each title may not be discrete, i.e., tasks within different titles may be performed by one individual. The functional titles are used throughout this manual for convenience in describing activities.

- **SC Coordinator:**

The SC Coordinator has overall responsibility for all SC data collection and processing activities and will be the main contact point for interaction with the NCI, the CC, UCLA and the Biorepository. The SC Coordinator will train or supervise the training of staff to perform their assigned duties and will oversee personnel and administrative procedures within the SC.

- **Examiners:**  
It is the responsibility of the examiners to:
  - ▶ Perform screening tests on intervention participants;
  - ▶ Complete a screening examination data collection form for each examination; and
  - ▶ Provide information to participants and answer participant questions about the examination.
- **Phlebotomist/Laboratory Technologist:**  
The blood collection and processing functions may be performed by one or more staff members.  
It is the responsibility of the phlebotomist to:
  - ▶ Draw blood from intervention participants for the PSA and CA-125 blood tests, the Biorepository, and the Processing Laboratory.
 It is the responsibility of the lab technologist to:
  - ▶ Process blood samples according to PLCO protocol; and
  - ▶ Package blood samples for shipment to UCLA, the Biorepository, and the Processing Laboratory.
- **Data Manager:**  
Each SC may have a slightly different role for their Data Manager but the main responsibility for this staff member should be to monitor the processing of the study data. The Data Manager should work with the SC Coordinator to monitor all receipt, scanning, coding, editing, shipping, and general processing of study data.
- **Office Staff:**  
It is the responsibility of the office staff to assist the SC Coordinator with all SC activities. In particular, clerical staff may be employed to schedule appointments, receipt forms and specimens, operate optical scanning equipment, and to perform mailing and telephone follow-up activities.
- **Lead Medical Record Abstractor:**  
Each SC should have a designated Lead Medical Record Abstractor. The responsibilities of the Lead Abstractor will include staffing, training, quality assurance, and communicating with SC staff (Coordinator, PI, Collaborating Physicians) and the CC. It is the responsibility of the Lead Abstractor to monitor the results of the External Quality Assurance process and re-train staff as necessary. See the Medical Record Abstracting Quality Assurance (MRO) Plan ([APPENDIX L](#)) for more details on the External Quality Assurance process.
- **Medical Record Abstractor:**  
It is the responsibility of the medical record abstractor to:
  - ▶ Obtain the necessary medical records for all participants with a positive screening examination and/or diagnosis of a PLCO cancer;
  - ▶ Abstract information from the medical records onto the appropriate Diagnostic Evaluation and/or Treatment Information forms;

- ▶ Abstract information from the medical records onto the Other Cancer Form; and
- ▶ Obtain the TNM staging for each PLCO cancer diagnosed.
- ▶ The medical record abstractor should have knowledge of medical record terminology, anatomy, physiology and concepts of disease in addition to basic medical coding instruction. The abstractor must also have a minimum of 2 years on the job experience abstracting medical records. The abstractor should also be trained on the PLCO forms.

- **Nosologist:**

It is the responsibility of the nosologist to:

- ▶ Code medical diagnoses from the medical record or as reported by the physician using the ICD-9 CM and ICDO-2 coding schemes, and to code the TNM staging when it is not available in the medical record.

The nosologist (medical coder) should have a medical background, including knowledge of medical terminology, anatomy and physiology, and concepts of disease, in addition to basic medical coding instruction.

The nosologist should also possess one or more of the following credentials:

**For ICD9-CM coding (in order of desirability):**

1. Certified Coding Specialist (CCS) - This individual has obtained sufficient coding expertise either through education, experience, or a combination of the two to pass an advanced coding exam and become certified.
2. Accredited Record Technician (ART) - An ART has at least an Associate's degree in Medical Record Science and has passed an accreditation exam. This individual must meet ART continuing education requirements to maintain accreditation.
3. Registered Record Administrator (RRA) - An RRA has at least a Bachelor's degree in Medical Record Science, has passed a registration exam. This individual must meet RRA continuing education requirements to maintain registration. If a person is an RRA and is currently doing medical coding, then s/he may be qualified to conduct medical coding. If, however, an RRA is doing supervisory work, then s/he is may not be up-to-date on medical coding.

**For ICD-O coding and TNM staging:**

1. Certified Tumor Registrar (CTR or CTR-eligible) - A CTR is an individual who has passed the Certification Examination for Cancer Registrars which is offered by the National Board for Certification of Registrars (NBCR). To maintain a certified status, a CTR must meet current continuing education requirements of the National Cancer Registrars Association (NCRA). To be eligible to take the Certification Examination, an individual must meet *one* of the following requirements as of the test date:
  - ▶ Two years full-time equivalent experience in the cancer registry field.

- ▶ Successful completion of a college level curriculum in cancer data management/cancer registry, and a work experience component composed of 120 hours in a CTR staffed computerized cancer registry or 240 hours in a non-staffed CTR staffed computerized cancer registry.
- ▶ One-year full-time equivalent experience in the cancer registry field *and* successful completion of college level curriculum in medical records, nursing, or other allied health field.
- ▶ One-year full-time equivalent experience in the cancer registry field *and* credentialed or licensed status in a recognized allied health field as determined by NBCR.
- **Physician Consultants:**
  - It is the responsibility of the physician consultants to:
    - ▶ Provide advice and assistance to the examiners; and
    - ▶ Perform quality assurance checks of screening examinations.

### 17.2.2 Training/Certification of SC Staff

The CC is responsible for training the SC Coordinators in the protocol and procedures for conducting the trial. The primary reason for training the SC staff is to ensure that the protocol is clearly understood and that standard procedures are followed across all SCs. Central training sessions conducted by the CC offer the opportunity for hands-on practice with reference materials, data collection instruments, blood processing protocols and equipment, and computer hardware and software.

The CC conducted an initial training session for SC Coordinators prior to the start of the pilot study. The purpose of this training was to familiarize the SC Coordinators with the requirements of the study and the systems that were implemented to support SC activities. Installation and training on the computer systems took place after the initial SC Coordinator training, on-site. Each SC submitted a comprehensive training and certification plan to the NCI at the start of the study. Periodic retraining sessions have taken place since the main study began. Training sessions may also be targeted at specific groups such as medical record abstractors, data managers, or medical technologists. For example, in accordance with the MRQ Plan ([APPENDIX L](#)), the CC will hold an annual training/workshop for the medical record abstractors and nosologists.

The SC Coordinator has ongoing responsibility for training all staff on form use and administrative procedures. In addition, the SC Coordinator must arrange for training of non-physician medical personnel on the performance of the screening examinations. Training/certification requirements for examiners are described in the protocols for the screening examinations. The training and certification processes for medical record abstractors and nosologists are outlined in the MRQ Plan ([APPENDIX L](#).)

For each examiner or trainer, the SC Coordinator must submit a completed **Record of Experience, Credentials and Training (ECT)** ([Appendix A-17-5](#)) to the NCI for review. This documents the examiner or trainer's qualifications to perform screening examinations for the PLCO trial. For each medical record abstractor or nosologist, the SC Coordinator must submit a completed **Record**

of Credentials, Medical Record Abstractor and Nosologist Registration Form (CAN, [Appendix A-17-10](#)) to the NCI for review. Staff must be deemed qualified by the NCI before they may perform duties for PLCO.

### 17.2.3 Staff Identification Numbers

After a staff member has been trained (and certified, in the case of examiners) and approved by NCI, s/he will be assigned an identification number through the System Administration module of the SMS. The 4-digit ID number will allow the SC considerable flexibility in assigning blocks of numbers to certain types of staff, if desired. For example, the SC coordinator may wish to assign all examiners ID numbers which start with "1," all office staff ID numbers which start with "2," etc.

Each staff ID will be a unique identifier throughout the trial. This ID will be recorded on all study forms completed by the staff member. This ID, once assigned, *cannot* be deleted or reassigned to someone else. This is necessary in order to maintain the link between staff members and the study data they collected or processed.

In order to process PLCO examination data in the computer system, the examiner ID on each data collection form must be valid. If an error occurs and an examination is performed by a "non-PLCO" examiner, the occurrence is a protocol violation and should be reported as such (See [Section 17.14](#)). A non-PLCO examiner is any examiner for whom a Record of Experience, Credentials and Training (ECT) has not been submitted and who has not been approved by the NCI. In such situations, the non-PLCO examiner should be assigned a staff ID. The indicator "non-PLCO" should be entered as the position title for the examiner. The examiner should be prohibited from performing additional examinations until s/he is approved by the NCI.

The SC Coordinator will assign each staff member an ID number through the "Staff" option in the Administration module of the SMS. In the staff table, the staff member's position should be abbreviated as described in the list of staff positions in [APPENDIX G](#). If the staff member holds multiple positions, all of them should be recorded. The SC Coordinator will control the issuance of IDs and the level of system access allowed to each staff member. Some staff members may never directly use the system. Some may be assigned "read only" access. Others will have full access, including the ability to randomize participants in the trial. The level of access is controlled by the SC Coordinator through the assignment of an access code to the individual staff member. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for more information on assigning access rights.

The SC Coordinator will monitor staff ID assignment using the Staff Report ([Appendix B-17-1: Staff Report](#)). This report lists the staff ID, satellite center affiliation (if any), name and position. The SC Coordinator should update the Staff ID information to reflect changes in positions and the departure or arrival of staff members. After a staff member leaves the PLCO Trial, his/her Staff ID should be flagged (\*) as no longer active.

## 17.3 Overview of Computer Systems Provided by the Coordinating Center

Computer systems will be provided by the CC to support the following SC activities:

- Recruitment;
- Randomization;
- Receipt control of forms and samples;
- Data entry and editing of forms;
- Study management activities, including expectations, participant status and tracing;
- Shipping of samples and forms; and
- Transmission and receipt of data files between SCs, the CC, UCLA, NCS, McKesson, the Biorepository, and the Processing Laboratory.

The PLCO computer system, PLCOnet, is a network of four or more workstations, a server and two printers. PLCOnet will be used to support the above activities. Study management activities will be supported by the Study Management System (SMS). Data entry and editing of forms will be supported by the Data Entry and Editing System (DEES).

**Note:** In May, 2004 the conversion of the SMS to a newer software platform was completed at all SCs. Some modules providing functionality for phases of the PLCO study completed prior to the conversion were not included in this newer version of the SMS. These modules include:

- Tracking and Summarizing Recruitment (TASR)
- Randomization and Enrollment (RAND)
- Obsolete portions of the reporting functions of various modules

The SMS supports the following functions:

- **Forms and Specimens Tracking** – enables the SC staff to monitor receipts and shipments of forms and specimens, to follow a participant's progress throughout the trial, and to report the participant's status at any given time. Over the entire course of the PLCO Trial, thousands of forms and specimens of various kinds will be collected and managed by the SCs. This module provides the tools by which these forms and specimens will be counted and accounted for at any time throughout the trial. It will also fulfill the requirements specified for an expectation system detailing upcoming events and will provide reports on participant status and trial progress at the SC.
- **Management of SMS Telecommunications** – provides support for the transmission of SMS data to and from UCLA, the Biorepository, NCS, McKesson, and the Processing Laboratory.
- **Data Export** – provides for the export of selected data items to files which may be used by the SC to perform customized data queries or to produce customized reports.
- **System Administration** – provides for the assignment and tracking of staff IDs, passwords and access rights.
- **Reports** – enables the SC staff to generate Management and Production Reports, to generate various labels (PID, physician, address, participant address, specimen box #, institute, and cards) and to create user-defined reports against the SMS database.

DEES was designed to work with an optical scanner to convert forms into electronic data. Once the data are collected, SCs edit the data to ensure accuracy and then move critical elements of that data to SMS. DEES also supports the following functions:

- **Data Entry** – the manual entry of data that the scanner cannot read (e.g., verbatim data);
- **Data View** – the visual inspection and search for scanned data;
- **Data Editing** – the editing of the scanned data to identify missing or incorrect information and manual setting of final disposition;
- **Reports** – the management of:
  - scanned data using a series of reporting tools
  - user-defined or ad hoc reports
  - reprinting of previously-generated reports;
- **Data Export** – the export of the data to a variety of file formats, which can then be easily imported and analyzed in any database application; and
- **Update SMS** - the transfer of data from DEES to SMS.

The Network Administration module of PLCOnet supports the overall management of the computer network. It provides functions such as data backup to tape, telecommunications, virus checking, and disk review and repair.

Users manuals will be provided to the SC for each component of PLCOnet. These manuals will detail all capabilities and procedures for using the system and generating reports, listings and other documentation. These manuals are titled *Study Management System User's Guide*, *Data Entry and Editing System User's Guide*, and *PLCO Network User's Guide*.

## 17.4 Management of Data Collection Activities

For each participant, data collection activities will take place at baseline (T0) and then annually for approximately 13 additional years (T1-T13). Additional data collection will take place for participants who are diagnosed with cancer or who die during the course of the trial. The SC Coordinator is responsible for managing all data collection activities which were described in detail in Chapters 2 through 16 of this manual. The following sections provide an overview of the scheduling of data collection activities, making requests for information, and the procedures for documenting missing data and nonresponse.

### 17.4.1 Timeframe for Data Collection Activities

In each study year, a variety of activities requiring data collection will be conducted for participants in both the intervention and the control groups. The intervention participants will be asked to complete a screening visit in each of the first six years of the study, and all participants will be asked to complete questionnaires annually for approximately thirteen years. As noted above, data will also be collected for participants who are diagnosed with cancer or who die during the course of the trial. As described in [Chapter 6.0](#) and [Chapter 7.0](#), the “reporting period” for collection of baseline data is from randomization until one month past randomization. The “reporting period” for collection of follow-up data is from one month prior to the randomization anniversary date

to one month after the randomization anniversary date. In addition, there is a delinquency period after each window during which data may be collected, if necessary. The length of this delinquency period varies by study activity. For all non-screening study activities, the delinquency period extends until 3 months following the date of randomization or the randomization anniversary date. For screening activities in the T0 through T4 study years, the delinquency period extends until 6 months following the date of randomization or the randomization anniversary date. For T5 screening activities, this delinquency period extends a full 12 months following the anniversary of randomization.

#### **17.4.2 Data Collection Outside the Window**

The SC should make every attempt to ensure that participants complete study activities within the window. This includes randomizing intervention participants at a time when they will be available during the window for the six years of screening. Ideally, participants will be screened at 12-month intervals with the interval being within one month of the randomization anniversary date. If this is not possible, screens should be scheduled allowing no more than 12 months and no less than 6 months between each screen. The following guidelines are for scheduling screening depending on whether the participant expects to habitually be unavailable for screening during the reporting window.

1. If a participant is unable to be screened during the reporting window during a single study year, but would like to continue to be screened during the window in the future, the next visit(s) should be scheduled within the reporting window.
2. If a participant is unable to be screened during the reporting window in a single study year and is not sure of future plans, begin scheduling attempts at the beginning of the reporting window for the next study year. If it becomes apparent that s/he will not be available for screening during the window, then attempt to schedule the visit 12 months after the last screening visit.
3. If a participant has a change of plans after s/he is enrolled, insists on being screened outside the window and anticipates doing the same in the following years (such as a "snowbird"), try to screen him/her at approximate 12-month intervals instead of during the reporting window.

Note that the system cannot track individuals outside their window and a participant will show up on expectations reports in accordance with the reporting window that is based on his/her randomization date.

The following chart (Exhibit 17-1) lists the study activities. For each activity the associated forms and data collection timeframes are also listed.

#### **Exhibit 17-1: Overview of Data Collection Activities and Forms**

Type of Data Collection	Activity	Instruments/Forms	Timeframe for Data Collection
Recruitment Data Collection	Identify Potential Participants and Screen for Eligibility	Eligibility Screener	Effort Complete
	Obtain Informed Consent	Informed Consent Form	Effort Complete
Baseline Data Collection (T0)	Randomize/Enroll Eligible Participants	Eligibility Verification Form	Effort Complete
	Collect Baseline Demographic and Health History Data	Baseline Questionnaire (M/F) Baseline Locator Form Dietary Questionnaire (Intervention only) Diet History Questionnaire (Controls only)	Effort Complete (as needed)
	Perform Screening Examinations (Intervention only)	Participant Control Record Blood Collection Form/Blood Test Results (file) Digital Rectal Screening Exam Form Flexible Sigmoidoscopy Screening Exam Form Chest X-ray Screening Exam Form Transvaginal Ultrasound Screening Exam Form Comments Continuation Form	Effort Complete (as needed)
	Document Nonresponse	Missing Data Form Nonresponse Form	Effort Complete (as needed)
Annual Data Collection (T1-T5)	Collect Annual Health History and Update Locator Information	Annual Study Update Followup Locator Form (optional)	From 1 month prior to RAD** to 3 months past RAD
	Collect Contamination Assessment Information (Control and Intervention)	Health Status Questionnaire (HSM/HSW)	As determined.
	Perform Screening Examinations (Intervention only)	Participant Control Record Blood Collection Form/Blood Test Results (file), (T1-T5) Digital Rectal Screening Exam Form (T1-T3) Flexible Sigmoidoscopy Screening Exam Form (T5 only) Chest X-ray Screening Exam Form (T1-T3, T3=smokers and former smokers) Transvaginal Ultrasound Screening Exam Form (T1-T3) Comments Continuation Form	T0 – T4: From 1 month prior to RAD** to 6 months past RAD T5: From 1 month prior to RAD** to 12 months past RAD
	Document Nonresponse	Missing Data Form Nonresponse Form	From 1 month prior to RAD** to 1 month prior to next RAD
	Collect Dietary Data	Diet History Questionnaire (T3 Interventions only)	From 1 month prior to RAD** to 3 months past RAD

Type of Data Collection	Activity	Instruments/Forms	Timeframe for Data Collection
Annual Data Collection (T1-T5) (continued)	Collect Buccal Cell Sample (Control only)	Buccal Cell Collection Kit	0.1
	Ascertain Cancer Status of Participants:  Confirm Suspected Cancers	Prostate Cancer Diagnostic Evaluation Form Lung Cancer Diagnostic Evaluation Form Colorectal Cancer Diagnostic Evaluation Form Ovarian Cancer Diagnostic Evaluation Form Other Cancer Confirmation Form Comments Continuation Form	From report of possible cancer to 1 month prior to RAD**
	Collect Cancer Treatment Information	Prostate Cancer Treatment Information Form Lung Cancer Treatment Information Form Colorectal Cancer Treatment Information Form Ovarian Cancer Treatment Information Form Comments Continuation Form	Within 1 year of report of cancer
	Search Cancer Registries	Registries Search List (not yet implemented)	Annually
Annual Data Collection (T6-T13)	Ascertain Vital Status of Participants: Search National Death Index Acquire Death Certificates	NDI Search List  Vital Status Confirmation List	Every year  As needed
	Collect Annual Health History Update Locator Information	Annual Study Update Follow-up Locator Form (optional)	From 1 month prior to RAD** to 3 months past RAD
	Document Nonresponse	Missing Data Form Nonresponse Form	From 1 month prior to RAD** to 3 months past RAD
	Ascertain Cancer Status of Participants:  Confirm Suspected Cancers	Prostate Cancer Diagnostic Evaluation Form Lung Cancer Diagnostic Evaluation Form Colorectal Cancer Diagnostic Evaluation Form Ovarian Cancer Diagnostic Evaluation Form Other Cancer Confirmation Form Comments Continuation Form	From report of possible cancer to 1 month prior to RAD**
	Collect Cancer Treatment Information	Prostate Cancer Treatment Information Form Lung Cancer Treatment Information Form Colorectal Cancer Treatment Information Form Ovarian Cancer Treatment Information Form Other Cancer Confirmation Form Comments Continuation Form	Within 1 year of report of cancer

\* RD = Randomization Date

\*\* RAD = Randomization Anniversary Date

### 17.4.3 Requests for Information

Requests for information will be made to participants, physicians, and institutions throughout the course of the trial. There are ten types of requests that are supported by the SMS:

1. Requests to participants to complete the Protocol Changes Consent ([Chapter 3.0](#));
2. Requests to participants to complete the Etiologic Studies Consent ([Chapter 3.0](#));
3. Requests to participants to complete the Diet History Questionnaire (Chapters 5 and 6) **Note:** Requests to complete the Baseline Questionnaire, Baseline Locator Form, and Dietary Questionnaire are no longer available from the SMS;
4. Requests to participants to complete the Annual Study Update ([Chapter 7.0](#));
5. Requests to participants to complete the Follow-up Locator Form ([Chapter 7.0](#));
6. Requests to participants to complete the Health Status Questionnaire ([Chapter 7.0](#));
7. Requests to cancer registries to search for PLCO participants ([Chapter 8.0](#)) (not yet implemented);
8. Requests to hospitals and physicians for medical records ([Chapter 8.0](#));
9. Requests to the National Death Index for matches with PLCO participants ([Chapter 9.0](#));
10. Requests to state vital statistics offices for death certificates ([Chapter 9.0](#)); and
11. **Note:** Requests to control participants to complete the Buccal Cell sample collection kit is no longer available from the SMS ([Chapter 18.0](#)).

The SC Coordinator will use the Requests component of the SMS to generate lists of participants for whom these requests must be made. Each type of request is described below:

- **Requests to participants to complete the Protocol Changes Consent:**  
Participants will be included on the PCC Directive ([Appendix B-3-1: PCC Directive/Late Directive](#)) if they were randomized to the Intervention group before July 1, 1999.
- **Requests to participants to complete the Etiologic Studies Consent:**  
All participants will be asked to complete an Etiologic Studies Consent (ESC). Participants randomized prior to the 4.1 systems upgrade (March 1998) will appear on the ESC Directive ([Appendix B-10-6: ESC Directive](#)) after the 5.2 systems upgrade. Participants randomized after March 1998 will be included on an ESC Directive at the time of random-

ization. If a request was already made and three weeks have passed with no receipt of the requested information, a late directive ([Appendix B-10-6: ESC Directive](#)) can be generated which indicates which participants may require follow-up action. Mailing labels can be generated for repeat mailings, if needed.

- **Requests to participants to complete the Baseline Questionnaire, Baseline Locator Form, and Dietary Questionnaire:**

Participants will be included on a Baseline Directive ([Appendix B-5-1: Baseline Directive](#)) as soon as they are randomized into the trial. If the request for completion of the Baseline Questionnaire, Baseline Locator Form and/or Dietary Questionnaire has been made and three weeks have passed with no receipt of the completed forms, a late directive can be generated which indicates which participants may require some action (telephone call, repeat mailing). Mailing labels can be generated for repeat mailings, if needed. **Note:** Requests to complete the Baseline Questionnaire, Baseline Locator Form, and Dietary Questionnaire are no longer available from the SMS.

- **Requests to participants to complete the Annual Study Update:**

Participants will be included on the ASU Directive ([Appendix B-7-1: ASU Directive - Participant due for New Form](#)) if they are entering their activity window for study years T1 through T12. If a request was already made and three weeks have passed with no receipt of the requested information, a late directive ([Appendix B-7-2: ASU Directive - Late Respondents](#)) can be generated which indicates which participants may require follow-up action. Mailing labels can be generated for repeat mailings, if needed.

- **Requests to participants to complete the Follow-up Locator Form:**

Although administration of the Follow-up Locator Form is optional, the SC Coordinator may generate an FLF Directive ([Appendix B-7-7: FLF Directive](#)) to indicate which participants are entering their activity window for study years T1 through T13. If a request was already made and three weeks have passed with no receipt of the requested information, a late directive can be generated which indicates which participants may require follow-up action. Mailing labels can be generated for repeat mailings, if needed.

- **Requests to participants to complete the Health Status Questionnaire:**

Participants will be included on the HSQ Directive ([Appendix B-7-8: HSQ Directive](#)) if they have been randomly chosen for Contamination Assessment. If a request was already made and three weeks have passed with no receipt of the requested information, a late directive ([Appendix B-7-8: HSQ Directive](#)) can be generated which indicates which participants require follow-up action. Mailing labels can be generated for repeat mailings, if needed.

- **Requests to cancer registries to search for PLCO participants:**

The Cancer Registries Request List ([Appendix B-8-1: Cancer Registries Request List](#), *this report has not yet been implemented*) will be used to facilitate a cancer registry submission. It will include all participants for

whom the SC has not received a death notification or a confirmation of cancer. The list will contain participant identifiers likely needed for the submission. (Because one list is being provided for all SCs, it is possible that it may not meet the specifications of all cancer registries.) The list can be generated as a hard copy list or as an ASCII file. It is expected that requests to cancer registries will be made on an annual (or less frequent) basis.

- **Requests to hospitals and physicians for medical records:**

Each SC may develop a letter or form to be sent to physicians and hospitals to request medical records. A sample letter for this purpose is provided in [Appendix C-8-2](#).

The Medical Record Background Report ([Appendix B-8-2: Medical Record Background Report](#)) will facilitate the process of requesting medical records. This report (one per participant) lists participant and physician identifying information and information on the reported cancer which will be needed to request and review the medical record. It also lists any participant cancers listed on the Baseline Questionnaire. The report can be generated for participants for whom a cancer has been reported and/or cancer confirmation activities need to be carried out. For example, this report can show participants with outstanding Diagnostic Evaluation forms (DE), all cancer confirmation forms (OCF), and Treatment Information forms (TI). Additionally, the report can be completed for participants who have complete cancer confirmation activities.

- **Requests to the National Death Index for matches with PLCO participants:**

The National Death Index List ([Appendix B-9-1: National Death Index List](#)) will identify all participants eligible for inclusion in an NDI, or NDI+, death submission. This includes all participants whose vital status is unknown as of the date through which the NDI database is currently updated. It is expected that submissions to NDI will be made on an annual (or less frequent) basis.

- **Requests to state vital statistics offices for death certificates:**

See [Section 9.2](#) for details.

- **Requests to participants to complete the buccal cell sample collection kit:**

Control participants with signed ESCs will be selected to receive the Buccal Cell Collection Kit based on the selection criteria outlined in [Chapter 18.0](#), and will be included on the Buccal Cell Directive ([Appendix B-18-1: Buccal Cell Directive/Late Directive](#)). If a request was already made and three weeks have passed with no receipt of the buccal cell sample at the Biorepository, a late directive ([Appendix B-18-1: Buccal Cell Directive/Late Directive](#)) can be generated which indicates which participants may require follow-up action. (**Note:** Requests to complete the buccal cell sample collection kit are no longer available from the SMS.)

The SC Coordinator should determine the appropriate follow-up for each type of request. In general, two mailings should be followed by telephone contact if no response has been received. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for detailed instructions for using the Requests module.

#### 17.4.4 Documenting Missing Data

The SC Coordinator will complete a **Missing Data Form (MDF)** ([Appendix A-17-1](#)) when a participant is unable or unwilling to complete a study activity before the end of the activity window for that study year. This may be due to a variety of reasons such as participant refusal, inability to locate the participant, suspected death of the participant, etc. The MDF includes subcodes to document additional information about why the activity was not completed.

The Missing Data Form will be completed as follows:

- The SC identifying information will be recorded on the top of the form and the Participant ID label will be affixed to the form.
- The box for each form that will not be completed will be checked.
- The study year code (T0 - T13) will be recorded.
- The code indicating the main reason for the missing data will be recorded the appropriate subcode will also be recorded. The possible reasons are:

- 1 -Refused Procedure/Activity
- 5 -Can't Locate/Contact
- 6 -Out of Window
- 7 -PLCO Organ Removed
- 8 -Other (Specify)
- C -Reported PLCO Cancer
- D -Deceased
- E -Erroneous Report of Cancer
- F -Follow-up Colonoscopy Indicated
- R -Records Could Not Be Obtained

Specifications for the Missing Data Form are in [Appendix A-17-1](#)

- The subcodes indicate additional information for the missing data. For more information, refer to [Appendix A-17-1](#).

After the form has been completed, it will be receipted into the SMS. This will "turn off" system expectations for the data collection form that was marked for the study year that was marked on the MDF. The completed MDF should be filed in the participant's study file. See [Section 17.6.1](#) for information on receipting forms.

In situations where a MDF should be deleted from SMS (i.e., actual study form received or found or the MDF was completed in error), the SC should delete the MDF from SMS but keep the hardcopy MDF in the participant's folder. SC staff should document on the MDF why the MDF was deleted from SMS and initial and date the form.

## 17.4.5 Documenting Nonresponse

When a participant will no longer be participating in any aspect of the study that involves participant contact, such as screening visits and completing questionnaires, due to a medical condition, refusal, or because s/he is lost to contact, the SC Coordinator will complete a Nonresponse Form (NRF) ([Appendix A-17-2](#)). (It should be noted that such “lost” participants will continue to be involved in follow-up activities that do not involve direct contact such as National Death Index searches, Cancer Registry searches, death certificate acquisition, etc., unless the participant has withdrawn consent in writing.)

The Nonresponse Form will be completed as follows:

1. The SC identifying information will be recorded on the top of the form and the Participant ID label will be affixed to the form.
2. The reason for nonresponse will be checked and medical conditions, refusals and loss of contact will be described in detail in the space provided.
3. The effective date (i.e., date of refusal, etc.) will be recorded.

Specifications for the Nonresponse Form are given in [Appendix A-17-2](#)

If the reason for non-response is refusal, at the time of the refusal, the SC may attempt to collect data for a final Annual Study Update, even if it is in the middle of the participant’s study year. However, only one ASU should be completed per participant per study year (See [Chapter 7.0](#)). In addition, the ASU should be receipted into the SMS prior to receipting the NRF.

The Nonresponse Form should be completed at the discretion of the SC Coordinator, but its use should be minimized. It should only be used when there is no reasonable chance that the participant will be willing or able to participate in study activities in the future.

After the form has been completed, it will be receipted into the SMS. This will “turn off” system expectations for all activities that involve participant contact. The completed NRF should be filed in the participant’s study file. See [Section 17.6.1](#) for information on receipting forms.

## 17.4.6 Documenting a Participant’s Request to Withdraw from the Study

If a participant requests to withdraw from the PLCO study, the request should be honored. However, the SC should not take any action beyond what is specifically requested by the participant. The SC should have in place a process to prioritize refusals/withdrawals for refusal conversion. If the SC has thoroughly reviewed a case and has judged a refusal as irreversible, a Non-Response Form should be completed to indicate the participant’s category of refusal. The Non-Response Form will list 3 categories of refusal:

1. **No Active Contact with Participant:** The participant has refused to participate in all activities involving participant contact.
2. **No Passive Follow-up (or active contact):** The participant has refused to participate in all activities involving participant contact and has requested specifically that no additional information about him/her be collected.
3. **Participant Withdraws Consent – Remove Information from PLCO Files\*:** The participant has refused to participate in all activities

involving participant contact and has requested that no additional information about him/her be collected. The participant has requested, specifically in writing, that all information already collected be removed from the PLCO files.

(\*The SC should receive a request in writing from the participant for NRF level 3.)

Following completion of the Non-Response Form, it should be receipted into the SMS. Receipt of a Non-Response Form will automatically remove the participant from any future expectations for examinations, specimen collection or questionnaires. If the participant is already in the activity window for an exam or questionnaire, a Missing Data Form must be completed for all current activities.

Until further notice, it will be the responsibility of the SC to keep track of any participants with a Refusal Level 2. The SC should discontinue all follow-up of these participants. The SC should not attempt to collect medical records or tissue samples. The SC should not attempt to ascertain the participant's cancer or vital status. In addition to the Non-Response Form, Missing Data Forms should be receipted for all forms currently listed as outstanding (i.e. medical record abstracting forms, etc.)

Until further notice, it will be the SC's responsibility to send any Non-Response Form receipted with Refusal Level 3 to the SC Coordinator at the CC. The SC should send to the CC:

1. Photocopy of the Non-Response Form
2. Photocopy of the participant's letter requesting records be destroyed
3. Photocopy of the SC's letter to the participant confirming that the data will be returned/destroyed, etc.
4. Photocopy of the Participant Overview Report.

The CC will initiate procedures to delete the participant information from all PLCO data files in all locations. Upon completion of the data purging process, a written report will be sent to the SC Coordinator. It will be the SC's responsibility to remove all hard copy documents from the PLCO files and dispose of them as dictated by the SC institutional IRBs. NCI is also requiring that the SC keep a copy of all participant documents and return the originals to the participant. In the event that there is litigation the SC must have a copy of the signed informed consent and all subsequent documentation.

Note: If the participant has withdrawn permission for biospecimen storage, either as part of his or her withdrawal from the study or without withdrawing from the study, the SC must send notification in writing to the SC Coordinator at the CC. The CC will instruct the Biorepository and UCLA to destroy the participant's samples. Upon completion of this activity, the CC will submit a report to the SC Coordinator listing all destroyed samples. In addition, the SC should also destroy any of the participant's samples that had not yet been shipped to UCLA or the Biorepository.

Upon receipt of the Non-Response Form with a refusal level of 3 and/or memo from the SC, the CC will coordinate the deletion of data from any of the applicable sources below.

- **The CC will delete all data from SMS and DEES using the script written for deleting duplicate randomizations. The CC will**

**request that the SC send a copy of the report generated during the online session and to delete any Privacy Act data.**

- **The CC will delete all applicable data from any of the CC data collection efforts. Any relevant hardcopy forms will be retrieved and returned to the SC. These efforts currently include:**
  - ▶ Contamination Assessment (HSW, HSM and receipt control system)
  - ▶ Dietary Questionnaire (DQX)
  - ▶ Diet History Questionnaire (DHQ)
  - ▶ RNA pilot effort
  - ▶ DHQ/DQX pilot effort
  - ▶ Buccal Cell pilot effort
  - ▶ Death Review efforts:
    - Death Certificate Data File
    - Death Review Processing and Tracking System (DRPTS)
    - Cause of Death Questionnaire (CDQ)
    - Death Review Committee forms
- **The CC will coordinate the removal of all data and/or specimens from:**
  - ▶ IMS
  - ▶ UCLA
  - ▶ Biorepository
  - ▶ Processing Laboratory
  - ▶ NCS
  - ▶ Analytic Laboratories
  - ▶ Buccal Cell Kit Mailing Company

Upon completion of the tasks above, the CC will forward a summary report and any applicable hardcopy documents to the Screening Center.

## **17.5 Organization of Study Data**

The SC Coordinator has overall responsibility for maintaining participant files. The following sections describe record keeping and data security measures.

### **17.5.1 Record Keeping of Hard Copy Data**

Each participant in the study must have a file at the SC. This file will be used to store all documents related to the participant such as:

- Completed Eligibility Screener;
- Signed Consent Form(s);
- Completed Baseline Questionnaire;
- Completed Baseline Locator Form;
- Completed Annual Study Updates;
- Completed Follow-up Locator Forms;
- Completed Screening Examination Forms;

- Completed Participant Control Records;
- Screening Test Results Reports;
- Result Letters to Participant and Physician;
- DEES Screening Examination Report;
- Missing Data and Nonresponse Forms;
- Completed Medical Record Abstract Forms (Diagnostic Evaluation, Treatment Information and Other Cancer Form);
- Pathology report, if participant diagnosed with cancer;
- TNM Classification form, if participant diagnosed with a PLCO cancer;
- All medical record documentation for cancer confirmation or death verification, including autopsy report;
- Other medical documentation (x-ray films, ultrasound films, etc.);
- Death certificate, if participant is deceased;
- Reports of Adverse Events for NIH-Sponsored Clinical Trials (if applicable);
- Administrative Tracking Form (if a randomized ineligible);
- SC Report of Protocol Violation (if applicable);
- Tracing documents;
- Appointment records;
- Unused Participant ID labels and blood sample ID labels;
- Additional correspondence.

It is suggested that all correspondence, tracing documents, and documents supporting cancer and vital status determinations be labeled with the participant's ID. It is also suggested that files be organized in Participant ID order as many of the study forms will not have the participant name recorded on them.

Study documents and data may not be stored in the participant's regular medical record at any hospital or institution with which the SC may be affiliated. Copies of screening results, however, may eventually become part of a participant's regular medical record as a result of referral of the participant to a physician for follow-up of an abnormal screening result. Study documents will be kept for approximately two years after the end of the study and then destroyed.

Throughout the life of the PLCO Trial study forms have been and will continue to be revised to improve data collection and/or to reflect protocol changes. When new forms are distributed, it is recommended that the SC keep on hand about 25 of each of the "old" version forms. These old versions may be needed for the correction or transcription of previously completed forms or simply for reference purposes.

### **17.5.2 Storage of Computer System Reports**

It is recommended that computer system reports, in particular, edit reports, be stored according to the following guidelines:

- **TASR Production Edits (Session Edit Reports)** - at least 2 months (This effort is complete.);

- **SMS Intra-form Edit** - at least 2 months;
- **SMS Inter-form Edit** - at least 2 months;
- **SMS UCLA Blood Transmittals** - do not discard - these reports may be particularly valuable when investigating blood problems;
- **DEES Forms Scanned Report** - at least 2 months;
- **DEES Key Field Error Report** - at least 2 months;
- **DEES Duplicate Records Reports** - at least 2 months;
- **DEES Edits** - at least 2 months;
- **Buccal Cell Reports** – at least 2 months;
- **All reports created automatically during update to SMS from DEES (UPDSMS)** - at least 2 months; and
- **All reports generated by SMS upon download of UCLA data, especially “Errors on PSA/CA-125 Analysis File - Results Returned from UCLA with No Corresponding Vial to BCF Records” Report - do not discard** - these reports may be particularly valuable when investigating blood problems.

Refer to the system manuals and upgrade documentation for more information regarding these reports.

### 17.5.3 Data Security

All participant files must be maintained in a locked area at the SC. The SC Coordinator will control access to this area. In particular, documents containing participant name and social security number such as the Baseline Questionnaire, the Annual Study Update, the locator forms, death certificate, and the Study ID Assignment Report must be access controlled.

Some SCs may wish to use a mailing house to distribute recruitment or other PLCO materials such as newsletters. Any SC wishing to release participant information to a mailing house, must first obtain from the mailing house, a written statement assuring that participant confidentiality will be maintained. A copy of the statement should be submitted to the NCI and the CC. If the SC is providing a list or file of names and addresses of potential participants, without any data elements linking the potential participant to enrollment in the trial, it is not necessary to obtain an assurance of confidentiality.

Access to the study computer systems will also be controlled. As described above, each SC staff member will be assigned a four-digit ID. The SC Coordinator will be responsible for determining the level of access allowed for each ID. For example, examiners may only be given read access to the SMS and the DEES, data entry clerks may be given read/write access to the DEES but no access to the SMS, and other staff may be given varying levels of access to both the SMS and the DEES. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for instructions on restricting system access.

In addition, all data files can only be accessed through the CC-provided software. The software itself is provided in executable form only and cannot be modified by SC staff. Only selected data items approved by the NCI may be exported to files for internal use at the SC utilizing the Data Export option in SMS and DEES.

#### 17.5.4 Documenting Loss of Hard Copy Data

Loss of a hard copy data collection form is considered a violation of the PLCO protocol and should be reported as such on the SC Report of Protocol Violation ([Appendix A-17-7](#)). The following section describes the actions to be taken in the event of such a loss.

In the event that a completed data collection form is lost before it can be receipted and scanned, the following rules should be applied:

1. If there is a source document, such as a dictated report, a new data collection form should be completed from the source document. The new form should be receipted and scanned.
2. If there is no dictated report, but there is a chest x-ray, a TVU film, or an FSG videotape or photograph, the original examiner (interpreter) should review the film and complete the examination form. If the original examiner (interpreter) is not available, another examiner (interpreter) should review the film and complete the examination form. The new form should be receipted and scanned. If the result on the new data collection form is different from the original result given to the participant, the new result should be reported to participant and a Protocol Violation form should be completed.
3. If there is no dictated report, and no film, video or photo, the SC should contact the participant to reschedule the examination. (Or in the case of a lost Baseline Questionnaire or ASU, the SC should contact the participant to administer the questionnaire again.) Note: a lost dietary questionnaire (DOX or DHQ) should not be re-administered. The repeat exam should be considered the next sequential visit of the study year. The result of the repeat examination should be reported to the participant. If the participant will not repeat the exam, a MDF should be completed and receipted for the examination. (Or if the participant will not complete the questionnaire, an MDF should be completed). A Protocol Violation form should be also completed to document the loss of the original form. Please note: If an ASU is lost before double data entry is completed, that is, it has been entered only once, the data should be deleted from the SMS and the participant should complete a new form.
4. In the event that a participant gets follow-up from a report of a positive exam and an MDF has been receipted for the examination (because all study documentation was lost before it was scanned in DEES and/or receipted in SMS and the participant could not or would not repeat the examination), this should be indicated on the Protocol Violation form. The SC should update the participant's cancer status in SMS to "S" for suspected with a source code of "PVF". "PVF" indicates that an explanation of the source may be found on a protocol violation form.

If an ASU form is lost prior to completing double data entry and the form is less than one year old, it should be re-administered to the participant. If the form is older than one year, the SC should not attempt re-administration. Instead, a MDF should be filed for the missing form and a Protocol Violation Report ([Appendix A-17-7](#)) should be completed.

In the event that a data collection form has been receipted and/or scanned before it is lost, the form should not be recreated from SMS and/or DEES data. The SMS and/or DEES data should not be deleted or modified. A Protocol Violation form should be should be completed to document loss of the data collection form.

In the event that a data collection form has been receipted in the SMS but has not been scanned, a current version of the missing Op-scan form can be completed with the few variables that are already receipted in the SMS. The form can be scanned, edited and finalized with an FIC (Final Incomplete) disposition. The reason 'lost hard-copy after form receipted should be documented in the comment section of the exam form and entered into DEES. A Protocol Violation form should be completed to document loss of the data collection form.

In the event that an entire study file is lost, the SC should access the system to determine which forms have been receipted and scanned for the participant during each study year. A new file should be created and a Protocol Violation form should be completed. The Protocol Violation form should contain to the extent possible, a list of all lost forms. A new signed informed consent form should be obtained from the participant and placed in the new file.

## 17.6 Processing Study Data

The SC Coordinator has overall responsibility for the processing of all study data. For each study activity a form will be completed to indicate that the activity took place or that the data will not be collected for that activity. Some forms will be completed by SC staff (such as the screening examination forms and medical record abstract forms), and others will be completed by participants (such as the Baseline Questionnaire and the Annual Study Update). Some of the forms are "opscan," that is, they are specially printed and the data are scanned into the system using an Optical Mark Reader. These are the Baseline Questionnaire, screening examination forms, and medical record abstract forms. Some forms are "non-opscan," that is, they are plain paper (usually photocopied) data collection forms. These are the Annual Study Update, the locator forms and the administrative forms such as the Missing Data Form, Report of Adverse Events for NIH-Sponsored Clinical Trials, etc. Data from opscan forms must be entered into DEES and SMS; data from non-opscan forms are entered primarily into SMS.

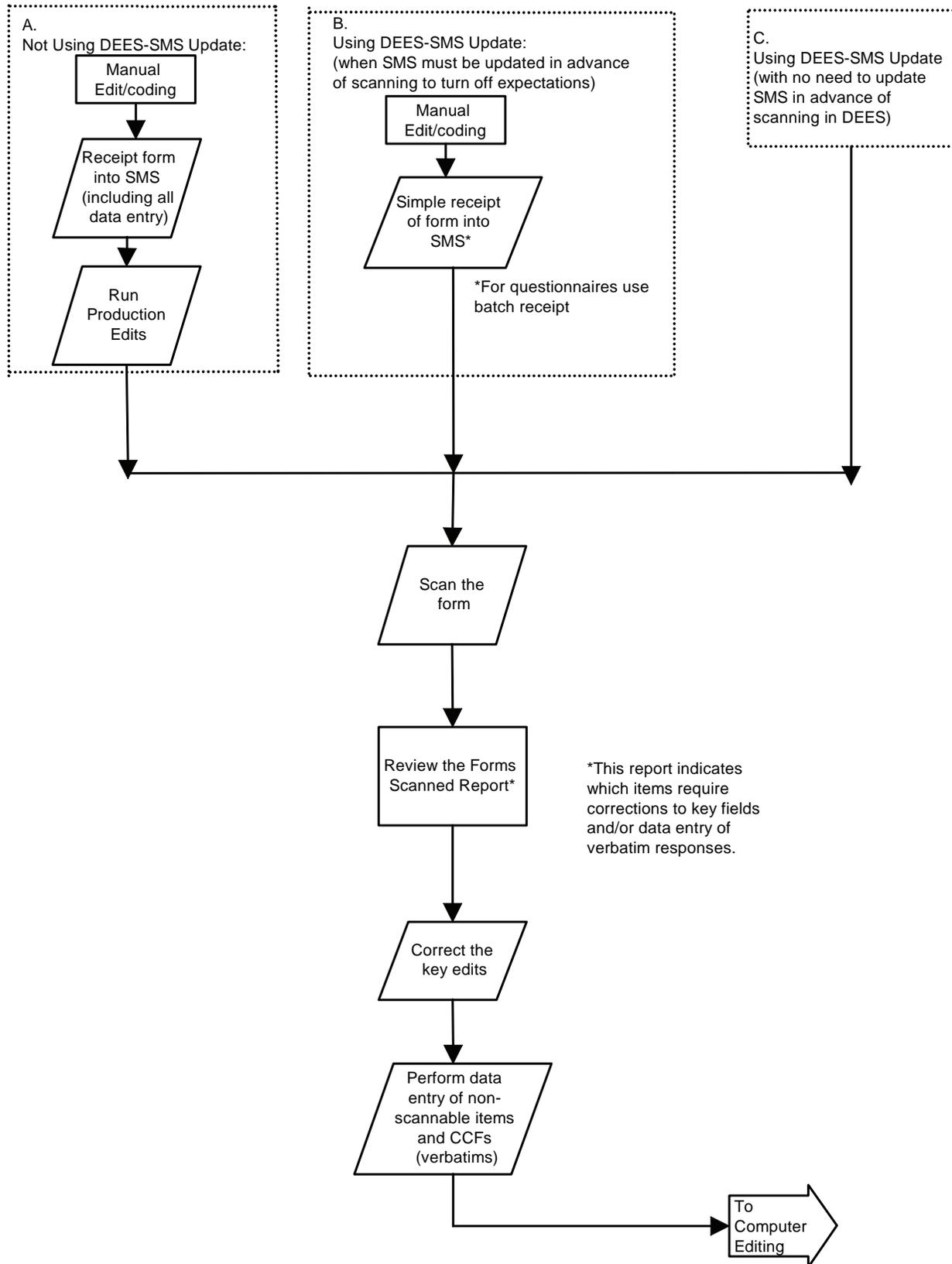
The major forms processing activities are as follows:

- **Manual edit (including coding)**
- **Receipt into SMS**
- **Scanning (opscan forms only)**
- **Data Entry of Non-Scannable Items (opscan forms only)**
- **Computer edit (SMS and DEES)**
- **Data retrieval**
- **Assignment of disposition code (final or interim - opscan forms only)**

These steps may be performed in several different orders, however it is recommended that opscan forms be scanned first, edited by the computer, finalized, and then receipted into the SMS using the DEES to SMS Update function.

This method is efficient and more accurate than keyed data entry into the SMS. The following flowchart (Figure 17-1) describes the processing of study data.

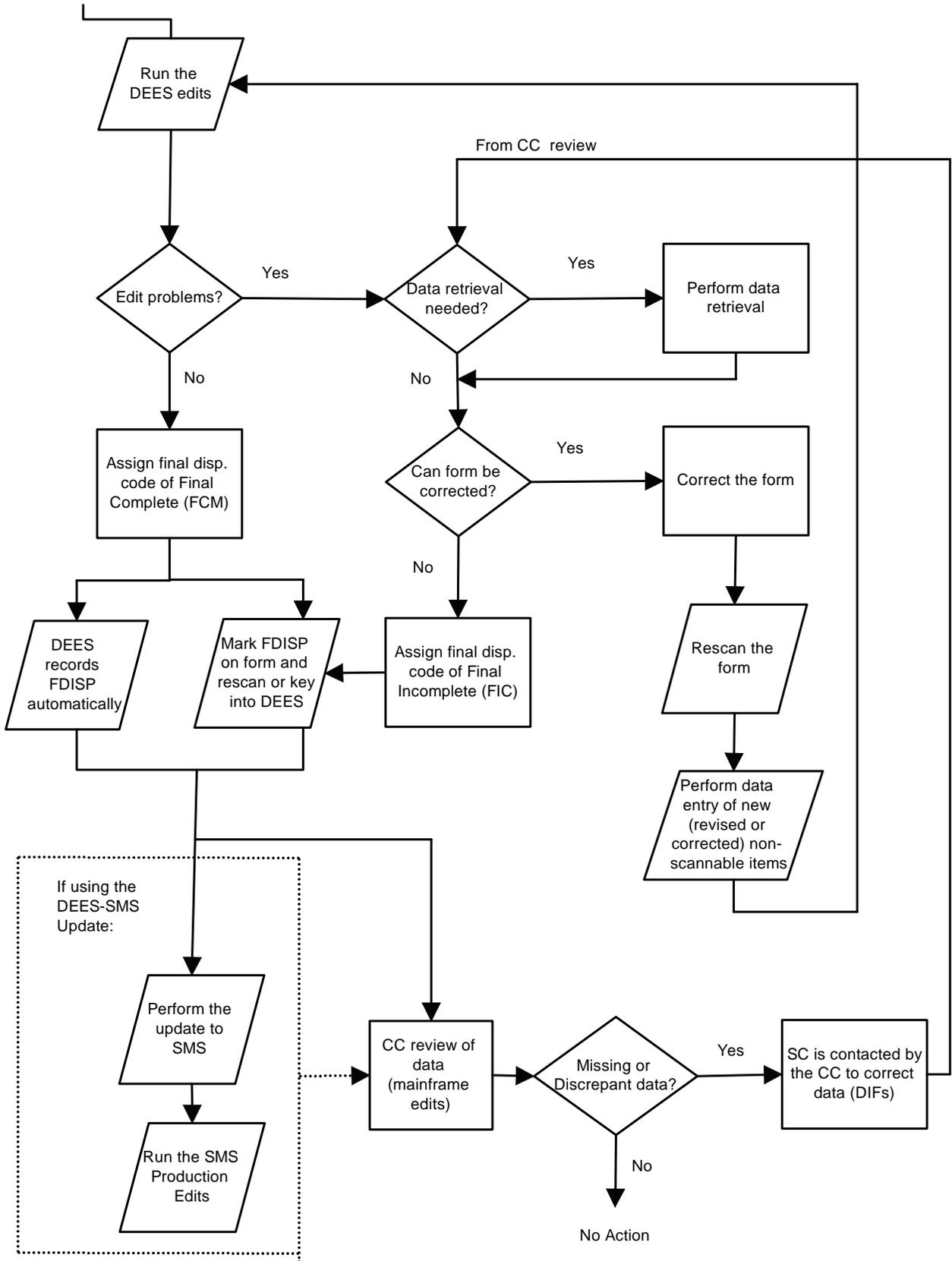
**Figure 17-1: Flow of Data Processing SMS Receipt and Editing / DEES Entry**



**Figure 17-1: Flow Chart of Data Processing (continued)**

From Receipt/Entry

**Computer Editing**



The administrative section of each data collection form includes the form processing items shown below in Figure 17-2.

<b>FORM PROCESSING</b>	
<b>(DARKEN CIRCLES AS STEPS ARE COMPLETED):</b>	
<input type="radio"/> Form Received into SMS	<b>Data Retrieval:</b>
<input type="radio"/> Manual Review Completed	<input type="radio"/> Attempted OR <input type="radio"/> None Required
<b>Data Entry of Non-Scannable Items:</b>	<b>Final Disposition:</b>
<input type="radio"/> Completed OR <input type="radio"/> None Required	<input type="radio"/> Final Complete (FCM) OR <input type="radio"/> Final Incomplete (FIC)

**Figure 17-2.** Administrative Section of Data Collection Forms

The SC staff may use these circles to mark the form processing steps as they are completed. The use of the form processing check boxes (with the exception of final disposition) is optional; they are provided as a tool for SC staff to see, at a glance, the processing status of each form. (See [Section 17.6.6](#) for a discussion of assigning final disposition).

The following sections contain an overview of each step in the processing of PLCO forms.

### 17.6.1 Manual Editing

Manual editing involves two main steps: (1) reviewing the form to check for legibility, completeness and consistency; and (2) making changes to the form after the review and/or data retrieval. The following are guidelines for manual editing:

1. Review the form for completeness and legibility.
2. Make any changes that do not require data retrieval.

#### **On opscan forms:**

- ▶ Make sure that the circles are *completely* blackened with a #2 pencil or a pen. Make sure that there are no check marks (instead of blackened circles). Darken any bubbles that are too light.
- ▶ Make sure that there are no stray marks near the answer circles. Any writing should be no closer than 1 inch from the answer categories. Make notes in the white space away from answer categories.
- ▶ If a change to an opscan bubble is needed, circle the original bubble in red, erase or "white-out" the original bubble, re-mark it in red, and mark the corrected bubble in pencil or pen, regardless of whether the participant used a similar pencil or pen on the other bubbles on the form. Mark your initials and the date next to the item.
- ▶ The SC should attempt to correct any errors where the participant or examiner has neglected to zero-fill a number (e.g., changing "7" to "07" in a two-column field), without performing data retrieval. If a "zero-fill" error on a critical data item cannot reasonably be corrected without contacting the participant or the examiner, then data retrieval must be performed.

3. Review the critical data items to determine whether or not they require data retrieval.
4. Perform data retrieval and annotate the form as follows:

If the item in question was left blank and, upon data retrieval, the participant or examiner is unwilling or unable to supply the data, leave the item blank, and mark your initials and the date near the question.

If the item in question was left blank and, upon data retrieval, the participant or examiner supplies the data, complete the item and mark your initials and the date near the question.

- ▶ If the new data involve an opscan bubble, you may mark the bubble in pencil or pen, regardless of whether the participant used a similar pencil or pen on the other bubbles on the form.
- ▶ If the new data involve a verbatim response, record the data in another color ink or pencil from the participant's original response.

If the item in question was completed incorrectly (e.g., an incorrect examination result) or required clarification, and the participant or physician supplied different or additional data, make the changes as follows and mark your initials and the date near the question.

- ▶ If the changes involve an opscan bubble, circle the original bubble in red, erase or "white-out" the original bubble, re-mark it in red, and mark the corrected bubble in pencil or pen, regardless of whether the participant used a similar pencil or pen on the other bubbles on the form.
- ▶ If the changes involve a verbatim response, using another color ink or pencil, cross out the original verbatim response with one line and write the corrected response near it; original verbatim responses should never be erased.

The specifications for the data collection forms should be consulted, as necessary, during manual editing. All changes to individual items on data collection forms should be initialed and dated. Any erasure or change that has not been initialed or dated will be considered a participant/examiner change.

#### **17.6.1.1 Coding**

Some data collected during the trial will be coded by the SC. Coding involves assigning a numeric code to verbatim responses or classifying responses into specified categories. The SC may wish to write these codes in another color ink directly on the data collection form. Many of the codes may also be selected from an on-line lookup table during the SMS receipt process. The following data will be coded:

- **Reported Cancers:**

Cancers reported on the Baseline Questionnaire (items 21 and 30), Other Cancer Form (item A.12) and the Annual Study Update (item 2) will be assigned 3-digit numeric codes by SC staff. The list of cancer codes is included in [Appendix I: Cancer Codes](#). When the form is receipted into the SMS, the code will be entered. In addition, if an "other" response is reported the verbatim will be entered.

- **Family Relationships:**

Relationships of family members with cancer that are reported on the Baseline Questionnaire (Q.21) will be assigned 2-digit numeric codes by SC staff. The list of relationship codes is included in [Appendix I: Cancer Codes](#).

- **Place of Birth:**

The participant's place of birth will be coded into a two-digit numeric. The list of location codes is included in [Appendix I: Cancer Codes](#).

- **Other responses:**

Occasionally, the participant may write out a response that is more appropriately ascribed to one of the coded categories. If the response that the participant has written in the margin matches one of the responses for a related question but is phrased differently, blacken the appropriate circle under the related question. The definition for each response to a given item is given in the form specifications.

For example, on the Baseline Questionnaire, if the participant writes, "I don't know" in the margin of a question in which "Don't Know" is a response category, blacken the circle next to "Don't Know."

The specifications for the data collection form will include the appropriate coding rules and should always be consulted when coding.

#### **17.6.1.2 Maintaining a Coding Decision Log**

A coding decision log should be maintained by the SC. The purpose of the log is to document all coding decisions made at the SC that are not covered in the coding rules outlined in the form specifications or in the PLCO Screening Trial Decision Logs.

Coding decisions are made when the SC changes a participant's response to a question, *without doing data retrieval to clarify the response*. If the SC makes a change based on an established rule (as given in the specifications or a subsequent PLCO Screening Trial Decision Log), it is not necessary to record it in the Coding Decision Log. If a change is made that is not guided by an established rule, it must be documented in the log.

The CC has developed a standard Coding Decision Log ([Appendix A-17-3](#)) which documents the following items:

- Sequential decision number;
- Participant ID;
- Today's date;
- Form ID;
- Data item;
- Participant response; and
- SC-determined response/code.

This log may be modified by the SC, however, the SC may only add additional data items to be collected; the items listed above may not be deleted from the log.

For example, on the Baseline Questionnaire - Female, Question 51 asks about the use of female hormones. If the participant wrote, "I take premarin" in the margin and did not darken any of the response circles, the SC may decide to darken the circle for "Yes," since Premarin is a female hormone. In this situation, the Coding Decision Log might look as follows:

Participant ID	Date	Form Code	Data Item	Participant Response	SC Determined Code
430000-1	12/4/93	BQF	51	"Took Premarin"	Recorded a Yes (2) response since this is estrogen therapy

After a review of the SC Coding Decision Logs, if the NCI determines that the way the SC coded a response was incorrect or inconsistent with other SCs, the SC will be responsible for cleaning the data from all affected participants. The Coding Decision Log will provide a list of the IDs of all participants who were subject to this change.

### 17.6.2 Data Retrieval

Data retrieval is the process of recontacting or revisiting the source of the information (participant, examiner, physician, laboratory, medical record, etc.) to obtain missing or incomplete information and to clarify confusing information. See [Chapter 6.0](#) for detailed information regarding data retrieval for the Dietary Questionnaire (DQX) and the Diet History Questionnaire (DHQ.) For detailed information about Health Status Questionnaire (HSQ) data retrieval, see [Chapter 7.0](#).

On the Baseline Questionnaire and Annual Study Update, a subset of the items on the form(s) are designated by NCI as "critical." Data retrieval is required for critical data items that are incomplete, unclear or not answered. If time and resources permit, data retrieval may also be performed for those items designated by NCI as non-critical. On the examination forms all items (except those related to forms processing) are considered critical. Critical data items will be identified on the specifications for the data collection form and, for Baseline Questionnaires, they will be identified on the DEES edit report.

Data retrieval from participants will involve contacting participants (usually by phone) to clarify their responses to critical data items. Data retrieval on non-critical data will be at the discretion of the SC Coordinator. Data retrieval should not be directed to the participant's physician, nor should the SC access medical records to obtain answers for items on the Baseline Questionnaire or Annual Study Update.

Although critical data items requiring data retrieval on questionnaires may be identified during the manual edit, to reduce participant burden, it may be preferable to wait until the computer edit ([Section 17.6.5](#)) is complete and all data retrieval items are identified, before attempting data retrieval. For examination forms, it is preferable to identify data retrieval items during the manual edit so that they may be resolved with examiners before or very soon after the participant leaves the clinic. It is not advisable to perform data retrieval on screening examination forms more than a few days after the examination is completed.

There are no requirements for the number of attempts that must be made to contact a participant for data retrieval on a Baseline Questionnaire or an Annual Study Update, and the SC Coordinator may set guidelines for how many attempts will be made to contact participants for data retrieval. The following are some suggested guidelines:

- At least 5 attempts are made to contact a participant by telephone.
- Each call is placed on a different day of the week, Monday through Friday.
- If possible, two additional calls are placed, one on Saturday, and one on Sunday.
- The first and last calls are separated by at least one week.
- The calls are made at different times each day, morning, afternoon and evening.

After data retrieval is performed, if the SC is using the optional form processing items, the data retrieval item may be completed. If data retrieval was attempted, whether successful or not, the circle marked "Attempted" should be darkened. If no data retrieval was required, the circle marked "None Required" should be darkened.

### **17.6.3 Receiving Forms and Specimens**

All study forms must be receipted into the Entry module of the SMS in order to indicate to the system that the activity was completed. Receipting involves entering the form type, the Participant ID, and key information contained on the form, into the SMS. For certain study forms, which represent activities that have been completed, only the ability to view already-receipted information is available from the SMS.

For all participants, both intervention and control, the forms to be receipted include:

- Eligibility Verification Form (view only)
- Baseline Questionnaire (view only)
- Locator Forms (Baseline - view only - and Follow-up)
- Diet History Questionnaire
- Annual Study Update
- Medical Record Abstract Forms
  - ▶ Diagnostic Evaluation Form
  - ▶ Treatment Information Form
  - ▶ Other Cancer Form
- Death Certificate
- Missing Data Form
- Nonresponse Form
- Administrative Tracking Form
- Etiologic Studies Consent
- Health Status Questionnaire (HSM/HSW - [Appendix A-17-8/Appendix A-17-9](#))

The following forms should be receipted for intervention participants only:

- Screening Examination Forms, including Blood Collection Form(s)
- Participant Control Record (view only)
- Dietary Questionnaire (view only)
- Protocol Changes Consent

Specimens will also be receipted into the SMS. A blood sample ID label will be affixed to the Blood Collection Form and will be entered when the Blood Collection Form is receipted. Blood test results will be receipted from data files transmitted electronically from UCLA. Returned buccal cell kits will be receipted from data files transmitted electronically from the buccal cell kit mailing company. (See [Chapter 18.0](#) for more information regarding the buccal cell collection procedures.) In the future, the SMS will be modified to allow receipt of pathology slides.

Non-opscan forms will be receipted via keyed data entry directly into the SMS. Opscan forms may be receipted via keyed data entry into the SMS, or via the DEES to SMS update. Both of these methods are described in the following sections.

#### **17.6.3.1 Receipt via Keyed Data Entry into SMS**

The following steps will be performed for keyed SMS receipt:

- The user will select the type of form or specimen from a menu and will be prompted to enter some key information from the form.
- The following key information from the top of each form, will be entered into the SMS for all forms
  - ▶ Participant ID (wand bar-coded label or type into the system);
  - ▶ Study Year (T0-T13);
  - ▶ Form Completion Date;
  - ▶ Receipt Date (defaults to today's date if not entered).
- Additional elements may be entered from some forms although the majority of data will be scanned using the Optical Mark Reader and will be handled by the DEES.

Forms of the same type may be batched and receipted at the same time to reduce keying errors and promote efficient use of the system. Although most forms must be receipted individually, some forms, such as consent forms and Eligibility Verification Forms, may be receipted into the system in batch. In batch, all identical receipt information will be entered once, followed by entry of individualized information such as Participant ID. (**Note:** Batch receipt is no longer available from the SMS.)

After forms and specimens are receipted, the participant's status will be automatically updated in the system and the next set of expectations (i.e., the next data due to be collected) will be generated for the participant. Each form that is receipted will affect the system's expectations for that participant. Refer to the *SMS User's Guide/SMS Upgrade Documentation* for more information on the expectations built into the SMS.

#### 17.6.3.2 Receipt via the SMS Update function

Receipt of data via the Update SMS Function is recommended because it is efficient and accurate. In order to receipt forms via the Update SMS, the user must first scan, edit and finalize a batch or several batches of opscan data collection forms. (See Sections 17.6.4, 17.6.5, and 17.6.6 below). The user will then select the Update SMS function from a menu in DEES and the valid data will automatically be updated to SMS. Any invalid data or data relating to blood vials that have already been shipped, will not be updated. Valid data from DEES that are successfully transferred will overwrite any data that are in the SMS. The user will be notified of updates to the Participant Control Record (PCR) which may affect reporting of examination results or to the participant's cancer status which may affect medical record abstracting and subsequent screening. If a PCR has not been receipted in the SMS for a specific participant, study year and visit, successful transfer of examination data from DEES will cause the PCR record to be created in the SMS.

### 17.6.4 Optical Scanning and Data Entry

All study op-scan forms will be scanned into the Data Entry and Editing System (DEES). Any data that are non-scannable (such as verbatim responses) will be keyed into the system. If an opscan form is damaged so that it cannot be scanned, the information from the damaged form should be carefully copied to a new form. It is recommended that a second person proof the copy before the copy is scanned. Both the copy and the original should be kept in the participant's study file.

Detailed instructions for operating the Optical Mark Reader and for data entry are given in the *DEES User's Guide*.

### 17.6.5 Computer Editing

After the forms have been scanned, the user may run one or more programs to edit the data for each form by doing range and logic checks to identify illogical, discrepant or missing data. The system will then print an edit report, generated by form type. As noted in [Section 17.5.2](#), it is recommended that these edit reports be stored for at least 2 months because they are often useful for problem investigation.

The edits should be carefully reviewed and updates made, as appropriate. It is required that all errors in the data involving critical data items be resolved through data retrieval (see [Section 17.6.2](#)). Any changes to be made to the data collection form as a result of the computer edits should be marked directly on the original form (as described in [Section 17.6.1](#)) and the form should be rescanned. After a form is rescanned, the computer edit should again be generated. Once the SC Coordinator is satisfied that the form is as clean as possible, a final disposition code (final complete or final incomplete) can be assigned.

It may not always be possible to correct the errors flagged by the DEES edit programs. An edit is intended to be a signal to the SC to investigate and determine the cause of the error. If, for example, the examiner simply could not ascertain a piece of information and left it blank on the form, a DEES error will be generated, but will not be able to be fixed, and the form should be coded with a disposition of "Final Incomplete" (See [Section 17.6.6](#) below). If, on the other hand the examiner did not follow a skip pattern correctly, the DEES errors should alert SC staff to contact the examiner to correct the form.

## 17.6.6 Assigning the Form Disposition

The SC is required to assign a disposition to each opscan form. There is one interim disposition and two final dispositions:

- **Interim Complete (ICM):** This disposition is available on the medical record abstract forms only. This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.)
- **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
- **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

1. by darkening the bubble on the opscan form and scanning it;
2. by keying the disposition into DEES;
3. by allowing the computer to assign the final disposition for forms with no errors (FCM only).

Note that with the installation of SMS Version 2.04, the DEES automatically assigns the disposition "Final Complete" (FCM) to each op-scan form that passes all edits. For forms scanned and edited after the SMS 2.04 upgrade was installed, it is not necessary to darken the Final Disposition circle in the Form Processing box on those forms that have been assigned a Final Complete (FCM) disposition by DEES. However, the Final Disposition field should be completed on all Final Incomplete (FIC) forms. All opscan forms scanned and edited prior to the installation of SMS Version 2.04 should have the final disposition marked on the form, even those forms for which the final disposition was keyed rather than scanned.

It is not advisable to finalize a form after making any type of change to the data (such as a verbatim) without running edits a final time. Although it may be unlikely, it is possible that a data entry error could be made while keying data (e.g., entering a verbatim in the wrong place) or the scanner may not perform in the same way it did previously and the data scanned may not be identical to what was scanned before. The edits will hopefully alert data management staff to any problems that result from data changes.

## 17.7 Shipping

Throughout the study, specimens and documents will be shipped in bulk from the SC to outside institutions including the CC, UCLA, the Biorepository, the Processing Laboratory, the pathology slide repository at the NCI, National Computer Systems (NCS), and the buccal cell kit mailing company - McKesson

Bioservices, Inc. The SMS supports shipping activities by providing transmittals to accompany shipments and a means of tracking what has been sent. An overview of these shipping activities is given below. These shipping activities are also discussed in the relevant previous chapters of this manual. (See [Chapter 6.0](#) for more details regarding dietary questionnaire (DOX/DHQ) shipments, [Chapter 7.0](#) for Health Status Questionnaire (HSQ) shipments, [Chapter 9.0](#) for Death Review materials shipments, and [Chapter 10.0](#) for blood sample shipments, and [Chapter 18.0](#) for buccal cell shipments.)

### **17.7.1 Shipping Blood Samples**

Blood samples collected from the intervention participants will be shipped to the central laboratory at UCLA for CA-125 and PSA testing, to the Biorepository for long term storage and eventual assays associated with adjunct studies, and to the Processing Laboratory for processing and long term storage (see [Chapter 10.0](#)).

Shipping to UCLA will be done on a weekly basis. Once a week, the SC Coordinator will generate a transmittal form for blood samples from the Shipping module of the SMS (See the *SMS User's Guide/SMS Upgrade Documentation*). All samples which were receipted without problems (that would prevent shipping) during the previous week will appear on the transmittal as available/due for shipment. The SC staff will locate and batch the blood vials according to the transmittal. If a specimen cannot be located, has been destroyed, or other problems are identified that will prevent shipping, the shipping clerk will cross the sample ID off the transmittal, remove the shipping date from the SMS and enter a problem code. At this point, a corrected transmittal should be generated. The SC Coordinator will retain one copy of the transmittal and send one copy to UCLA with the specimens. The specimens will be packed and shipped according to the specifications in [Chapter 10.0](#) of this manual.

Shipments to the Biorepository will be done at least once per month and will be handled in the same manner as shipments to UCLA, with a computer-generated transmittal being produced by the SMS. Shipments to the Processing Laboratory will be done daily and will be documented using a transmittal that is maintained manually. See [Chapter 10.0](#) for more information on the shipping of blood samples.

### **17.7.2 Shipping Pathology Slides**

Procedures for shipping pathology slides are under development.

### **17.7.3 Shipping Dietary Questionnaires**

At baseline, intervention participants will complete the Dietary Questionnaire (DOX) and starting in December 1999 control participants will complete the Diet History Questionnaire (DHQ). Starting July 1, 2002, completed dietary questionnaires (DOX) will be shipped to Westat for optical scanning. As with other shipments, a transmittal will be generated listing all receipted questionnaires not previously shipped. One copy of the transmittal will accompany the shipment and the second copy will be filed at the SC. Note: The SC should always generate the DHQ and DOX transmittals *prior* to the monthly data transmissions to the CC. This way the data delivered to the CC will be current,

listing the dietary questionnaire receipts and shipments. See [Chapter 6.0](#) for additional details on shipping dietary questionnaires. (**Note:** Shipping of the Dietary Questionnaire is no longer available from the SMS.)

## 17.8 Transmission of Data to the Coordinating Center

The SCs will transmit data to the CC on a monthly basis using the Zip Drive Data Transmission options in the Administration module of PLCOnet. When the data transmission application is run, the system will automatically compress and save SMS and DEES data files on a secure Zip disk attached to one of the workstations at the SC. The SC then mails the disk overnight FedEx to the CC for processing. Certain information including names, addresses, social security numbers, physicians and hospitals will not be transmitted. Refer to the *Network User's Guide/Telecommunications* for instructions for sending monthly data transmissions.

Prior to the beginning of each calendar year (January-December), a schedule for data transmission to the CC will be sent by the CC to the SC. Prior to 2002 data transmission was sent according to the study year schedule (October-September).

The CC will perform quality assurance checks of the data received from the SCs and will notify the SC Coordinator of any problems with the data (see [Section 17.15.2](#) below).

## 17.9 Coordination of Data Collection and Reporting in Satellite Centers

A number of SCs have satellite centers where randomization and screening activities take place. It is crucial that the collection and reporting of data in these centers be coordinated with the main center. There are three types of SC activities which must be coordinated between the main and satellite centers: (1) randomization and enrollment of participants, (2) processing and storage of forms and specimens, and (3) status reporting.

Since the main center will house the PLCO computer network that is used for randomization, the satellite centers must call the main center to confirm eligibility and randomize participants. Participant ID labels will be distributed in advance of randomization to each of the satellite centers (see [Chapter 4.0](#)).

All SCs with satellite centers must record satellite center ID on all forms which contain a field for collecting this information (such as Baseline Questionnaires, Medical Record Abstracting forms, and exam forms). All data collection forms and specimens must be receipted and entered into the SMS and the DEES which are located at the main center. It is strongly suggested that all completed participant study forms be stored centrally at the main center after they are entered into the computer. Forms completed at satellite centers should be mailed to the main center for data entry and storage. The satellite centers may want to set up study folders for each participant at the center to store Participant ID labels, blood sample ID labels, forms in process, and copies of completed forms. Blood samples may be stored at each satellite center and shipped on dry ice separately to the laboratory, provided a freezer is available to store the samples at -70 degrees and staff is available to ship the samples to UCLA, the Biorepository, and the Processing Laboratory. If this is not possible, the samples should be mailed or hand carried to the main center (either

on dry ice if already frozen or within four hours of collection) where they will be included with other samples for shipment. Currently, the SMS does not provide separate transmittals for satellite centers.

Periodically, the satellite centers will require status information regarding study activities for participants seen at their center. Status reports will be generated from the SMS at the main center and sent to the satellite centers as needed. The ad hoc report and data export features of the system may be used to generate reports sorted by satellite center.

## 17.10 Managing Participant Transfers

Only intervention participants may be transferred from one SC to another. Control participants who relocate should be followed by mail at their new address. If an intervention participant wishes to relocate to a new SC area and wishes to continue to participate in the trial, the following steps should be taken to complete the transfer:

1. The participant must sign a new consent form to be provided by the new SC. If the participant has already signed an Etiologic Studies Consent (ESC), s/he will not have to sign a second ESC at the new SC. In these circumstances the ESC expectations and receipt issues will be updated and transferred to the new SC.
2. All data collection forms that are in process should be completely processed, cleaned and finalized before the transfer is initiated. Once this has been completed, the SC should generate the Participant Overview Report (POR) ([Appendix B-17-10: Participant Overview Report](#)).
3. The signed consent form, copies of all hard copy records, the Participant Overview Report and several sheets of the individual's Participant ID labels should be sent with a cover memo from the old SC to the new SC. The cover memo should include the participant's PID number, randomization date and whether or not they have been screened for the current study year. The letter should document the plan for the participant or the SC to complete any outstanding expectations listed on the Participant Overview Report. The letter should also explain the circumstances of the transfer, including the participant's new location, and his or her attitude toward the trial. Copies of the cover memo and the Participant Overview Report should be sent to NCI and to the CC. The SC should ensure that all participant identifiers (i.e., name and address) have been deleted on the Participant Overview Report (black magic marker or white out can be used).
4. When the CC receives the memo describing the transfer, the CC will contact both SCs and will move selected SMS computer records from the originating SC to the receiving SC. The CC will contact the originating SC to resolve any outstanding forms documented on the Participant Overview Report prior to completing the transfer process in the study management system. The originating SC should not receipt any additional forms for the participant once the CC has completed the transfer process in the SMS. If any forms are received by the originating SC, the originating SC should coordinate with the transfer SC and the CC regarding the receipt of the additional forms. If the participant transfers at the beginning of a study year, there will be open expectations for that study year. The originating SC should not receipt any Missing Data

Forms to address open expectations that will be handled by the destination SC. Receipting of Missing Data Forms may result in a conflict of the particular activity status for the transfer participant. The CC will automatically mark the participation status field in the SMS as PT (participant transferred) at the originating SC and AP (added participant) at the receiving SC. This will effectively remove the participant from all expectation reports produced by the originating SC for subsequent study year activities. All transfer participants' PIDs will remain constant throughout the trial and will not change.

5. Once the consent, copies of forms and cover letter are received at the new SC and the appropriate files have been transferred, the new SC can initiate contact with the participant to administer questionnaires or schedule screening exams, as necessary.
6. Participants who return to their original SC are then assigned a status of RT (return transfer.) In these cases the SC must manually track all expectations, as the system does not support returns.

Note that if a participant wishes to transfer to another SC, the new SC should accept the transfer, unless justifiable reasons for not accepting the transfer are provided.

If a transfer participant requires death or cancer confirmation, the SCs involved should contact the CC MRA Coordinator to discuss the appropriate method of record collection and forms completion. It will be very important for both SCs to work together and cooperate with each other to ensure the best data collection for transfer participants. The timing and location of the participant's death or cancer diagnosis/ treatment will play a part in determining which SC should conduct the followup and complete the appropriate forms. In most cases, the originating SC will be expected to collect the appropriate records then forward them to the new SC for abstraction and forms completion. Note: Regardless of the circumstances, once the forms are completed and ready for receipt, they will have to be receipted/scanned at the SC where the participant is currently active.

## 17.11 Monitoring Data Collection Activities

Throughout the study, the SC Coordinator will be responsible for monitoring all data collection activities. This will be done using reports generated from the SMS. The standard PLCO reports are listed in Exhibit 17-2. The SC Coordinator may also wish to develop additional manual or automated reports to supplement those supplied by the SMS. The SMS provides a facility for ad hoc queries of the study data and export of selected data items to files, enabling the SC Coordinator to produce customized reports as needed. The following sections describe standard reports for monitoring recruitment status, enrollment status, participant status, SC activities related to screening and follow-up, and cancer incidence. (**Note:** A number of reports related to completed study efforts are no longer available from the SMS. These reports will be so noted.)

**Exhibit 17-2. Overview of PLCO Reports**

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
MONITORING REPORTS:					
Recruitment Status	Recruitment Summary Report (B-2-1) (No longer available)	For current period and for the study to date, summarizes potential participants by recruitment status.	SMS	TASR/REPORTS/MANAGEMENT/ SUMMARY No longer available	Effort Complete (As Needed)
Recruitment Status (continued)	Recruitment Progress Report (B-2-2) (No longer available)	Shows the number of potential participants by recruitment status, and those with eligibility pending by gender, race and age group.	SMS	TASR/REPORTS/MANAGEMENT/ PROGRESS No longer available	Effort Complete (As Needed)
	Eligibility Screener Review (B-2-3) (No longer available)	Shows potential participants who have not returned screeners, and those who have returned them but have not signed the consent.	SMS	TASR/REPORTS/MANAGEMENT/ ELIGIBLE No longer available	Effort Complete (As Needed)
	Session Edits (Production Edits) for Individual Tracking (B-2-4)	Lists errors and inconsistencies in the TASR database.	SMS	TASR/REPORTS/PRODUCTION/ EDITS No longer available	Effort Complete (As Needed)
	Possible Duplicates in TASR (B-2-5) (No longer available)	Lists possible duplicates among potential participants in the TASR database based on combinations of name and date of birth.	SMS	TASR/REPORTS/PRODUCTION/ DUPL No longer available	Effort Complete (As Needed)
	Age Review Report (B-2-6) (No longer available)	Lists potential age ineligible for whom a recruitment status has not been set in TASR.	SMS	TASR/REPORTS/PRODUCTION/ AGE No longer available	Effort Complete (As Needed)

Monitoring Activity	Report Name (MOOP Appendix)	Description of Report	System Module	System Path	Recommended Frequency
	Organization Report (B-2-7) (No longer available)	Lists information on organizations that the SC has contacted for recruitment.	SMS	TASR/ORGANIZ/REPORTS/ RORGANIZ No longer available	Effort Complete (As Needed)
	Scheduled and Completed Presentations (B-2-8) (No longer available)	Summarizes information on presentations that the SC has made.	SMS	TASR/ORGANIZ/REPORTS/ PRESENT No longer available	Effort Complete (As Needed)
Recruitment Status (continued)	Materials Distribution (B-2-9) (No longer available)	Shows the distribution of PLCO recruitment materials to organizations.	SMS	TASR/ORGANIZ/REPORTS/ MATERIALS No longer available	Effort Complete (As Needed)
	Summary of Contacts with Organizations (B-2-10) (No longer available)	Summarizes the SC's contacts with organizations.	SMS	TASR/ORGANIZ/REPORTS/ TOTALS No longer available	Effort Complete (As Needed)
	TASR/RAND Comparison Report (B-2-11) (No longer available)	Compares data in TASR to data in RAND to identify eligible potential participants who have not been randomized, randomized participants whose recruitment status is not eligible, and possible duplicates.	SMS	TASR/REPORTS/PRODUCTION/ COMPARE No longer available	Effort Complete (As Needed)
	Eligibility Contact Report (B-2-12) (No longer available)	Lists the last date contacted and current age for individuals in TASR who have not yet been enrolled.	SMS	TASR/REPORTS/PRODUCTION/ ELCON No longer available	Effort Complete (As Needed)
Enrollment Status	Enrollment Status Report (B-4-3) (No longer available)	Summarizes the number of participants enrolled in each study arm during a specified month and year, and cumulatively.	SMS	RAND/REPORTS/ENROLLMENT No longer available	Effort Complete (As Needed)

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
	Enrollment Summary Report (B-4-4) (No longer available)	Summarizes the number of participants in each study arm and age group. Shows mean age overall, mean age by age group, and gender frequency by study arm and age group.	SMS	RAND/REPORTS/ SUMMARY No longer available	As Needed
SC Population Status	Non-Participation Status Summary (B-17-3)	Shows distrib. of non-participants by status (medical condition, refused, deceased, lost contact) within aged group, gender and randomization group.	SMS	Reports/Management/ Non-Participation Status	Monthly
	Population Profile Report (B-17-4)	Shows distribution of participants by age, gender, race and educational level within randomization group.	SMS	Reports/Management/ Population Profile	As Needed
Individual Participant Status	Participant Overview Report (B-17-10)	Shows rand. date, rand. Group, participation status, vital status, transfer status, scheduling notes, cancer status, exam results, and all receipted and outstanding forms for an individual participant.	SMS	Reports/Management/ Participant Overview	As Needed

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
Questionnaires, Screening and Follow-up	PCC Directive/Late Directive (B-3-1)	Lists the participants who are due for the PCC and the form has not been completed.	SMS	Requests/Annual/PCC	Weekly
Questionnaire Screening & follow-up continued	Results Pending Report (B-6-1)	Lists all participants for whom screening exam results are pending (exams with RP status.)	SMS	Reports/Production/Exam Reports/RP Status	Weekly
	One or More Exam Statuses = Results Pending (RP) Three or More Weeks Since Exam Date (B-6-2)	Lists all participants for whom at least one examination is still pending three or more weeks after the examination date.	SMS	Reports/Production/Exam Reports/Late RP	Weekly
	Referrals for Exam Forms (B-6-3)	Displays the referral levels assigned to individual examinations.	SMS	Reports/Management/Exam Referrals	Weekly
	Examination Summary Report (B-6-5)	Displays summaries of exams performed by examiner ID and by outcome.	SMS	Reports/Management/Examination Summary	Monthly
	Screening Test Results Report (B-6-6)	Shows the results of each participant's screening tests for a given study year.	SMS	Shipping/Test Results	Weekly
	Screening Test Results Report Not Sent Three or More Weeks Since Exam Date (B-6-7)	Lists all participants whose screening visit took place three or more weeks previously, but an STRR was not sent.	SMS	Reports/Production/Exam Reports/Not Sent Reports	Weekly

Monitoring Activity	Report Name (MOOP Appendix)	Description of Report	System Module	System Path	Recommended Frequency
	Additional Screening Test Results Report Should be Sent Reflecting New Exam Results (B-6-8)	Lists PIDs whose exam results have changed and/or PCR was revised	SMS	Reports/Production/Exam Reports/Send STRR	Weekly
Questionnaire Screening & follow-up continued	Tracing Log (B-7-3)	Shows participant name, address, DOB, and other locator information useful for tracing participants	SMS	Reports/Tracing/NewLog	As Needed
	List of Participants in Tracing (B-7-4)	Lists participants whose status is "In Tracing."	SMS	Reports/Tracing/List	As Needed
	ASU/PSH Forms Received (B-7-5)	Lists ASU forms received within a specified date range.	SMS	Reports/Production/ASU Reports/ASU Forms Received	Weekly
	ASU Response Rate Report (B-7-6)	Calculates the response rate for the ASU forms by study year.	SMS	Reports/Production/ASU Reports/ASU Response Rate	As Needed
	HSQ Status Report (B-7-10)	For each PID in the sample, lists the date the HSQs were generated, loaded, mailed, receipted and shipped to Westat. Also shows vital status, participation status, and MDF receipt date.	SMS	Reports/Production/HSQ Status and Summary Reports/HSQ Status	As Needed
	HSQ Summary Report (B-7-11)	Lists the number of forms processed and outstanding.	SMS	Reports/Production/HSQ Status and Summary Reports/HSQ Summary	As Needed
	Screening Examination Reports (B-11-1 through B-15-1)	"Decoded" or English versions of screening exam forms.	DEES	Reports/Production/Screening Exam Reports	As Needed

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
Questionnaire Screening & follow-up continued	Count/List of MDFs (B-17-2)	Summarizes number of received MDFs by form type, lists MDFs for specific PIDs, lists MDFs for specific form types.	SMS	Reports/Production/MDFs Received Reports	Monthly
	Buccal Cell Summary Report (B-18-1)	Presents count and percentage of controls with ESC and Buccal Cell kits mailed, ESCs and Buccal Cell samples received, and MDFs received.	SMS	Reports/Production/Buccal Summary Reports	Weekly
	Open Forms/Specimens Report (B-17-8)	Lists all delinquent or outstanding forms by form type.	SMS	Reports/Production/Open Forms Report	Weekly
Cancer Incidence and Mortality	Medical Record Background Report (B-8-2)	Lists locator information, etc. for participants with an outstanding MRA form.	SMS	Requests/medical Background	As Needed
	Cancer Confirmation List (B-8-3)	Shows all participants for whom a possible cancer has been reported and an outstanding DE, TI, or OCF still exists.	SMS	Reports/Production/Cancer Confirmation List	As Needed
	Vital Status Confirmation List (B-9-2)	Shows all participants who are reported as deceased and/or require confirmation of death.	SMS	Reports/Production/Vital Status Confirmation List	Monthly
	Death Certificate Receipt Report (B-9-3)	Displays date of death and PID upon receipt of a death certificate.	SMS	Entry/Other/DCF	Automatic

Monitoring Activity	Report Name (MOOP Appendix)	Description of Report	System Module	System Path	Recommended Frequency
	Participants with Cancer on Death Certificate Report (B-9-5)	Lists all participants who have a cancer reported on their death certificate.	WESTAT	Not Applicable	Monthly
	Algorithm for Death Review (B-9-6)	This report identifies cases selected for the Death Review and/or for Principal Investigator review.	Westat	Not Applicable	Monthly
	Abstracting Schedule Report, (This report is no longer available)	Shows suspected cancers for which a DE form is outstanding and confirmed cancers for which a TI form is outstanding.	--	No longer available	--
MANAGEMENT SUPPORT REPORTS:					
Randomization/ Enrollment	Interactive Randomization Report (B-4-1) (no longer available)	Displays randomization information for each PID after interactive randomization	SMS	RAND/ENROLL/INTENTRY No longer available	Effort Complete
	Batch Randomization Report (B-4-2) (no longer available)	Displays information on participants who were successfully randomized and those that were not randomized from a batch submission.	SMS	RAND/ENROLL/(ASCIIMP TASCIMP DBFIMP) No longer available	Effort Complete
	Randomization Assignment Report (B-4-5) (no longer available)	Shows group assignment, gender, date of birth and the date of randomization for each participant.	SMS	RAND/REPORTS/RANDOM No longer available	Effort Complete (As Needed)

Monitoring Activity	Report Name (MOOP Appendix)	Description of Report	System Module	System Path	Recommended Frequency
	Study ID Assignment Report (B-4-6)	Lists name, PID, randomization date, gender, date of birth, modified date of birth, randomization group and phone number for each participant.	SMS	Reports/Other/Study ID Assignment Report	As Needed
Scheduling Activities	Baseline Directive/Late Directive (B-5-1) (no longer available)	Lists the participants who are in their reporting window for the BQ, BLF and DQX and the form(s) have not been completed.	SMS	FAST/REQUESTS/BASELINE No longer available	Weekly
	DHQ Directive/Late Directive (B-6-10)	Lists the participants who are due for the DHQ and the form has not been completed.	SMS	Requests/Annual/DHQ	As needed
	ASU Directive/Late Directive (B-7-1, B-7-2)	Lists the participants who are in their reporting window for the ASU and the form has not been completed.	SMS	Requests/Annual/ASU	Weekly
	FLF Directive/Late Directive (B-7-7)	Lists the participants who are in their reporting window for the FLF and the form has not been completed.	SMS	Requests/Annual/FLF	Weekly
	HSQ Directive/Late Directive (B-7-8)	Lists the participants who are due for the HSQ and the form has not been completed.	SMS	Requests/Annual/HSQ	Weekly
	ESC Directive/Late Directive: Intervention (B-10-6)	Lists the participants who are due for the ESC and the form has not been completed.	SMS	Requests/Annual/ESC	Weekly

Monitoring Activity	Report Name (MOOP Appendix)	Description of Report	System Module	System Path	Recommended Frequency
	Buccal Cell Directive/Late Directive (B-18-3)	Lists the participants who are due for a completed Buccal Cell kit and no kit has been completed.	SMS	Requests/Annual//BUC	Weekly
	Intervention Activities Report (B-17-6)	Lists PIDs of Intervention participants who are entering, continuing in, or leaving the reporting window, and current delinquent participants.	SMS	Reports/Management/Annual Activities	Weekly
Shipping	Dietary Questionnaire Transmittal (B-6-9) (No longer available)	Shows the PID of each receipted DQX not previously shipped for scanning.	SMS	FAST/SHIPPING/DIETARY/DQX No longer available	Effort Complete
	Diet History Questionnaire Transmittal (B-6-11)	Shows the PID of each receipted DHQ not previously shipped for scanning.	SMS	FAST/SHIPPING/DIETARY/DHQ	Monthly
	Health Status Questionnaire (HSQ) Transmittal Log (B-7-9)	Shows the PID of each receipted HSQ not previously shipped for processing.	SMS	Shipping/HSQ	Monthly
	Death Certificate Transmittal Log (B-9-4)	Lists death certificates that have been receipted and are ready to be shipped for processing.	SMS	Shipping/Death Certificates	Monthly

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
	UCLA Transmittal Log (B-10-1)	Shows all blood samples collected and receipted at the SC the previous week before the shipment of samples to UCLA.	SMS	Shipping/UCLA	Weekly
	Biorepository Transmittal Log (B-10-2)	Shows all blood samples collected, receipted, and stored at the SC, without problems, for the previous month before the shipment of samples to the Biorepository.	SMS	Shipping/Biorepository	Monthly
	UCLA Pre-Transmittal Log (B-10-4)	Shows all blood samples collected, receipted, and stored at the SC, for the previous month before the shipment of samples to UCLA.	SMS	Shipping/UCLA/ Pre-Transmittal	Weekly
	Biorepository Pre-Transmittal Log (B-10-5)	Shows all blood samples collected, receipted, and stored at the SC, for the previous month before the shipment of samples to the Biorepository.	SMS	Shipping/Biorepository/ Pre-Transmittal	Monthly
Quality Assurance	Report of BQ/RAND Discrepancies (B-4-7)	Identifies potential randomized ineligible based on certain responses on baseline questionnaires	DEES	Reports/Production Reports/BQ/RAND Discrepancy Report	Effort Complete

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
	Duplicate Forms Report (B-5-2)	Identifies duplicate forms of the same form type (and study year and visit number, if applicable) scanned for the same PID.	DEES	Reports/Edit Reports/ Duplicate Forms Report	Monthly
	QA Checks Report (B-6-4)	Shows discrepancies between the results of regular examinations and medical record abstract forms, and their associated QA forms.	SMS	Reports/Management/ QA Checks	Weekly
	UCLA Laboratory Receipt and Discrepancy Reports (B-10-3)	Reports generated upon downloading of UCLA results into the SMS.	SMS	Entry/UCLA Results/ Print Last UCLA Entry Report	Automatic
	Biorepository Blood Collection on or After 5/4/98 for Participants Who Have Not Signed An ESC (Biorepository Activity Without ESC Report) (B-10-7)	Identifies participants who had biorepository blood drawn without a receipted ESC.	SMS	Reports/Management/ Bio Activity without ESC	Monthly
	T3 Blood Tubes 12/13 Shipped Late Report (B-10-8)	Identifies those participants whose T3 tubes (#012 and #013) were sent late to the processing lab.	SMS	Reports/Management/ Tubes 12/13 Shipped Late	As needed
	Production Edits Report - SMS (B-17-9)	Lists errors and inconsistencies within a single data collection form or among forms of different types.	SMS	Reports/Edits	Weekly
	Production Edits Report - DEES (B-17-13)	Lists errors and inconsistencies for individual forms that are scanned.	DEES	Reports/Edits Reports/ Edit Report	At Least Weekly

<b>Monitoring Activity</b>	<b>Report Name (MOOP Appendix)</b>	<b>Description of Report</b>	<b>System Module</b>	<b>System Path</b>	<b>Recommended Frequency</b>
	DEES/SMS Comparison Report (B-17-14)	Compares like data items in SMS and DEES for all OPSCAN forms	DEES	Reports/Production Reports/DEES-SMS Data Comparison Report	Weekly
	Key Field Edits Report (B-17-15)	Identifies OPSCAN forms scanned with a key field error (Also available at time of scanning)	DEES	Reports/Edit Reports/Key Field Edits Reports	As Needed
General SC Management	Number of TASR Eligibles, Participants Randomized and Screens Performed per Recruitment Source (B-2-13) (No longer available)	Shows the number of TASR eligible, randomized, and screened participants by ID source.	SMS	FAST/OUTPUT/MANAGEMENT/ MORE/COUNTS No longer available	Effort Complete (As Needed)
	Staff Report (B-17-1)	Lists the SC staff members, their assigned ID number, satellite center (if applicable), and position.	SMS	Reports/Other/Staff Report	As Needed
	Participant Information Sheet (B-17-5)	Provides a summary of all locator information.	SMS	Reports/Production/Participant Information Sheet	As Needed
	Summary of Scanned Forms Report (B-17-11)	Lists all forms scanned by form type	DEES	Reports/Production Reports/Summary of Forms Scanned Reports	As Needed
	Report of DEES Final Disposition (B-17-12)	Identifies PIDs by form type for which a given form has or has not had a final disposition assigned.	DEES	Reports/Production Reports/Final Disposition Report	Monthly
	SMS/DEES Synchronization Reports (B-17-16)	Identifies forms scanned in DEES but not in SMS or receipted in SMS but not yet scanned.	DEES	Reports/Production Reports/SMS-DEES Synchronization Report	Monthly

Monitoring Activity	Report Name (MOOP Appendix)	Description of Report	System Module	System Path	Recommended Frequency
	Scanned Forms Count Report (B-17-17)	Summarizes number of forms scanned by date and by form type	DEES	Reports/Production Reports/Forms Count Report	As Needed

### 17.11.1 Monitoring Recruitment Status

As described in [Chapter 2.0](#), the SC Coordinator will monitor the status of all recruitment activities and report summary information to the CC on a monthly basis. SCs which choose to use the Individual Tracking module of the SMS will be able to generate the reports described below for monitoring recruitment. The recruitment effort has been completed. (**Note:** These reports are no longer available from the SMS.)

- **Recruitment Summary Report** ([Appendix B-2-1: Recruitment Summary Report](#))

This report summarizes the recruitment status of all potential participants in the Tracking and Summarizing Recruitment (TASR) module. It can be requested for the current reporting period, or a previous reporting period. It also lists the reasons specified for the recruitment category "Non-Participant, Other Reason."

This information will be used by the NCI to determine whether the SC is meeting contract commitments. It will also enable the SC Coordinator to identify any problems with recruitment and to redirect recruitment resources, if necessary.

- **Recruitment Progress Report** ([Appendix B-2-2: Recruitment Progress Report](#))

The Recruitment Progress Report will enable the SC Coordinator to monitor recruitment goals by gender, race and age group and to monitor work performed for the current period and for the project to date.

- **Eligibility Screener Review Report** ([Appendix B-2-3: Eligibility Screener Review](#))

The Eligibility Screener Review Report will enable the SC Coordinator to monitor the progress of eligibility determination for potential participants. This report will include two parts:

*Part I* provides a list of potential participants who have not yet returned their Eligibility Screener. It lists the tracking number, the potential participant's name, and telephone number. It may be used for follow-up of individuals to ascertain their interest in the trial.

*Part II* provides a list of potential participants who have returned their Eligibility Screener but for whom eligibility has not yet been determined. It lists the tracking number, the potential participant's name, telephone number, and date the Screener was returned. It may be used for follow-up of individuals to verify the information on the screener or to sign an informed consent.

- **Session Edits (Production Edits) for Individual Tracking** ([Appendix B-2-4: Session Edit Report for Individual Tracking](#))

This report prints a list of errors and inconsistencies for each record in the TASR database, as well as a key for decoding error message codes.

- **Possible Duplicates in TASR** ([Appendix B-2-5: Possible Duplicates in TASR](#))

This report lists possible duplicates among potential participants in the TASR database. This report will allow the SC Coordinator to monitor the integrity of the recruitment database.

- **Age Review Report** ([Appendix B-2-6: Age Review Report](#))

This report lists potential age ineligible for whom a recruitment status has not been set in TASR. The report shows their tracking number, name, date of birth, gender, and current age. It can be used to identify those potential participants who need to be contacted as they become age eligible.

- **TASR/RAND Comparison Report** ([Appendix B-2-11: TASR/RAND Comparison Report](#))

This report compares data in TASR to data in the Randomization and Enrollment (RAND) module to identify eligible potential participants who have not been randomized, randomized participants whose recruitment status is not eligible, and possible duplicates.

- **Eligibility Contact Report** ([Appendix B-2-12: Eligibility Contact Report](#))

This report lists the date contacted and current age for those individuals in TASR that have not yet been enrolled in the study.

The following reports will allow the SC Coordinator to monitor recruitment with outside organizations:

- **Organization Report** ([Appendix B-2-7: Organization Report](#))

This report lists information on organizations the SC has contacted for recruitment using data entered into TASR from the Contact Information screens.

- **Scheduled and Complete Presentations** ([Appendix B-2-8: Scheduled and Complete Presentations](#))

This report summarizes information on presentations entered into TASR using the Presentations to Organization screen.

- **Materials Distribution** ([Appendix B-2-9: Materials Distribution](#))

This report displays information on the distribution of PLCO recruitment materials to organizations.

- **Summary of Contacts with Organizations Report** ([Appendix B-2-10: Summary of Contacts with Organizations](#))

This report summarizes contacts with organizations. It shows the number of organizations in the database, the number for whom at least one presentation was done, the total number of presentations to date, and the total number of attendees over all presentations.

### 17.11.2 Monitoring Enrollment Status

The SC Coordinator will be responsible for monitoring the enrollment of participants in the trial to ensure that the number and profile of enrollees are in accordance with contract specifications regarding age and sex distributions. The enrollment effort has been completed. (**Note:** These reports are no longer available from the SMS.)

- **Enrollment Status Report** ([Appendix B-4-3: Enrollment Status Report](#))

This report will show the total number of participants assigned Participant IDs and the number of participants assigned to each group for the month and cumulative for the study. The Enrollment Status Report will enable the SC Coordinator to monitor monthly recruitment goals.

- **Enrollment Summary Report** ([Appendix B-4-4: Enrollment Summary Report](#))

This report will show the number of participants in each study arm and age group. It will also show the mean age overall and within age group, and the gender distribution by study arm and age group. It may be generated for a specified range of randomization dates.

This report will enable the SC Coordinator to monitor enrollment to date against contract commitments and to redirect efforts if the race, gender, or age distribution of enrollees is skewed.

### 17.11.3 Monitoring SC Population Status

The SC Coordinator is responsible for monitoring the status of the total group of participants at the SC to ensure that overall participant characteristics meet contract requirements (i.e., there is an even distribution among age groups, etc.). The SC Coordinator will also monitor participation status using the following reports.

- **Non-Participation Status Summary** ([Appendix B-17-3: Non-Participation Status Summary](#))

This report will show the distribution of all non-participants (i.e., participants for whom a Nonresponse Form has been receipted) by status category within randomization group, age and gender. These status categories are: medical condition, deceased, refused further participation and lost contact.

This report will enable the SC Coordinator to identify and monitor retention issues.

- **Population Profile Report** ([Appendix B-17-4: Population Profile Report](#))

This report will show the distribution of intervention and control participants by age, gender, race, and education level.

The Population Profile Report will allow the SC Coordinator to measure recruitment and enrollment progress against their contract commitments. It will also highlight workload issues (e.g. older participants or lower average education levels may increase data retrieval effort).

### 17.11.4 Monitoring Individual Participant Status

In addition to monitoring the total group of PLCO participants, the SC Coordinator is responsible for monitoring the status of individual participants to ensure that each participant completes study activities in a timely manner. The following SMS report will support the monitoring of individual participant status.

- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#))

This report gives a summary of the study information for a participant such as PID, name, gender, date of birth, address, randomization date, and randomization group. Prior adenoma detection, vital status, cancer status, medical record abstracting information, transfer status, and scheduling notes are also presented as well as forms that are outstanding or receipted, and exam results. Since the receipt of forms and specimens indicates the successful collection of study data, the SC Coordinator will use this report on a regular basis for monitoring the status of participants in the study.

### 17.11.5 Monitoring Questionnaire Administration, Screening and Followup

As noted earlier, an activity is not considered completed until its associated form has been receipted into the Forms and Specimens Tracking (FAST) module of the SMS. The following reports generated from this module will enable the SC Coordinator to monitor questionnaire administration, screening, and followup activities by monitoring the receipt of study forms.

- **Results Pending Report** ([Appendix B-6-1: Results Pending Report](#))

This report lists all participants for whom screening examination results are pending (status of RP). This report may be used to monitor the timely processing of data collection forms and reporting of results.

- **One or More Exam Statuses = Results Pending (RP) Three or More Weeks Since Exam Date** ([Appendix B-6-2: One or More Exam Statuses = Results Pending Three or More Weeks Since Exam Date](#))

This report lists all participants for whom at least one examination is still pending (RP status) three or more weeks after the examination date. This report may be used to monitor the timely processing of data collection forms and reporting of results.

- **Referrals for Exam Forms** ([Appendix B-6-3: Referrals for Exam Forms](#))

This report displays the referral levels assigned to individual examinations. It may be requested for specific Participant IDs, for all examinations that took place during a range of dates or for all participants.

- **Examination Summary Report** ([Appendix B-6-5: Examination Summary Report](#))

This report generates summaries of exams performed. The user may select any combination of exams and a range of visit dates. This is a five-part report: (1) exams performed, (2) exams by examiner ID, (3) exams by outcomes, (4) outcome by examiner, and (5) exams by gender. The Coordinator may use this report to monitor workload for examiners as well as examiner performance.

- **Screening Test Results Report Not Sent Three or More Weeks Since Exam Date** ([Appendix B-6-7: Screening Test Result Report Not Sent Three or More Weeks Since Exam Date](#))

This report lists all participants whose screening visit took place three or more weeks previously, but a Screening Test Results Report (STRR) has not been sent. The SC Coordinator may use this report to monitor the timely reporting of screening examination results.

- **Additional Screening Test Results Report Should be Sent Reflecting New Exam Results** ([Appendix B-6-8: Additional Screening Test Result Report Should Be Sent Reflecting New Exam Results](#))

This report lists participants whose exam results have changed and/or the PCR was revised. Listed on the report are the PID, study year, exam date, final worst-case exam result (for all exams), STRR date, and last updated date for the STRR.

- **Tracing Log** ([Appendix B-7-3: Tracing Log](#))

This report provides all current locator information for the participant obtained from the Baseline Locator Form and Followup Locator Form(s). It shows the PID, full name of the participant, date and place of birth, social security number, mother's maiden name, and other names. The SC Coordinator can use this report to organize information that may be useful for tracing participants (not currently implemented).

- **List of Participants in Tracing** ([Appendix B-7-4: List Of Participants in Tracing](#))

This report lists the PIDs for participants currently "In Tracing" showing their date of birth, gender, study group, participant status, and number of tracing attempts. Each time a Tracing Log ([Appendix B-7-3: Tracing Log](#)) is generated for a participant, the date the Tracing Log was generated is automatically updated on this report, indicating the most recent date. The SC Coordinator may use this report to manage tracing activities and to monitor retention of participants (not currently implemented).

- **ASU/PSH Forms Received** ([Appendix B-7-5: PSH/ASU Forms Received](#))

This report lists Annual Study Update forms received within a specified date range and will allow the SC Coordinator to monitor the completion of ASU forms.

- **ASU Response Rate Report** ([Appendix B-7-6: ASU Response Rate Report](#))

This report gives the response rate for the ASU by study year. This report lists the number expected, number received, and response rate for the Intervention group, Control group, and overall.

- **HSQ Status Report** ([Appendix B-7-10: HSQ Status Report](#))

For each PID in the sample, this report lists the date the Health Status Questionnaire (HSM or HSW) was generated, loaded, mailed, received, and shipped to the CC. This report also lists participation status, vital status, transfer status, and Missing Data Form (MDF) receipt date.

- **HSQ Summary Report** ([Appendix B-7-11: HSQ Summary Report](#))

This report gives summary figures for the HSM, HSW, and overall HSQs. Listed by study year are the numbers of forms loaded, mailed, received, and shipped to the CC. Counts are also given for the number of outstanding forms, those which have been “followed-up” and the number of MDFs received for HSQs.

- **Screening Examination Report** ([Appendix B-11-1: Screening Examination Report - Chest X-Ray through B-15-1](#))

This report lists the current “decoded” or English versions of screening exam forms and their results.

- **Count/List of MDFs** ([Appendix B-17-2: Count/List of MDFs](#))

This report includes three separate listings: (1) count of receipted Missing Data Forms by form type, (2) list of Missing Data Forms for PIDs specified by the user, and (3) Missing Data Forms for specific forms.

- **Open Forms/Specimens Report** ([Appendix B-17-8: Open Forms/Specimens Report](#))

For individual Participant IDs, this report will show all delinquent or outstanding forms or specimens. For participants who are past the delinquency period with no MDF receipted, the report indicates that an MDF is outstanding for the form.

The Open Forms/Specimens Report will enable the SC Coordinator to monitor individual participant activities, and to direct efforts to collecting outstanding data prior to the end of the participant’s reporting window.

- **Buccal Cell Summary Report** ([Appendix B-18-1: Buccal Cell Directive/Late Directive](#))

This report presents counts and percentages of Controls with Etiologic Studies Consents (ESC) and Buccal Cell kits mailed, ESCs and Buccal Cell samples receipted, and MDFs receipted.

### 17.11.6 Monitoring Cancer Incidence and Mortality

The SC Coordinator will be responsible for monitoring the incidence of PLCO cancer and death among participants during the study period. The following SMS reports will facilitate this monitoring activity.

- **Medical Record Background Report** ([Appendix B-8-2: Medical Record Background Report](#))

This report is generated for participants with a suspected or confirmed cancer. It lists locator information, date of birth, modified date of birth, and cancer information (such as outstanding medical record abstracting forms, cancer status, cancer type, and ICD-9-CM codes.)

- **Cancer Confirmation List** ([Appendix B-8-3: Cancer Confirmation List](#))

This report will list outstanding cancer information in five categories: participants expecting Diagnostic Evaluation (DE) forms due to positive screens, participants expecting DE forms for reported PLCO cancers, participants expecting Other Cancer Forms (OCF) for reported non-PLCO cancers, Treatment Information (TI) forms expected for confirmed PLCO cancers, and a summary section. It will be used to indicate

which participants require collection of information on diagnostic follow-up and treatment.

- **Vital Status Confirmation List** ([Appendix B-9-2: Vital Status Confirmation List](#))

This report will identify participants whose vital status is presumed deceased (P), confirmed deceased (C), or confirmed deceased without a death certificate (N.)

- **Participants with Cancer on Death Certificate Report** ([Appendix B-9-5: Participants with Cancer on Death Certificate Report](#))

This report, generated by the CC, will identify participants who have a cancer reported on their death certificate. It shows PID, study year, cancer type, date of death, cancer code, and a cancer disposition.

- **Algorithm for Death Review** ([Appendix B-9-6: Algorithm for Death Review](#))

This report, generated by the CC, identifies cases selected for the Death Review and/or for Principal Investigator review. It lists, by SC, participants that are assigned to death review (AR), certified (AC), or rejected (XX) because of insufficient information.

## 17.12 SC Operations Support (Management Support Reports)

A number of reports will be available to support the SC Coordinator in the management of SC operations. Throughout the study, it will be crucial for the SC staff to be able to link a participant with his/her Participant ID. The following reports will be available as reference listings of PLCO participants.

- **Randomization Assignment Report** ([Appendix B-4-5: Randomization Assignment Report](#))

This report will show the group assignment (intervention or control), gender, date of birth, and the date of randomization for each Participant ID.

The Randomization Assignment Report will be used by SC staff as a reference report for daily SC activities. (**Note:** This report is no longer available from the SMS.)

- **Study ID Assignment Report** ([Appendix B-4-6: Study ID Assignment Report](#))

This report will show the name, Participant ID, gender, date of birth, modified date of birth, home phone number, and randomization group for each participant in the study. The report may be sorted alphabetically or by Participant ID. Since participant name is not recorded on many study documents, this report will provide a critical link between the participant's study ID and the participant's name.

The Study ID Assignment Report will be used by SC staff as a reference report for daily SC activities. Because the report contains Privacy Act information, access to this report will be controlled by the SC Coordinator.

There may be instances in which the SC Coordinator wishes to review and utilize locator information for a particular participant. This may be necessary for a variety of SC operational activities such as scheduling, return calls, etc. A report designed for this purpose is described below:

- **Participant Information Sheet** ([Appendix B-17-5: Participant Information Sheet](#))

This report provides a summary of all locator information, including dates the information was provided, and mimics the Tracing Log ([Appendix B-17-3: Non-Participation Status Summary](#)).

- **Participant Overview Report** ([Appendix B-17-10: Participant Overview Report](#))

This report gives a summary of the study information for a participant such as PID, randomization date, randomization group, participant name, gender, date of birth, address, participation status, prior adenoma detection, vital status, scheduling notes, cancer status, exam results, and all receipted and outstanding forms for an individual participant.

Activities of the SC will be scheduled such that all participants complete their required baseline and annual activities during their reporting period, and if necessary, during their delinquency period. The SMS will produce activities reports which will enable the SC Coordinator to identify participants who are due to complete study activities, or who require follow-up to complete an activity (i.e. participants who are delinquent). **The Annual Activities Report will contain two sections: Intervention and Control.** This report is described below:

- **Annual Activities Report - Intervention** ([Appendix B-17-6: Intervention Activities Report](#))

This report will show which intervention participants are entering their activity window, are currently in their activity window, or are leaving their window. It will also show delinquencies.

The SC Coordinator should use this report for scheduling screening visits and monitoring the SC workload and may request this report as often as needed.

- **Annual Activities Report - Control** ([Appendix B-17-7: Control Activities Report](#))

This report will show which control participants are entering their activity window, are currently in their activity window or are leaving their window. It will also show delinquencies.

The SC Coordinator should use this report for determining when to initiate a request in the SMS for the participant to complete the Annual Study Update (ASU) and the Follow-up Locator Form (FLF). The SC Coordinator may request this report as often as needed.

Another aspect of operations support is quality assurance of management system data. Reports will be generated which will provide information on missing and inconsistent data. This includes:

- **Production Edits Report** ([Appendix B-17-9: Production Edit Report](#))

There are two versions of this report:

- ▶ **Intra-Forms Edit Report:** This report prints a list of errors and inconsistencies within a data collection form. The user may run the report for a single form, a category of forms (exams, medical, etc.), or all forms. In addition, the user may select a particular edit or several edit checks to be run.
- ▶ **Inter-Forms Edit Report:** This report prints a list of errors and inconsistencies among forms of different types. It compares the data for all forms and specimens for a specific PID or Sample ID. The user may run the report for selected PIDs, a range of PIDs, selected Sample IDs, a range of Sample IDs, and 'ALL.' In addition, the user may select a particular edit or several edit checks to be run.

### 17.13 Monitoring Adverse Events

SCs are responsible for monitoring the occurrence of any adverse events among participants in the intervention group, which may be related to their participation in the trial. Medical complications, which occur while the participant is physically at the SC having screening examinations, should be documented on the appropriate screening examination form (See Chapters 10-15). This information will be communicated to the CC and NCI through transmitted data. SCs must also document serious adverse experiences, which occur after the participant leaves the SC. As of May 1st, 2003, the screening centers' requirements for reporting serious adverse events have been revised. The screening centers should begin reporting serious adverse events to the CC within two weeks of being notified of a serious adverse event requiring IRB notification. Serious adverse events are defined as fitting into one or more of the following categories:

- death
- life threatening
- inpatient hospitalization
- persistent or significant disability/incapacity
- medical or surgical intervention to prevent one of the above outcomes
- other (specify).

These serious adverse experiences will usually be reported back to the SC either by the participant or his/her physician. It is not expected that the SCs will solicit this information, however, if reported, it must be documented. This reporting will be done using the **Report of Adverse Events for NIH-Sponsored Clinical Trials (RAE)** ([Appendix A-17-11](#)). Specifications for the completion of the RAE are also provided in [Appendix A-17-11](#). This form is designed to collect the appropriate information for review by NCI and the CC. Upon receiving the report, the CC will make a photocopy for its records and immediately send the form to NCI. NCI will review all the events and determine which, if any, require notification to all the SC IRBs. The SC should inter-

nally track adverse events that do not require reporting to NCI on the report of Adverse Events form. Tracking tools such as an Excel spreadsheet can be utilized to maintain a list of the non-serious adverse events.

## 17.14 Documenting and Resolving Protocol Violations

Throughout the trial, the SC may make errors, which are considered violations of the PLCO protocol. Some examples of protocol violations are:

- Randomization of a participant with the wrong gender;
- Randomization of the same participant more than once;
- Randomization of a participant with the wrong date of birth in situations where the participant provided the correct date of birth but the SC entered it incorrectly;
- Mislabeled or lost forms and specimens;
- Administration of screening examinations to control participants;
- Sending the wrong results to a participant, resulting in inappropriate follow-up; and
- Wrong screening exam protocol administered.

All protocol violations should be documented on a SC Report of Protocol Violation form ([Appendix A-17-7](#)). The following items are collected on this form:

- type of protocol violation;
- participants affected (PIDs);
- how the protocol violation occurred;
- how the SC discovered the protocol violation;
- corrective actions the SC has taken or plans to take;
- corrective actions needed by the CC; and
- actions the SC has taken or plans to take to prevent the recurrence of the protocol violation.

To ensure the resolution of each violation, it is important that the SC Report of Protocol Violation forms are filled-out completely and in detail. Completed SC Report of Protocol Violation forms should be faxed or mailed to the CC Coordinator. On a periodic basis, the CC and the NCI will review the protocol violations to determine whether there are an excess of protocol violations or any patterns related to protocol violations at any of the SCs.

### 17.14.1 Documenting and Resolving Duplicate Randomization

The guidelines below describe the steps that should be taken to resolve a duplicate randomization within the same SC. The steps are different based on the study group assignment given at the time of the second randomization.

If a participant is randomized twice, *first as a control, then as an intervention*, the first randomization should be maintained. The SC that performed the second randomization should complete the following activities to document and resolve the error and follow the participant:

1. Complete a Protocol Violation Form. Send the original to the CC Coordinator, and file a copy in both of the participant's study files.

2. Discard Biorepository blood. Do not send blood to the Biorepository. If blood samples have been shipped to the Biorepository, notification must go in writing to your CC Coordinator and the Biorepository. Information must include:
  - ▶ Participant IDs (both the Intervention and the Control IDs)
  - ▶ Sample IDs and the sequence numbers for each vial
  - ▶ Date of Blood Draw
  - ▶ Biorepository Ship DateAt this time, the CC will contact the Biorepository and take any necessary action.
3. Do not send blood to UCLA. Either discard blood collected for PSA/CA-125II or, if the participant so requests, have it analyzed by an SC designated laboratory (cost to be incurred by the SC.) If blood has been shipped to UCLA, notification must go in writing to your CC Coordinator and User Support. Information must include:
  - ▶ Participant ID
  - ▶ Sample ID and sequence number
  - ▶ Date of Blood Draw
  - ▶ UCLA Ship Date

Upon receipt of this letter, the CC will write a memo to UCLA notifying them of the errors. User Support will make the necessary corrections to the SC database.

4. The participant should be informed of the error. It is recommended that this be done both in writing and by a telephone call from the Principal Investigator. However, the decision of whether or not to analyze the blood and report the results of the blood test and other examinations to the participant and/or to his or her physician is left to the SC. If results are reported, this should be documented in the "Notes" area of the Participant Status data entry screen under the original randomization PID. In addition, if written results are sent to the participant and/or the physician, a copy of what was sent should be placed in both of the participant's study files.
5. Under the original randomization PID, use the "Notes" area in the Participant Status data entry screen to enter the result of each examination (i.e., AS, AN, NG or IN), the date of screening, the date results were sent to the participant (if results were sent to the participant), and a brief explanation of why the inadvertent screening occurred.
6. Dietary Questionnaires: If the participant completed a Dietary Questionnaire (DQX) under the second PID, this too should be noted on the protocol violation form so that the data can be deleted. The following scenarios could occur:
  - ▶ The participant completes the DHQ under the original (control) PID then completes the DQX under the second PID (intervention.)
  - ▶ The participant does not complete the DHQ under the original (control) PID but does complete the DQX under the second PID (intervention.)

In either case, the DQX completed under the second PID should not be sent to NCS for scanning. If it has already been sent to NCS, the CC should be notified so that the data can be deleted. The hardcopy DQX should be kept in the participant's file at the original SC. In the second scenario where the participant has not completed a DHQ, an MDF-DHQ should be receipted under the original PID so that this participant is not approached to complete another dietary questionnaire.

7. After steps 1 through 6 above have been completed, the SC should call User Support.
8. Upon receipt of the Protocol Violation Form and after steps 1 through 7 above have been completed, the CC will make the appropriate corrections (i.e. delete all forms and references to the intervention group PID) in the SC database.
9. If the participant had one or more screening tests that were positive (AS), it is not necessary for the SC to complete a DE form or TI form for the participant *unless* the positive screen leads to a diagnosis of a PLCO cancer which is reported on the ASU. Only upon report of a PLCO cancer should the original SC collect diagnostic and treatment information for a control who was screened. To initiate the collection of diagnostic information, an entry should be made in the Participant Status Cancer Screen under the original randomization PID.
10. The participant should remain in the control group and should not receive PLCO screening tests in subsequent years.

If a participant is randomized *first to the control group then again to the control group* or *first to the intervention group then to the control group*, the first randomization should be maintained. The SC where the second randomization occurred should complete the following activities to document and resolve the error and follow the participant:

1. Complete a Protocol Violation form. Send the original to the CC Coordinator, and file a copy in both of the participant's study files.
2. Dietary Questionnaires: If the participant completed a dietary questionnaire (DQX or DHQ) under the second PID or completed multiple dietary questionnaires, this too should be noted on the protocol violation form so that the scanned data can be deleted. The following scenarios could occur:
  - ▶ Participant randomized twice as a control and completed two DHQ forms. If this happens, the DHQ completed under the second PID should not be sent to NCS for scanning. If it has already been sent to NCS, the CC should be notified in order to delete the data.
  - ▶ Participant randomized twice as a control and only one DHQ was completed but under the second PID. If this happens, the DHQ should be relabeled as the original PID and receipted (at the original SC). It should be shipped, by the original SC, to NCS as usual.
  - ▶ Participant randomized first as an intervention then as a control and both a DQX and DHQ were completed. If this happens, the DHQ completed under the second PID should not be sent to NCS for scanning. Instead it should be kept in the participant's file. If it has already been sent to NCS, the CC should be notified in order to delete the data.

- ▶ Participant randomized first as an intervention then as a control and only one dietary questionnaire was completed but it was the DHQ under the second PID. If this happens, the DHQ should be relabeled as the original PID and receipted (at the original SC.) It should be shipped, by the original SC, to NCS as usual.
3. Upon receipt of the protocol violation form, User Support will contact the SC to make the appropriate corrections in the SC database (i.e., delete all references to the second PID).

### 17.14.2 Documenting and Resolving Randomized Ineligibles

If the SC becomes aware that a randomized participant was ineligible at the time of randomization, the participant should be documented as a “randomized ineligible” on an **Administrative Tracking Form (ATF)** ([Appendix A-4-2](#)). The following information should be recorded on this form:

- **the date the SC discovered that an ineligible individual was randomized;**
- **the reason the individual was not eligible for the trial at the time of randomization; and**
- **the method of discovery.**

**Note:** The SC is not required to complete a Protocol Violation Report. The CC will use ATF reports to determine the number of randomized ineligible protocol violations that have occurred for each SC within a given timeframe. It is therefore important that the SC completes the “Method of Discovery” section of the ATF so it is clear to NCI whether or not the participant provided accurate eligibility information prior to randomization.

The purpose of the ATF is to differentiate between the following types of situations that may involve randomization of ineligible individuals:

- Intervention and control individuals who were randomized in error (i.e., the participant provided information to the SC indicating his/her ineligibility, but the SC failed to exclude him/her from the trial);
- Intervention and control individuals who were randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization, (e.g., from a review of the baseline questionnaire, during screening or follow-up of screening, through conversations with the participant, etc.) that the information provided had been incorrect.

Refer to [Appendix A-4-2](#) for specifications for completion of the Administrative Tracking Form.

The Report of BQ/RAND Discrepancies (formerly the Randomized Ineligible Report) ([Appendix B-4-7: Report of BQ/RAND Discrepancies](#)) is automatically generated from Baseline Questionnaire data to identify *potential* randomized ineligibles. This report will identify participants whose Eligibility Screener shows that they are eligible but then later their Baseline Questionnaire shows one or more exclusion criteria. For example, a participant may have marked on their Eligibility Screener that they had not had a PSA, colonoscopy, flexible sigmoidoscopy or barium enema but then this is contradicted on their Baseline Questionnaire. Data retrieval to confirm the timing of the screening exam

reported on the Baseline Questionnaire is not required, since NCI will consider all such participants to be contaminated, regardless of the exam timing. The SC does not need to complete an ATF for these cases.

All individuals discovered to be ineligible at the time of randomization will continue to be followed regardless of the method of discovery. If a randomized ineligible is in the screening arm of the trial, s/he should be offered all screening examinations unless the reason for ineligibility precludes screening as follows:

- If the reason for ineligibility is the absence of the prostate, lung or colon, the screening test(s) associated with that organ should not be performed. In addition to completing the Administrative Tracking Form, a Missing Data Form (MDF) with Reason Code 7, subcode 777 should be completed for the related screen expected in the current study year to “turn off” system expectations for screening examination data.
- If the reason for ineligibility is prior PLCO cancer, the cancer should be confirmed by a review of the medical record or by contact with the participant’s physician. The Administrative Tracking Form should be completed indicating whether or not the cancer is confirmed. If the cancer is confirmed, item 2a on the ATF should be completed and the screening test(s) for that cancer should not be performed. If the cancer is not confirmed, the participant should be offered the screening tests for that cancer.

As with all other participants, if a randomized ineligible refuses a screening test, the test should not be performed.

## **17.15 Quality Assurance Program**

A comprehensive PLCO Quality Assurance Plan is included in [APPENDIX L](#). Due to the decentralized design of the study, the SCs have a significant responsibility for the quality of the data and each SC is responsible for developing a SC-specific QA plan which addresses each aspect of the PLCO QA Plan. The procedures and systems described in this manual are designed to aid the SCs in attaining a high level of quality in all areas of the trial.

Quality assurance measures will include internal monitoring of data quality by the SCs, additional monitoring of data quality by the CC, comprehensive training for SC Coordinators, site visits by CC staff and the NCI project officers, and the central monitoring committees. The following sections describe these aspects of quality assurance.

### **17.15.1 Screening Center Monitoring of Data Quality**

The SC Coordinator will be responsible for the quality of the data entered into the SMS and the DEES. As described previously in this chapter, computer edits will be generated to assist the center in assuring that data entered into the system is clean. It is the responsibility of the SC Coordinator to take action (such as remedial training) if certain staff members are not completing forms adequately. The SC Coordinator must also make sure that data retrieval is done with participants for critical items missing from data forms they completed. Further, the SC Coordinator should review work done by staff members using the SMS. This will usually be accomplished through a critical review of reports generated by the system or ad hoc reports requested through the system.

### **17.15.2 Coordinating Center Monitoring of Data Quality**

The SCs are responsible for transmitting data to the CC on a regular basis. The CC reviews these data for quality assurance and provides feedback to the SCs on any data inconsistencies and errors. CC quality assurance reports are generated quarterly for each SC. Inconsistencies and errors are recorded on Data Investigation Forms (DIFs) which are dated and mailed to the appropriate Screening Centers. Screening Center data management staff are required to investigate the problem, clean the data, as necessary, document the process on the DIF and return the completed form to the CC. Additionally, the SCs are required to send specific data editing reports generated at the SC to the CC on a semi-annual basis. Output from these reports is reviewed and summarized, and feedback is provided to the SCs for prioritizing their data cleanup efforts.

### **17.15.3 Reporting to the NCI**

The SCs will submit a semi-annual report to the NCI. In addition to required elements for this report specified in the contract, this report will include the items listed below.

- Identification of new staff and/or equipment;
- Report of training and certification activities;
- Report on examinations performed for quality assurance.

These items of information are needed to monitor compliance with the quality assurance protocols established for the PLCO trial.

### **17.15.4 Site Visits**

Site visits will be conducted by personnel from the NCI and/or personnel from the CC. In many instances both the NCI and the CC staff will visit a SC together, but due to scheduling barriers, this may not always be possible. The purpose of these visits is to:

- Ensure that the study protocol is being followed and to assess any protocol violations;
- Conduct a data audit of a random sample of participant study files for accuracy, consistency, and completeness;
- Ensure that members of the SC staff are aware of any procedural changes that can affect the screening of participants and the quality of the data collected;
- Survey procedures for correction of data through edit queries;
- Review output of SC quality assurance reports to assess data management and quality assurance procedures;
- Observe SC's daily operations;
- Check storage and documentation of laboratory specimens.

Problems noted at the site visits will be brought to the attention of appropriate study personnel, i.e., the SC Coordinator, the CC Project Director, the Principal Investigator and the NCI Project Officers.

### **17.15.5 Monitoring Committees**

Two central committees will play a major roll in monitoring protocol adherence throughout the trial. These include the Monitoring and Advisory Panel (MAP) and the PLCO Steering Committee. These groups will meet regularly to discuss problems and make changes in trial procedures.

# 18.0 BUCCAL CELL COLLECTION PROTOCOL

## 18.1 Buccal Cell Collection Overview

In May 2000, the collection of buccal cell samples from PLCO control participants was implemented. The activity will provide a DNA resource for the assessment of genetic factors associated with disease in the control arm and effectively double the size of the etiologic component of the PLCO Trial for this type of investigation. The expanded sample size will allow for comparison of interrelationships, and for the study of relatively rare diseases.

The PLCO Buccal Cell Collection includes two major components: 1) mailing the Etiologic Studies Consent Form (ESC) to control participants who have not previously signed an ESC, and 2) mailing buccal cell collection kits to control participants who have signed an ESC. Briefly the ESC and Buccal Cell Collection procedures will include the following steps:

- ESC Procedures
  - ▶ Monthly, generate the SMS ESC Requests (Directive and Mailing) for control participants;
  - ▶ Mail ESC, ESC Cover Letter, FAQ Sheet and Buccal Cell Brochure to participants;
  - ▶ Receipt ESC into the SMS; and
  - ▶ ESC non-response follow-up.
- Buccal Cell Collection Procedures

### Procedures to send kits

- ▶ Monthly, generate the SMS Buccal Cell Requests (Directive and Mailing). These functions identify control participants who have an ESC receipted and should have a buccal cell kit sent to them. The functions then generate the file that is transmitted to the Kit Assembly Company and create the SMS buccal cell record;
- ▶ Monthly, transmit the electronic file generated by the SMS Buccal Cell Requests (Directive and Mailing) to the Kit Assembly Company;
- ▶ The Kit Assembly Company will prepare the buccal cell collection kits with cover letters and mail kits to control participants; and
- ▶ Monthly, retrieve an electronic file from the Kit Assembly Company's computer and import this file into the SMS. This file will document that kits have been mailed to the selected participants;

### Procedures to document receipt of samples

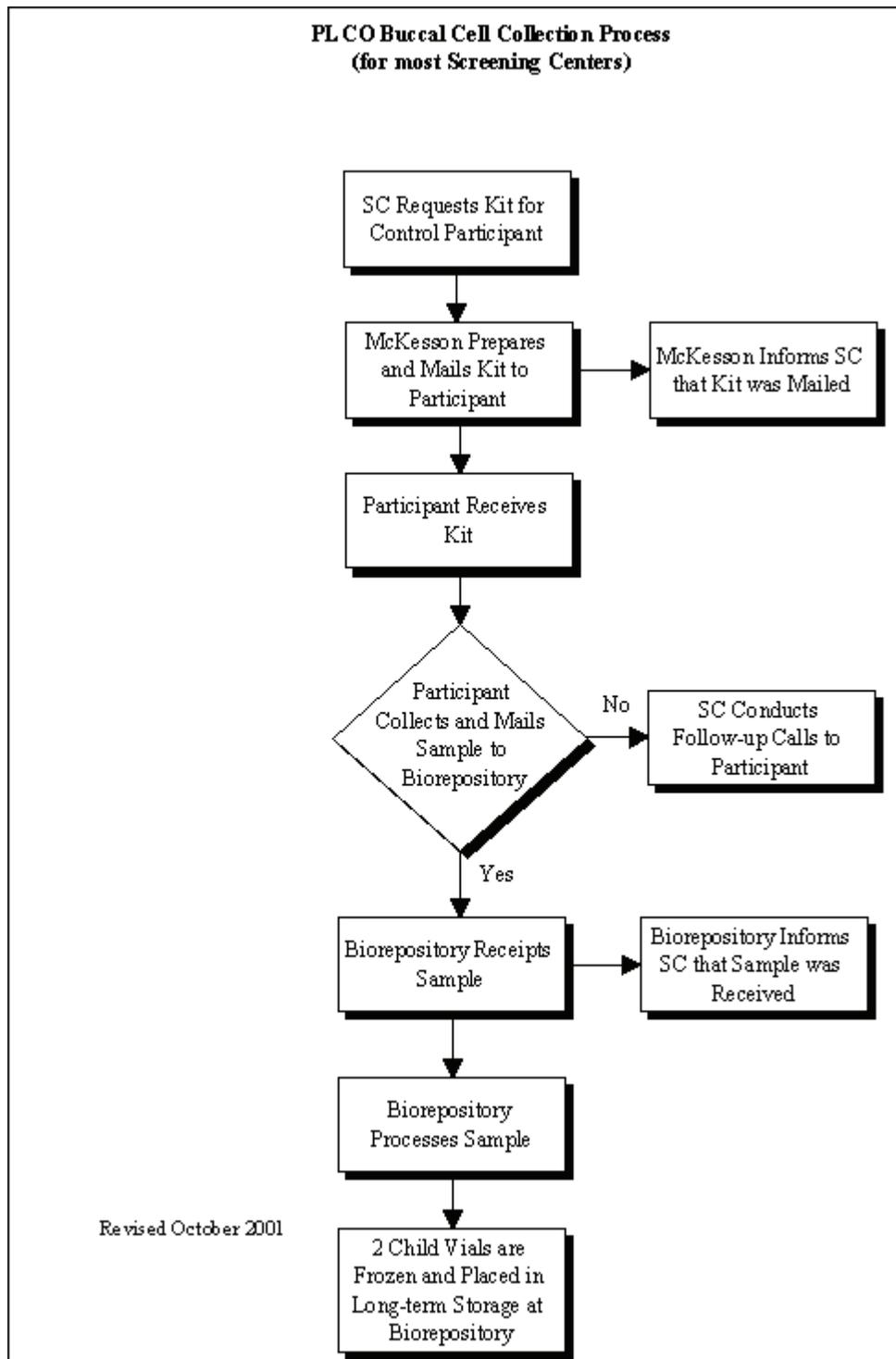
- ▶ Weekly, retrieve an electronic file from the Biorepository that identifies buccal cell samples receipted at the Biorepository and import this file into the SMS. This file will update the SMS buccal cell record; and
- ▶ Conduct Buccal cell sample non-response follow-up.

For most SCs, buccal cell kit assembly and mailing will be performed by the Kit Assembly Company, McKesson BioServices Corporation of Rockville, MD. However, due to concerns over releasing participant identifiers, the University of Minnesota and the University of Pittsburgh SCs will prepare and mail their own

kits. The SCs using the Kit Assembly Company's services will be responsible for requesting kits for participants and the Kit Assembly Company will assemble and mail the kits directly to the participants.

Each control participant will be mailed a buccal cell collection kit to his/her home and asked to provide one buccal cell sample (also known as loose cheek cells or a saliva sample). The kit will include a screw-top collection container, a small bottle of commercially available mouthwash such as Scope mouthwash, a leak-proof Bitran bag with an absorbent pad and a cushioned mailer. The Participant Directions ([Appendix A-18-1](#)) included with the kit instruct the participant to fill the collection container up to the fill line with mouthwash, to swish the mouthwash from the container around in his/her mouth for 45 seconds, and then to expectorate the mouthwash back into the collection container. The participant will place the sealed, filled collection cup and an absorbent pad in a leak-proof Bitran bag, and mail the sample at ambient air temperature (20° - 28° C) directly to the Biorepository in a pre-addressed postage-paid cushioned mailer. Buccal cell sample receipt and processing will be completed by the NCI Biorepository in Frederick, Maryland. The Biorepository will receive individual samples mailed directly from participants on a daily basis and will process, freeze, and store the buccal cell samples. Weekly, the Biorepository will generate a sample receipt file for each SC and transmit the files to the NIH mainframe computer. The SCs will retrieve the sample receipt file from the NIH mainframe computer and import the file into the Study Management System (SMS) to document receipt of the buccal cell samples. The SCs will then telephone participants with outstanding buccal cell samples and encourage them to return a sample. A flowchart of the buccal cell collection process is included in Exhibit 18-1.

**Exhibit 18.1**  
**PLCO Buccal Cell Collection Process**  
**(for most Screening Centers)**



The Buccal Cell Collection chapter is divided into three parts. The first part outlines Screening Center (SC) procedures for mailing Etiologic Studies Consents (ESCs) to previously enrolled control participants who have not signed an ESC. The second part of this chapter contains the buccal cell collection procedures relating to requesting buccal cell collection kits for participants and documenting sample receipt at the Biorepository. The third part of this chapter focuses on those SCs performing their own kit assembly and mailings. This chapter does not include specifics on the tasks to be performed by either the Kit Assembly Company or the Biorepository, but rather how those tasks relate to the SCs. If procedures differ for those SCs responsible for performing their own kit assembly and mailing, clarification will be provided in the applicable sections.

## **18.2 ESC Administration for Control Participants**

All control participants must complete an ESC prior to collection of the buccal cell sample. The purpose of the ESC is described in detail in [Chapter 3.0](#) (Obtaining Informed Consent). For more details regarding the ESC (and obtaining it from participants), please refer to [Chapter 3.0](#) of the MOOP. The administration of the ESC to control participants who have not previously signed an ESC will be the focus of this section. Additional topics included in this section are:

- ESC Cover Letters, FAQ and Brochure;
- ESC Specific to Control Participants;
- Administration of the ESC to Control Participants;
- Documenting the Results of Obtaining ESC;
- ESC Non-response;
- ESC Re-mailing; and
- ESC Reports.

### **18.2.1 ESC Cover Letters, FAQ Sheet and Brochure**

A prototype of the ESC Cover Letter is provided in [Appendix C-18-1](#). The ESC Cover Letter briefly describes the purpose of the ESC and introduces the buccal cell collection process. It will accompany two copies of the ESC and the postage-paid return envelope. Also included in this mailing are a FAQ Sheet ([Appendix A-18-2](#)) and the Buccal Cell Collection ESC Brochure ([Appendix A-18-3](#)). Both of these documents were developed to answer potential questions participants may have regarding the ESC and buccal cell collection. The FAQ Sheet was first implemented in October 2000 and the brochure was added in September 2001. Participants are requested to read, sign, and return one copy of the ESC to the SC. Cover letters and modified FAQ Sheets must be submitted to NCI, with a copy to the CC's SC Coordinator, for review and approval.

### **18.2.2 ESC Specific to Control Participants**

The prototype of the ESC for previously enrolled controls ([Appendix C-18-2](#)) describes only the sample collections that pertain to control participants. Any language specific to the intervention participants has been removed from the original combined ESC consent ([Appendix C-3-3](#)). For ESC administration related to buccal cell collection, SCs must use a version of the ESC specific to

control participants. ESCs must be submitted to NCI, with a copy to the CC's SC Coordinator, for review and approval.

Control Participants who have previously signed an ESC do not have to be re-consented as part of the buccal cell collection effort.

### **18.2.3 Administration of the ESC to Control Participants**

This section provides information on the actual administration of the ESC to control participants including: ESC Expectations; ESC Requests (Directive and Mailing); and Generating and Mailing the ESC Cover Letter and ESC.

#### **18.2.3.1 ESC Expectations**

All control participants must complete an ESC prior to collection of the buccal cell sample. The SMS ESC expectations are the same for all control participants and were modeled after the ESC expectations for intervention participants. However, ESC expectations for control participants are triggered in one of two different ways depending on whether the participant was enrolled before or after the 4.1 systems upgrade (installed in March 1998). Guidelines for each group of control participants follow.

- **Control Participants Enrolled After the 4.1 Systems Upgrade (Newly Enrolled Controls)**

All control participants randomized after the 4.1 systems upgrade (March 1998) receive expectations for a signed ESC at the time they are randomized. SCs should continue to administer ESCs to potential controls and receipt signed ESCs and MDF-ESCs according to current procedures. Refer to [Chapter 3.0](#) for more information. Control participants who have already signed an ESC will not be re-consented for the ESC as part of the buccal cell collection.

- **Control Participants Enrolled Prior to the 4.1 Systems Upgrade (Previously Enrolled Controls)**

Currently, previously enrolled controls (those randomized prior to the 4.1 systems upgrade – March 1998) do not have an ESC expectation. Previously enrolled controls will receive an ESC expectation when the following two steps have been completed 1) the participant is selected in an ESC Directive; *and* 2) the ESC Mailing option has been completed. For these participants, ESC expectations will only be triggered by completion of an SMS ESC mailing.

- **All Control Participants**

For all control participants, once an ESC expectation has been triggered the ESC expectation remains as "Outstanding." There will be no "Delinquent" or "MDF-ESC" expectations. Expectations for the ESC will be *turned off* with the receipt of either an ESC or an MDF-ESC. Only control participants with a receipted ESC will be included in the Buccal Cell Directive.

#### **18.2.3.2 ESC Requests (Directive and Mailing)**

Control participants without a receipted ESC will be selected to be mailed an ESC by generating the SMS Requests/Annual/ESC/Directive followed by the SMS Requests/Annual/ESC/Mailing. At this point, the SMS will document that the participant has been mailed an ESC and will trigger the ESC expectations

as discussed in [Section 18.2.3.1](#). After January 2000, SCs will complete the ESC Requests/Directive and Mailing process once a month.

### ESC Requests/Directives

The ESC Requests Directive identifies control participants that should receive the ESC. This directive is *not* based on participant randomization/anniversary windows. For each SC, a set number of control participants will be selected with the generation of each ESC directive. These numbers were originally assigned so that the ESC mailing effort would be completed over a two-year period, but the numbers were reduced in the 7.1.2 SMS upgrade (May 2001) to allow the SCs more time to complete non-response follow-up calls. ESC mailings are projected to continue through January 2004 for most SCs. The ESC mailing numbers were established to ensure a ready pool of participants would have an ESC receipted and in turn be eligible for the buccal cell directive. The number of control participants selected for each SC's ESC Requests Directive is as follows:

Screening Center	Number of Control Participants Included in ESC Requests Directive (after resumption of mailings in September 2001)
University of Colorado Health Sciences Center	120
Georgetown University	106
Pacific Health Research Institute (Hawaii)	73
Henry Ford Hospital	227
University of Minnesota	500*
Washington University – St. Louis	78
Pittsburgh Cancer Institute	167
University of Utah School of Medicine	56
Marshfield Clinic	110
University of Alabama at Birmingham	N/A**

\* Minnesota will mail 500/month outside of the SMS.

\*\* Alabama administered the ESC at the time of randomization

Control participants will be excluded from the ESC Directive under the following conditions:

- Receipt of a Non-Response Form (NRF);
- Participant status of "deceased" or "in tracing";
- Receipt of an ESC;
- Receipt of an MDF-ESC; and
- Creation of an SMS ESC mailing record (SMS ESC mailing completed, but ESC not yet receipted).

After all ineligible participants have been excluded, control participants will be selected in this order: 1) participants with a record in the cancer table; and 2) participants with the earliest randomization dates will be selected until the ESC Directive limit is reached. Each time the ESC directive is generated (and the mailing is completed), this selection process will be repeated.

SCs are encouraged to be current on all ESC and MDF-ESC receipting (for those participants randomized after March 1998) prior to generating the ESC directive each month. This will help minimize participants being selected for an ESC Directive when they have already signed an ESC or refused to sign the ESC.

Individual Directives (IDirective) will be used to re-mail an ESC to a participant. More details are provided in [Section 18.2.3.6](#) (ESC Re-mailing). Late Directives (LDirective) will be used to identify participants in need of follow-up due to ESC non-response. Under LDirective when Mailing is then chosen, the system will process the Phone Directive and Call Record Merge File similar to that done for the ASU. (This will be done for both the control and intervention ESC LDirectives.) Additional information on ESC Follow-up is provided in [Section 18.2.3.5](#) (ESC Non-response). RDirective regenerates a previous ESC directive and functions the same as the ASU RDirective. See the SMS Systems Upgrade Documentation for more details on ESC Directive options.

### **ESC Requests/Mailing**

The Requests Mailing option must be completed after the generation of the ESC Requests Directive. This function has two purposes: 1) it creates the mail merge file that is used to generate PID labels, ESC cover letters and participant address labels; and 2) it prompts the SMS to document that this person has been mailed an ESC which in turn triggers the SMS ESC expectation for the participant.

#### **18.2.3.3 Generating and Mailing the ESC Cover Letter and ESC**

This section provides instructions for generating the ESC Cover Letters. Also provided in this section are guidelines for labeling, assembling, and mailing the ESCs.

1. Generate the merge files using the SMS Requests/Annual/ESC/Directive and Mailing option.
2. Generate an address label for each selected participant using MAILING option or by using the merge file and a word processing merge document.
3. Generate PID labels (2 needed per participant) using SMS Reports/Labels/PID and import the merge text file generated from the MAILING. PID labels can also be printed using the merge file and a word processing merge document.
4. Generate a participant specific ESC Cover Letter for each selected participant using the merge file.
5. For each selected participant, place a PID label on the signature page(s) of two ESCs.
6. Generate return address labels (with the SC address) for the ESC return envelope.

7. Label the mailing envelope and the ESC return mailing envelope according to your SC's procedures for mailing the ESCs. Apply the required postage to each envelope.
8. Mail the participant the following items:
  - ▶ Participant specific ESC Cover Letter,
  - ▶ Two copies of the ESC (each labeled with the participant's PID on all signature pages),
  - ▶ FAQ Sheet,
  - ▶ Buccal Cell Brochure, and
  - ▶ ESC postage-paid, pre-addressed return envelope.

#### **18.2.3.4 Documenting the Results of Obtaining ESC**

Procedures for the SMS receipt of ESCs for controls will be the same as those for intervention participants. When a signed ESC is received at the SC, receipt the ESC into the SMS under SMS/Entry/Forms/Other/ESC. Receipt of the ESC will include the following variables:

- PID;
- Acknowledgement of Signature A (research on cancer) and date signed; and
- Acknowledgement of Signature B (research on diseases and conditions other than cancer) and date signed.

Once the participant's identification number is entered, the SMS user will be prompted to verify the participant's name on the ESC with the name appearing on the SMS entry screen. The acknowledgment for each signature in the SMS will require a "yes" or "no" answer. If either signature date was estimated, mark the estimated date flag on the ESC receipt screen in the SMS. If necessary, complete date estimation according to [Appendix A-7-1](#) (Forms Completion Specifications for the Annual Study Update, Item 5, Today's Date) of the MOOP.

For those SCs that use an ESC with only one signature and date, the receipt screen must be completed as follows:

- If a participant has checked off "yes" to both types of research, then the acknowledgement of the signature and date must be entered twice, once as signature A and once as signature B.
- If approval has only been given for one type of research, then only the signature that corresponds to that type of research will be receipted as "yes". The other signature will be marked "no." (For example, if a control participant only gives permission for his buccal cells to be used for research involving diseases and conditions other than cancer that affect his age group, then signature A would be marked as "no," and signature B would be marked as "yes.")
- If the participant responded "no" to both types of research, do not receipt the ESC, instead, receipt an MDF-ESC. (Refer to [Chapter 17.0](#) for information on completion of the Missing Data Form.)

Once the signed ESC has been receipted into the SMS, file the ESC in the participant's file. If a participant signs the ESC but does not indicate a "yes" or "no" response, telephone the participant and record the participant's response

on the ESC. Then initial and date the ESC and update the SMS. If a participant does not sign the ESC, return it to the participant for his/her signature.

*Only receipt an MDF-ESC if a participant refuses to sign the ESC. If a participant refuses to sign the ESC, he/she should not be asked again, and an MDF-ESC should be completed. An MDF-ESC will never be expected, but should be receipted if a participant refuses to sign the ESC. In order to differentiate between participants who refused the ESC and those who simply did not return it, code 1 = Refused for participants who actively refused, and code 5 = Can't Locate for participants who simply did not return it.*

If a participant returns a signed ESC after an MDF-ESC has been receipted, first delete the MDF-ESC record, and then receipt the ESC. Only those participants with an ESC receipted will be eligible for the Buccal Cell Directive.

#### **18.2.3.5 ESC Non-response**

If an ESC has not been received within 3 weeks of the date it was mailed, the SC will contact the participant once by telephone to remind him/her to sign and return the ESC. SCs will also have the **option** of using the ESC LDirective to complete a second mailing of ESCs to participants who have not responded to the first mailing. *However, if after the second mailing the participant has not responded, SCs will still be expected to contact the participant by telephone.* Recommendations for contacting the participant by telephone are outlined below.

#### **Recommendations for Follow-up on ESC Non-response**

It is recommended that up to 5 attempts be made to contact the participant by telephone as follows:

- Each call is placed on a different day of the week, Monday-Friday.
- If time and resources permit, 2 additional calls are placed, one on Saturday, one on Sunday.
- The first and last calls are separated by at least one week.
- The calls are made at different times each day (morning, afternoon, evening).

#### **18.2.3.6 ESC Re-mailing**

If the participant loses the ESC or the participant says he/she did not receive the ESC, the SC will run the ESC IDirective (SMS/Requests/Annual/ESC/IDirective). The SC will generate an ESC cover letter and label two copies of the ESC with the participant's PID on the signature pages. Then, the SC will mail the ESC cover letter, ESCs and the postage-paid, pre-addressed envelope to the participant. After a second mailing, the SC will follow-up with non-respondents as noted under [Section 18.2.3.5](#) (ESC Non-response).

#### **18.2.3.7 ESC Reports**

This section describes SMS reports that may be used to monitor the administration of ESCs to control participants. The Open Forms Report identifies control participants with an outstanding ESC expectation. The Participant Overview report displays the ESC status and also lists outstanding ESC expectations. The ESC status appears under "scheduling notes" as one of the following:

- ESC receipted (ESC receipted for participant);
- MDF-ESC receipted (MDF-ESC receipted for participant); and

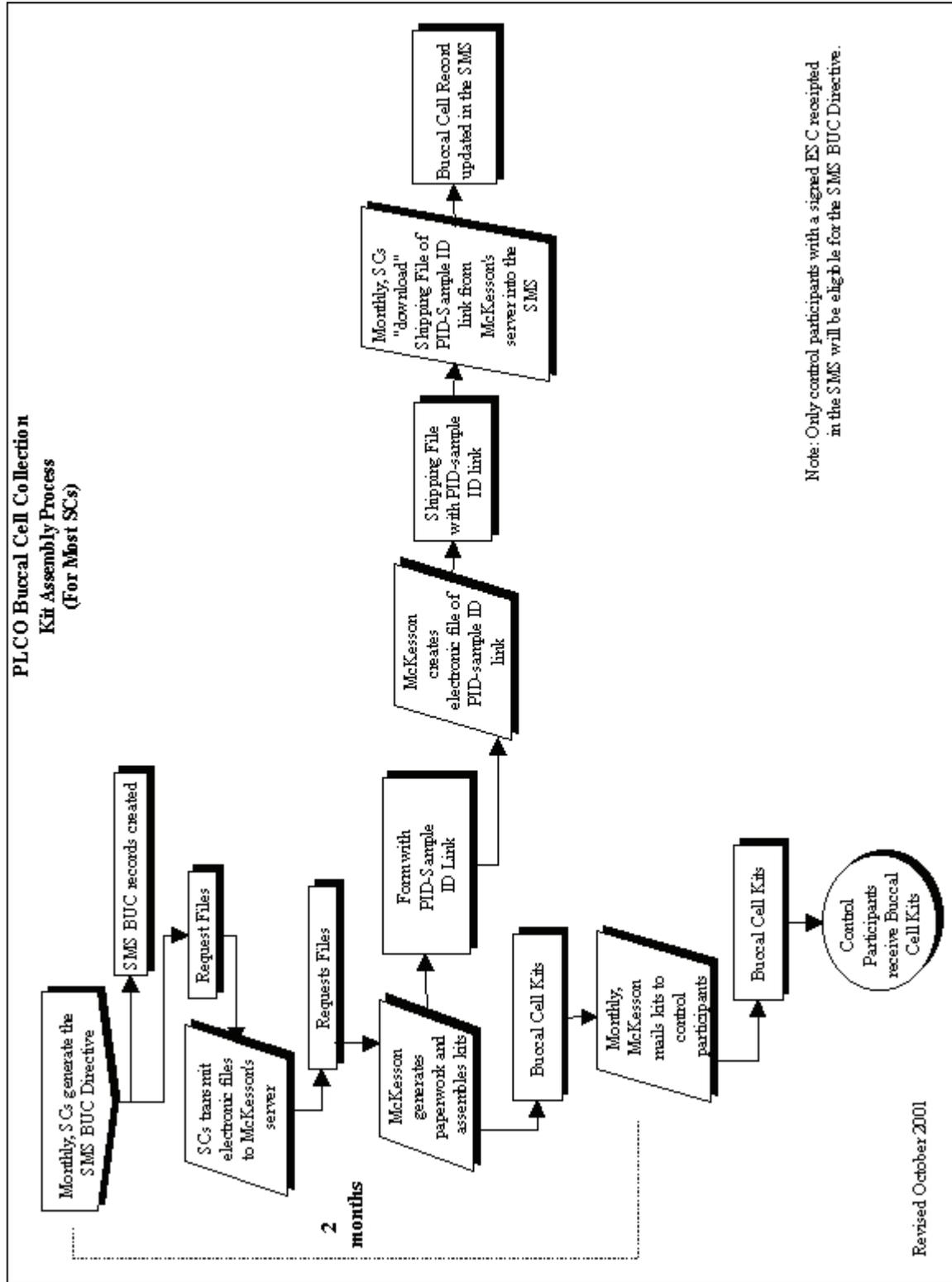
- "Blank" (neither ESC nor MDF-ESC receipted).

SCs may also use the Call Record merge file to assist with identifying participants needing ESC non-response follow-up. See [Section 18.2.3.2](#) (ESC Requests, Late Directive) for more details.

### **18.3 Buccal Cell Collection Procedures**

This section describes procedures related to sending advanced postcards, buccal cell collection kits, and procedures for documenting sample receipt at the Biorepository. As outlined in [Section 18.1](#) (Buccal Cell Collection Overview, Buccal Cell Collection Procedures), the actual kit assembly and mailing for most SCs will be performed by the Kit Assembly Company, McKesson BioServices, Inc. SCs responsible for mailing their own kits will need to refer to Section 18.6 for additional procedures specific to their mailing approach.

To aid in the understanding of the major buccal cell collection components, two flow charts have been included in this section. The first flow chart outlines the Buccal Cell Collection Kit Assembly Process (see Exhibit 18-2) and the second flow chart depicts the Buccal Cell Sample Receipt Process (see Exhibit 18-3).





### 18.3.1 Buccal Cell Collection Schedule

Kit mailings for the first six months were performed at a reduced rate to provide SCs, the Kit Assembly Company, and the Biorepository an opportunity to refine their procedures. Participants from the Colorado, Hawaii, Henry Ford, Pittsburgh, and Utah SCs began receiving kits in May 2000. In June 2000, Georgetown, Washington University, Marshfield, and Alabama SC participants began receiving kits and in August 2000, the Minnesota SC begin mailing kits to their participants. After the start up period, the number of kits mailed each month was increased. The effort was originally expected to be completed in 36 months. To allow SCs more time to complete their non-response follow-up calls, the number of control participants selected for kit mailings each month was reduced. The mailing numbers were modified as part of the 7.1.2 SMS upgrade (May 2001) and the reduction was realized when the kits were mailed in July 2001. Due to the slower mailing schedule, initial buccal cell collection kit mailings to control participants are projected to continue through September 2004. The projected completion date will vary by SC with many SCs completing initial kit mailings in early 2004. Initial kit mailing estimates specific to each SC are provided in later in this section. Buccal cell collection kits will be mailed to participants according to the SC Buccal Cell Kit Mailing Schedule. This schedule will be provided to SCs, the Kit Assembly Company and the Biorepository under separate cover.

The number of participants selected by the SMS Buccal Cell Directive (see [Section 18.3.4](#) for more details) to receive buccal cell kit each month are listed below:

Screening Center	# of Kits per month beginning Aug 2001*
University of Colorado Health Sciences Center	118
Georgetown University	99
Pacific Health Research Institute (Hawaii)	51
Henry Ford Hospital	221
University of Minnesota	286**
Washington University – St. Louis	149
Pittsburgh Cancer Institute	158
University of Utah School of Medicine	133
Marshfield Clinic	152
University of Alabama at Birmingham	61
Totals	1428

\* The numbers listed above do not include kit remnants.

\*\* Minnesota will send 286 kits from 6/01-10/01 then 500 kits from 11/01-7/03.

### **18.3.1.1 Buccal Cell Collection Advance Postcard**

Following the events on and after September 11, 2001, most SCs began to send participants postcards to inform them that they will be receiving a buccal cell kit in an effort to avoid having them confuse the buccal cell kit with a suspicious package. Each SC has specific contact information on the postcard.

SCs mail the buccal cell kit advance postcard to control participants selected for buccal cell kit mailings two weeks prior to when the participants kits are mailed. When determining the schedule to mail postcards, the SCs using McKesson for kit mailings (all except Minnesota and Pittsburgh), should account for the approximate two month lag time between when the buccal cell Request file is transmitted to McKesson and the kits are mailed to participants (e.g. participants included in the Request File transmitted to McKesson in January would be mailed kits in March). Buccal cell kit advance postcards should be sent to all participants receiving a buccal cell kit regardless of whether he/she is going to receive a first or second (re-mail) buccal cell kit.

To generate mailing labels for the postcards, SCs need to use the archived requests text files created each time the buccal cell Requests/Mailing option is completed. The archived requests text file contains participant names and addresses and is a copy of the file transmitted to McKesson for kit mailings. Archived text files are saved under the PLCO/SMS/BUCRT directory as Rnnyymm#.txt where:

- R stands for Requests File;
- nn = Screening Center ID;
- yy = 2-digit year;
- mm = 2-digit month; and,
- # = sequential number from 1 to 9.

For more information on the file structure of the Requests File, refer to the PLCO Buccal Cell Collection systems documentation. SCs may print mailing labels using the SMS label option (SMS/Reports/Labels/Address/Text File) and the requests text file (Rnnyymm#.txt). SCs needing assistance with locating the Request Files or printing mailing labels should contact PLCO User Support.

### **18.3.2 Situations in Which a Buccal Cell Sample Should Not Be Collected**

If a participant has not signed the ESC, a buccal cell sample should not be collected. If a buccal cell sample is lost or destroyed after it is mailed by the participant or receipted at the Biorepository, no attempts will be made to obtain a replacement sample.

### **18.3.3 Buccal Cell Collection Kits**

The buccal cell collection kit will consist of the following components:

- Large Cushioned Mailer [7 1/4" x 12"] (to mail the kit to the participant);
- Small Cushioned Mailer [6" x 10"] (to mail the sample to the Biorepository);
- 15 ml Nalgene Cryogenic Vial (collection cup with sample ID label)\*\*;
- Absorbent pad (to absorb potential spills during sample shipment);

- Leak proof Bitran bag [6" x 6"] (to contain potential spills during sample shipment);
- 1.5 oz bottle of Scope Mouthwash (for sample collection);\*\*
- Clear plastic bag with side pouch (to hold kit materials);
- Participant specific Buccal Cell Collection Cover Letter; and
- Participant Directions (photocopied on light blue paper).\*\*

\*\*There should be no substitutions for these products without prior NCI approval.

A sample kit was provided to each SC. Since the kit may become contaminated when its contents are examined by SC staff, this kit is to be used for reference purposes only and is not for participant use. *[Note: In an effort to reduce DNA contamination, gloves must be worn whenever anyone other than the participant handles the collection cup outside of the Bitran bag.]*

#### **18.3.3.1 Participant Directions**

A copy of the participant directions for collecting the buccal cell sample is provided in [Appendix A-18-1](#). The Kit Assembly Company will insert a copy of these directions into each buccal cell kit and the same directions will be used for all 10 SCs.

If SCs find that participants are having difficulty understanding the instructions, or if additional instructions are being provided over the telephone to participants, SCs should report this to the Buccal Cell Coordinator at the CC. SC comments will be monitored and participant collection instructions will be modified if necessary.

If a participant states that they cannot use the Scope mouthwash provided, due to allergies and/or alcohol content, water may be used for the buccal cell collection. Participants should be instructed to substitute water for the mouthwash in the collection instructions.

#### **18.3.3.2 Buccal Cell Collection Kit Cover Letter**

Buccal cell collection kits will be sent to participants with a participant specific cover letter. The Buccal Cell Collection Kit Cover Letter provides an overview of the buccal cell collection procedures and a prototype letter is presented as [Appendix C-18-3](#). All cover letters must be approved by NCI (and copied to the CC's SC Coordinator) prior to use.

#### **18.3.3.3 Buccal Cell Sample ID Labels**

Prior to being sent to participants, the collection cups will be pre-labeled with a self-adhesive sample ID label. The label includes both an eye-readable and a bar-coded sample ID and sequence number. A red fill-line is also printed on the label to illustrate how full the participant should fill the collection cup with mouthwash in preparation for collecting the sample.

The Kit Assembly Company will affix the buccal cell sample ID labels to the collection cups when the buccal cell collection kits are assembled. Each buccal cell collection kit will include a unique buccal cell sample ID. A sample ID will be assigned to a participant when the kit is assembled. The sample ID number for the buccal cell samples will be a nine-digit number. The first seven digits (2 alpha and 5 numeric characters) are the unique collection ID (for example PC12345). The last three digits (numeric) are the specimen ID and will be "024" for the buccal cell samples. To assist with sample receipt at the Biore-

pository, both the sample ID and specimen ID numbers are combined into one barcode on the label. Buccal cell samples will also be identified in the SMS by the combined sample ID and specimen ID numbers (for example PC12345024).

*[Note: The barcode symbology used for the buccal cell sample ID labels is Code 128. SCs performing kit assembly will need a barcode reader that supports Code 128. This will not be required for SCs not performing kit assembly since these SCs will receive electronic files with eye-readable data and will not need to scan the buccal cell sample ID labels.]*

#### **18.3.3.4 SC Sample ID Ranges**

Specific sample ID ranges have been assigned to each SC and are listed below. The sample ID will be used to identify the sample with the participant's SC.

### **Buccal Cell Sample ID Ranges**

<b>Screening Center</b>	<b>SC ID</b>	<b>Range begins at:</b>	<b>Range ends at:</b>
University of Colorado Health Sciences Center	SC01	PL10000	PL17999
Georgetown University	SC02	PL18000	PL23999
Pacific Health Research Institute (Hawaii)	SC03	PL24000	PL30999
Henry Ford Hospital	SC04	PL31000	PL46999
University of Minnesota	SC05	PL47000	PL65999
Washington University – St. Louis	SC06	PL66000	PL73999
Pittsburgh Cancer Institute	SC08	PC10000	PC19999
University of Utah School of Medicine	SC09	PL74000	PL82999
Marshfield Clinic	SC10	PL83000	PL93999
University of Alabama at Birmingham	SC11	PL94000	PL99999

#### **18.3.4 Procedures to Request Kit Mailings**

This section describes the procedures related to requesting that buccal cell collection kits be sent to control participants.

##### **18.3.4.1 Buccal Cell Expectations**

A buccal cell (BUC) expectation denotes that the participant has been *mailed* a buccal cell collection kit and has not returned a buccal cell sample to the Biorepository. The SMS Buccal Cell (BUC) expectations are the same for all control participants. Control participants will receive a BUC expectation when the following three steps have been completed:

1. the participant is selected in a BUC Directive;
2. the BUC Mailing option has been completed; and
3. the Kit Assembly Company's shipping file containing the record for that participant has been receipted into the SMS.

For control participants, once a BUC expectation has been triggered the buccal cell expectation remains "Outstanding." There will be no "Delinquent" or "Miss-

ing Data Form (MDF-BUC)" expectations. Expectations for the buccal cell sample will be *turned off* with the SMS receipt of either a Biorepository record documenting the receipt of a buccal cell sample or an MDF-BUC. If a person dies after a kit was mailed and a participant vital status code of deceased or presumed deceased is entered in the SMS, the participant's BUC expectation is also turned off. SMS entry of an "in tracing" (IT) participation status code or receipt of a non-response form (NRF) with a reason code of either "refused" (RF), "lost contact" (LC), or "medical condition" (MC) will also turn off the participant's outstanding BUC expectation. It is not necessary to complete an MDF-BUC in these instances. Refer to the Buccal Cell Systems Documentation for more details on BUC Expectations. (**Note:** Buccal cell Requests are no longer available from the SMS.)

#### **18.3.4.2 Buccal Cell Requests (Directive and Mailing)**

All control participants must complete an ESC prior to collection of the buccal cell sample. Only control participants with a receipted ESC will be included in the Buccal Cell Directive. Control participants will be selected for buccal cell collection kit mailing by generating the SMS/Requests/Annual/BUC/Directive followed by the Mailing. An example of the SMS Buccal cell (BUC) Directive is provided in [Appendix B-18-1: Buccal Cell Directive/Late Directive](#). At this point, the SMS will create the buccal cell record for the participant. However, the BUC expectation will not be triggered until the Kit Assembly Company's mailing record is receipted. Refer to [Section 18.3.4.1](#) (Buccal Cell Expectations) for more information on BUC expectations.

**SCs will complete the Buccal Cell Requests/Directive and Mailing process once a month.** This process will produce an electronic file, which will be transmitted to the Kit Assembly Company as described in [Section 18.3.4.3](#) (Transmission of Buccal Cell Requests Files to the Kit Assembly Company).

**SCs will generate and transfer the electronic Requests Files to the Kit Assembly Company according to the Buccal Cell Requests and Shipping File Transfer Dates provided under separate cover to the SCs and Kit Assembly Company.**

#### **Buccal Cell Requests/Directives**

The Buccal Cell Requests Directive identifies control participants that should receive a buccal cell collection kit. This directive is *not* based on participant randomization/anniversary windows. For each SC, a set number of control participants will be selected with the generation of each buccal cell directive. More information regarding the number of kits to be mailed each month is provided in [Section 18.3.1](#). If less than the set number of participants is eligible for the BUC Directive, the number of participants selected for the Directive will be displayed on the screen and included in the Directive counts. SCs may note this for future reference, but no additional action is necessary. If no participants are eligible for the BUC Directive a message will be displayed on the screen. In the event that no participants are eligible for the BUC Directive, the SC must fax or email this information to the Kit Assembly Company (McKesson) and copy the Buccal Cell Coordinator at the CC. McKesson's email address is [Steve.Lindenfelser@mbs-mckhboc.com](mailto:Steve.Lindenfelser@mbs-mckhboc.com) and the fax number is (301) 838-9753.

Control participants will be excluded from the Buccal Cell Directive under the following conditions:

- Receipt of a Non-response Form (NRF);

- Participant status of “deceased” or “in tracing”;
- Receipt of an MDF-BUC;
- Receipt of an MDF-ESC;
- Creation of an SMS buccal cell mailing record (SMS buccal cell mailing completed, but documentation of Biorepository buccal cell sample receipt not yet receipted into the SMS); and;
- Participants with a value in the “Special ASU” field on the Participant Status screen.

An MDF-BUC with a code of “other” and a specify of “pilot participant” has been entered for *all* Buccal Cell Pilot participants.

After all ineligible participants have been excluded; control participants will be selected in this order: 1) participants with a record in the cancer table; and 2) participants with the earliest randomization dates will be selected until the Buccal Cell Directive limit is reached. Each time the Buccal Cell Directive is generated (and the mailing is completed), this selection process will be repeated.

SCs are encouraged to be current on all ESC receipting prior to generating the buccal cell directive each month. This will help ensure that an adequate number of participants are eligible for the Buccal Cell Directive.

Individual Directives (IDirective) will be used to mail a second buccal cell collection kit to a participant. More details are provided in [Section 18.3.7](#) (Requesting a Second Buccal Cell Collection Kit). Late Directives (LDirective) will be used to identify participants who have not returned a buccal cell sample and are in need of follow-up. Refer to [Section 18.3.6](#) (Buccal Cell Sample Non-response) for additional information on LDirective. To reduce the potential of sending duplicate kit mailing requests for the same PID, RDirective is not operable for the BUC Directive. See the Buccal Cell Systems Documentation for more details on Directive options.

### **Buccal Cell Requests/Mailing**

The Requests Mailing option must be completed after the generation of the Buccal Cell Requests Directive. This function has two purposes: 1) it creates the electronic file that will be transmitted to the Kit Assembly Company, and 2) it prompts the SMS to create the SMS buccal cell record. The Requests file is sorted by PID.

#### **18.3.4.3 Transmission of Buccal Cell Requests Files to the Kit Assembly Company**

The SCs will generate the BUC Requests/Mailing and transmit the electronic file to the Kit Assembly Company according to the Buccal Cell Requests and Shipping File Transfer Dates provided under separate cover to the SCs and Kit Assembly Company. SCs will be notified by the Kit Assembly Company’s staff if their BUC Requests File was not received or if there were problems with the file. SCs will report any problems with the Requests File or file transmission to PLCO User Support. For specific instructions on completing the Requests File transmission refer to the Buccal Cell Systems Documentation.

Once the SC requests file is received, the Kit Assembly Company will begin to produce the participant-specific kit cover letters, participant address labels, and participant-specific buccal cell forms. Final assembly of the kits will be completed and the buccal cell collection kits will be mailed to participants. All

participants in a given BUC Requests File will be mailed their buccal cell collection kits on the same day, usually within 2 months of receipt of the Requests File. For example, if the SC generates and transmits the BUC Requests File to McKesson in February, McKesson will mail kits to those participants in April.

[Note: Those SCs performing kit assembly and mailing will not transmit files to the Kit Assembly Company. Instead, each month, a set number of partially assembled kits will be mailed from the Kit Assembly Company to those SCs. Refer to [Section 18.6](#) Buccal Cell Collection Procedures for SCs Assembling and Mailing Kits for more details.]

### **18.3.5 Procedures to Document Receipt of Samples**

This section describes procedures related to documenting the receipt of buccal cell samples. Procedures for participant follow-up, documenting non-response, requesting a second buccal cell kit, and handling a returned collection kit are also included in this section.

#### **18.3.5.1 Retrieval of Buccal Cell Shipping Files from the Kit Assembly Company**

All buccal cell kits will be mailed to participants according to the SC Buccal Cell Kit Mailing Schedule provided to the SCs, the Kit Assembly Company, and the Biorepository under separate cover. Once the kits have been mailed to the participants, the Kit Assembly Company will document the date the kits were mailed to the participants. The Kit Assembly Company will then prepare an electronic file (Shipping File) that includes the following variables for each participant: PID, sample ID (including specimen ID number), and date kit mailed to participant. This file will be placed on the Kit Assembly Company's server the day after the kits are mailed. Each SC will retrieve their own file according to the Buccal Cell Requests and Shipping File Transfer Dates provided to the SCs and the Kit Assembly Company under separate cover. For more information on the file retrieval process, refer to the Buccal Cell Systems Documentation.

Once the file is retrieved, the SC will receipt the Shipping File into the SMS through SMS/Entry/Buccal/Receipt from Company. The SMS will then update the corresponding SMS buccal cell records indicating that the participants have been mailed kits. **It is at this point that the BUC Expectations are triggered for those participants.** If any difficulties are encountered or if any error reports are generated during this process, contact PLCO User Support immediately.

[**Note:** *Those SCs performing kit assembly will not retrieve the Shipping File from the Kit Assembly Company. Instead, those SCs will prepare an electronic file linking the PID to the appropriate sample ID sent to the participant and the date the kit was mailed to the participant. Refer to [Section 18.6](#) for more information.*]

#### **18.3.5.2 Documenting Buccal Cell Sample Receipt at the Biorepository**

Participants will be instructed to mail their buccal cell samples directly to the Biorepository using the postage-paid, pre-addressed cushioned mailer provided in the buccal cell collection kit. If a participant inadvertently sends a buccal cell sample to the SC rather than the Biorepository, mail the sample to the Biorepository within one day of receiving the sample. Mail the buccal cell samples at ambient temperature. Do not freeze buccal cell samples or add these

samples to PLCO blood sample shipments. The Biorepository mailing address for *buccal cell samples* is:

PLCO Trial  
National Cancer Institute-FCRDC  
Bldg. 1066/Repository  
P. O. Box B Bldg. 1050  
Frederick, MD 21702-9913

*(Do not use this address for PLCO blood shipments.)*

SCs will be informed of buccal cell sample receipt at the Biorepository through the *weekly* SMS import of the Biorepository Sample Receipt File. Each week's Sample Receipt File will include only the samples received at the Biorepository between Friday of the previous week to Thursday of the current week. Files will be created by the Biorepository and made available to SCs on Friday afternoons by 5:00 p.m. EST/EDT. Each week, SCs must retrieve their Biorepository Receipt File after 5:00 p.m. EST/EDT on Fridays or any time prior to noon on the following Tuesday.

Data transmission of the Biorepository Sample Receipt File is described in Buccal Cell Systems Documentation. SCs will import the Biorepository Sample Receipt File into the SMS through SMS/Entry/Buccal/Receipt from Biorepository. More information on importing the Sample Receipt File is provided in the Buccal Cell Systems Documentation.

When the Biorepository Sample Receipt File is receipted into the SMS, the buccal cell records for those samples included in the file will be updated with the date the buccal cell sample was received at the Biorepository. This in turn will close the BUC Expectation for those participants whose samples were received.

### **18.3.6 Buccal Cell Sample Non-response**

If the buccal cell sample has not been received at the Biorepository within 3 weeks of the date the Buccal Cell Collection Kit was mailed, the SC will contact the participant once by telephone to remind him/her to collect and mail the sample. Recommendations for contacting the participant by telephone are outlined below.

#### **Recommendations for Follow-up on Buccal Cell Sample Non-response**

It is recommended that up to 5 attempts be made to contact the participant by telephone as follows:

- Each call is placed on a different day of the week, Monday-Friday.
- If time and resources permit, 2 additional calls are placed, one on Saturday, one on Sunday.
- The first and last calls are separated by at least one week.
- The calls are made at different times each day (morning, afternoon, evening).

*[Note: Colorado, Hawaii, Washington University, and Utah will initiate follow-up calls more than 3 weeks after the kit was mailed due to increased kit mailing and sample return times. Follow-up calls will begin at 4 weeks for Colorado and Washington University, and 5 weeks for Hawaii and Utah. SCs considering altering the time from kit mailing to*

*initiating follow-up, must contact the Buccal Cell Coordinator at the CC prior to altering the follow-up call schedule.]*

### **Identifying Participants Requiring Follow-up**

In addition to the Open Forms and Participant Overview Reports, SCs may use the BUC LDirective/Mailing call record merge file to identify participants who were mailed a buccal cell collection kit more than 3 weeks ago, but who have not returned a buccal cell sample (and do not have an MDF-BUC). The BUC call record merge file is produced through the BUC LDirective/Mailing. An example of the SMS Buccal Cell (BUC) Late Directive is provided in [Appendix B-18-1: Buccal Cell Directive/Late Directive](#). Participants with outstanding buccal cell samples will continue to be included in the BUC LDirective/Mailing call record merge file until either the Biorepository receipt file documenting the arrival of the buccal cell sample at the Biorepository is receipted into the SMS, or an MDF-BUC is receipted for the participant. SCs may execute the SMS BUC LDirective/Mailing at anytime. However, SCs will need to establish a method for differentiating between participants requiring follow-up and those that have received follow-up.

More specific information on the Buccal Cell Call Record Merge file and the Buccal Cell Call Record is provided in the Buccal Cell Systems Documentation. SCs may also print the Participant Information Sheet for additional information relevant to contacting the participant.

### **Documenting Buccal Cell Non-response**

*An MDF-BUC will never be expected, but should be receipted if a participant refuses to provide a buccal cell sample. If one successful follow-up call has been made (or if 5 call attempts have been made) and the participant has not provided the buccal cell sample, an MDF-BUC may be receipted. **The study year for MDF-BUC must match the study year of BUC expectation.*** Refer to Participant Overview or Open Forms Report to verify the study year of a participant's buccal cell expectation. (Refer to [Chapter 17.0](#) for information on completion of the Missing Data Form.)

If a participant has an MDF-BUC receipted, and later provides a buccal cell sample; the information documenting the sample receipt will be imported into the SMS. Refer to [Section 18.3.9](#) (Buccal Cell Collection Reports), REDITS/Form (INTER) Reports, for more information on how identify participants with both an MDF-BUC and buccal cell sample receipted.

If a person dies after a kit was mailed and a participant vital status code of deceased or presumed deceased is entered in the SMS, the participant's BUC expectation is turned off. SMS entry of an "in tracing" (IT) participation status code or receipt of a non-response form (NRF) with a reason code of either "refused" (RF), "lost contact" (LC), or "medical condition" (MC) will also turn off the participant's outstanding BUC expectation. It is not necessary to complete an MDF-BUC in these instances.

### **Viewing the Buccal Cell Record**

Since all updates to the SMS buccal cell record will be made through the import of electronic files from the Kit Assembly Company and the Biorepository, SCs have only the option to view the SMS buccal cell record. SCs may view a participant's buccal cell record(s) through SMS/FAST/VIEW/BUCCAL or SMS/FAST/ENTRY/BUCCAL/UPDATE.

### 18.3.7 Requesting a Second Buccal Cell Kit

Participants will only be mailed a second buccal cell kit if they report that the original kit was lost, destroyed, or never received. Do not request more than 2 kits for a given participant. Prior to requesting that a second kit be mailed to a participant, SCs should view the participant's SMS buccal cell record(s) and verify that only one kit has been mailed. The buccal cell record contains a mailing number indicator designating the number of kits that have been mailed. Although this second kit request process will often be referred to as kit re-mailing, participants will be mailed a new buccal cell collection kit from the Kit Assembly Company. Participants expecting a second buccal cell collection kit should be cautioned that they may not receive the second kit for approximately 3 months from the time the kit re-mailing is requested.

If the participant reports that he/she lost or did not receive a complete buccal cell collection kit, request that *one* more kit be mailed the participant by running the **Buccal Cell IDirective** (SMS/Requests/Annual/BUC/IDirective) followed by the Mailing. The SMS will add the participants flagged for a kit re-mailing when the next BUC Directive/Mailing is run. Complete all kit remain requests prior to generating the next BUC Directive/Mailing. Refer to the Buccal Cell Systems Documentation for more information.

SCs are cautioned that *both* the BUC IDirective and Mailing must be completed when requesting kit remailings. SCs may elect to keep copies of the IDirectives as re-mail requests are generated throughout the month and then compare them to the next full BUC Directive to make sure all remain requests have been included on the current BUC Directive. This comparison should be completed after running the BUC Directive and prior to running the Requests/Mailing.

IDirective is used only to request a second kit for participants that have already been shipped one kit through the SMS Requests/Mailing. Do not use BUC IDirective for requesting first-time mailings to participants.

If two kits are mailed to a participant, receipt of a sample from either kit will turn off the BUC expectation. If two kits were mailed, only **one** expectation will be listed on the Open Forms Report, the Participant Overview and included in the LDirective. From the time the remain request is sent to the Kit Assembly Company until the second kit is mailed, the BUC expectation is turned off. Once the second kit is mailed, the BUC expectation is once again triggered.

[**Note:** Those SCs performing kit assembly and mailing will remain kits directly to participants. The Kit Assembly Company will provide partially assembled kits to these SCs for a kit-remailing surplus. Refer to [Section 18.6](#) for more information.]

### 18.3.8 Returned Buccal Cell Collection Kits

When the SC receives a buccal cell kit that was returned to the SC from the U.S. Post Office and not delivered to a participant, the SC will complete the following steps in the order listed below:

- Change the participant's status to "in tracing" by entering "IT" into the SMS Participation Status field on the Participant Status screen.
- If the participant's forwarding address was not provided, attempt to find the participant's new address.
- If the forwarding address was provided by a source other than the participant, validate the address by contacting the participant.

- Once the participant's address has been confirmed, remove the participant from "in tracing" status by deleting "IT" from the SMS Participation Status field on the Participant Status screen.
- Request that an additional kit be sent to the participant using the SMS Buccal Cell IDirective followed by the MAILING option. (This is the same option used to request a kit when the participant reports a kit as lost or destroyed.)
- The SMS will add a record for the participant when the next BUC Directive/Mailing is run and the Kit Assembly Company (or SCs performing kit assembly and mailing) will mail the kit to the participant.

SCs are cautioned that the participant's original BUC expectation will remain outstanding until the BUC Directive/Mailing is completed. After the BUC Directive/Mailing is completed the participant's BUC expectation will be removed by the SMS and an additional BUC record will be created for the participant. Once the Kit Assembly Company's Shipping File containing the mailing record for the participant's new address is imported into the SMS, a new BUC expectation will be triggered by the SMS. Receipt of the Shipping File will also update the participant's second BUC record.

SCs should retain any returned buccal cell collection kits. If the SC is unable to store the returned buccal cell collection kits, contact the Buccal Cell Coordinator at the CC.

### **18.3.9 Buccal Cell Collection Reports**

This section describes SMS reports that were developed or modified to assist with monitoring the buccal cell collection effort. Information specific to each report is provided below. Additional information regarding these reports is also provided in the Buccal Cell Systems Documentation.

#### **Open Forms**

The Open Forms Report identifies control participants with an outstanding Buccal Cell expectation. Buccal Cell samples are considered "outstanding" from the date the kit was mailed. On the Open Forms Report, the buccal cell sample "Latest Due Date" is assigned based on the kit mailing date plus 21 days. SCs may use this report to identify those participants requiring follow-up for non-response.

#### **Participant Overview**

The Participant Overview report displays the Buccal Cell status as one of the following:

- BUC - Received Participant's buccal cell sample received at the Biorepository and documented in the SMS
- BUC - Outstanding Participant has been mailed a buccal cell collection kit, but sample has not been returned
- MDF-BUC - Received MDF-BUC receipted for participant

---

#### **Buccal Cell Call Record**

SCs may use the Buccal Cell Call Record merge file (created by running the BUC LDirective) and the Buccal Cell Call Record to assist with identifying participants needing buccal cell sample non-response follow-up. This Buccal Cell Call Record provides information specific to the buccal cell effort. Additional information on the Buccal Cell Call Record and the variables included in the Buccal Cell Call Record merge file is provided in the Buccal Cell Systems Documentation. Additional information is also provided in [Section 18.3.6](#) (Buccal Cell Sample Non-response).

### **REDITS/Form (INTER) Reports**

Unlike other forms, buccal cell does not have an interactive check for a previous receipt of an MDF when the Biorepository Sample Receipt Files are imported into the SMS. EM # 18, unlikely condition, identifies participants with both a receipted buccal cell sample and an MDF-BUC. Study year is ignored for this comparison. Resolve these edits by deleting the MDF-BUC record. Interform edit #52, identifies participants with incomplete or blank address information. Resolve these edits by completing the participant's address information and regenerating the BUC Directive/Mailing.

### **Buccal Cell Summary Report**

The Buccal Cell Summary Report ([Appendix B-18-2: Buccal Cell Summary Report](#)) provides counts and percentages of control participants with ESCs mailed and receipted, buccal cell kits mailed, Buccal Cell samples receipted, MDFs (ESC and BUC) receipted, and the number of participants with an outstanding buccal cell sample. Descriptions for some of the report variables follow:

- "Number of Controls Mailed an ESC" reflects only those participants that were mailed an ESC using the ESC control SMS Requests/Mailing;
- "Number of Controls with ESC Receipted" includes all controls with an ESC receipted and may include participants that are not reflected in the "Number of Controls Mailed an ESC";
- "Number of Controls with an MDF-ESC Receipted" "includes all controls with an MDF-ESC receipted and may include participants that are not reflected in the "Number of Controls Mailed an ESC"; and
- "Number of Controls Shipped Kit" includes only participants that have actually been mailed a buccal cell kit and have a date in the SMS ship-date field.

Additional specifications are provided in the Buccal Cell Systems Documentation.

### **18.3.10 Target Response Rates**

The target response rate for ESC mailings to control participants is 70% and the target combined ESC and buccal cell kit response rate is 65%, making the approximate target buccal cell kit response rate 93% (please note that the buccal cell kit response rate is dependent upon the ESC response rate thus the combined target response rate is given). Each SC should attempt to comply to these target response rates.

## 18.4 Reporting Medical Complications of the Buccal Cell Collection

Participant reported medical complications that occur prior to, during, or after the participant collects the buccal cell sample should be documented by the SC and the note placed in the participants file. If the event is considered life threatening, it should also be documented on the Report of Adverse Events for NIH Sponsored Clinical Trials (see [Chapter 17.0](#)). The CC will provide information on medical complications to the NCI for monitoring purposes. The SC must also monitor medical complications so that appropriate action can be taken should any problems become apparent.

## 18.5 Specimen Collection Standardization and Quality Assurance

The responsibility to provide quality assurance for the PLCO buccal cell collection is shared between the Screening Centers, the Kit Assembly Company and the Biorepository. Each institution will follow specific procedures that will collectively provide overall quality assurance for the buccal cell collection.

The screening centers are required to monitor their follow-up call effort to ensure that all required calls have been completed on-time, and that the non-response follow-up requirements specified in [Section 18.2.3.5](#) (ESC Non-response) have been met for each participant. The SCs must have quality assurance procedures in place to verify that the above requirements are met. It is suggested that the SCs maintain an electronic or hard copy log of these follow-up attempts. Upon review of the monthly Buccal Cell Compliance main-frame report, the CC will follow-up with any SC who appears to be behind in making their follow-up calls promptly. The SCs are also responsible for reporting any problems with buccal cell collection to the CC in a timely manner and for promptly taking any necessary corrective action as directed by the CC.

The Kit Assembly Company has developed quality control procedures for their operation and is responsible for compliance with these established procedures. Adherence to these procedures will ensure that kits contain all required supplies, and that the sample ID on the collection cup is correctly linked to the participant identifying information included in the kit. The critical QA responsibility for the Kit Assembly Company is the assurance that the participant receives the collection cup with the sample ID that is linked to the participant identifying information in the Kit Assembly Company's database. The Kit Assembly Company will document any problems in a monthly report to the CC. Screening centers who are not using the Kit Assembly Company and are mailing their own kits are required to submit a QC plan for the kit assembly effort as specified in [Section 18.6.14](#) (SC Quality Assurance Procedures for Buccal Cell Collection).

The Biorepository must have QC procedures in place to assure the accuracy of sample receipt, data entry, and adherence to the buccal cell processing protocol. Upon receipt of the collected samples, the Biorepository will check the condition and quality of the samples. They will report any problems to the CC and document any problems noted on a written log. This written log will include problems encountered during sample receipt and processing and will be submitted to the CC as part of the monthly report. The Biorepository will use the BSI-II system to receipt the samples. The use of barcode labels and

the BSI-II receipt system will provide satisfactory QC for sample receipt data entry. The Biorepository will ensure that each buccal cell processor is trained on the buccal cell sample processing protocol and procedures for documenting sample receipt and processing. The trainee should demonstrate competence in these areas to the trainer before the trainee is allowed to perform the activities unsupervised.

## **18.6 Buccal Cell Collection Procedures for SCs Assembling and Mailing Kits**

For most SCs, the Kit Assembly Company, McKesson BioServices Corporation (McKesson) of Rockville, MD will perform buccal cell kit assembly and mailing. However, two SCs (the University of Minnesota and the University of Pittsburgh) will receive partially assembled buccal cell collection kits from the Kit Assembly Company, perform final kit assembly and mail the kits to participants. This section provides information and procedures specific to SCs assembling and mailing kits to participants and supplements [Section 18.1](#) (Buccal Cell Collection Overview, Buccal Cell Collection Procedures) of this Chapter.

### **18.6.1 Buccal Cell Collection Overview Specific to SCs Mailing Kits**

The remainder of this chapter will focus on the procedures specific to those SCs performing final kit assembly and kit mailing. For SCs mailing buccal cell collection kits directly to participants, the PLCO Buccal Cell Collection includes two major components: 1) mailing ESCs to control participants who have not signed an ESC, and 2) mailing buccal cell collection kits to control participants who have signed an ESC. While some of these procedures are similar to those followed by SCs using the Kit Assembly Company, other procedures differ. Briefly the ESC and Buccal Cell Collection procedures specific to SCs mailing kits will include the following steps:

#### **ESC Procedures**

- ▶ Monthly, generate the SMS ESC Requests (Directive and Mailing) for control participants;
- ▶ Mail ESC and ESC Cover Letter to Participants;
- ▶ Receipt ESC into the SMS; and
- ▶ ESC non-response follow-up.

#### **Buccal Cell Collection Procedures**

- ▶ Procedures to mail kits  
Each procedure is performed monthly.
- 1. Generate the SMS Buccal Cell Requests (Directive and Mailing). These functions identify control participants who have an ESC receipted and should have a buccal cell kit sent to them. The functions generate the text file that is used by the SCs to generate participant-specific paperwork for the kit and create the SMS buccal cell record;
- 2. Use the text file generated by the SMS Buccal Cell Requests (Directive and Mailing) to generate participant-specific Kit Cover Letters, mailing address and PID labels needed for kit assembly;
- 3. Receive partially assembled kits from the Kit Assembly Company;

4. Assemble the buccal cell collection kits with Kit Cover Letters and mail kits to control participants; and
5. Generate an electronic file linking the participant's PID to the sample ID on the collection cup that was mailed to the participant. This file will be generated through use of the SHIPKIT System or through the use of a like system created by the SC. Once the file is generated, import it into the SMS. This file will document that kits have been mailed to the selected participants.

**Procedures to document receipt of samples**

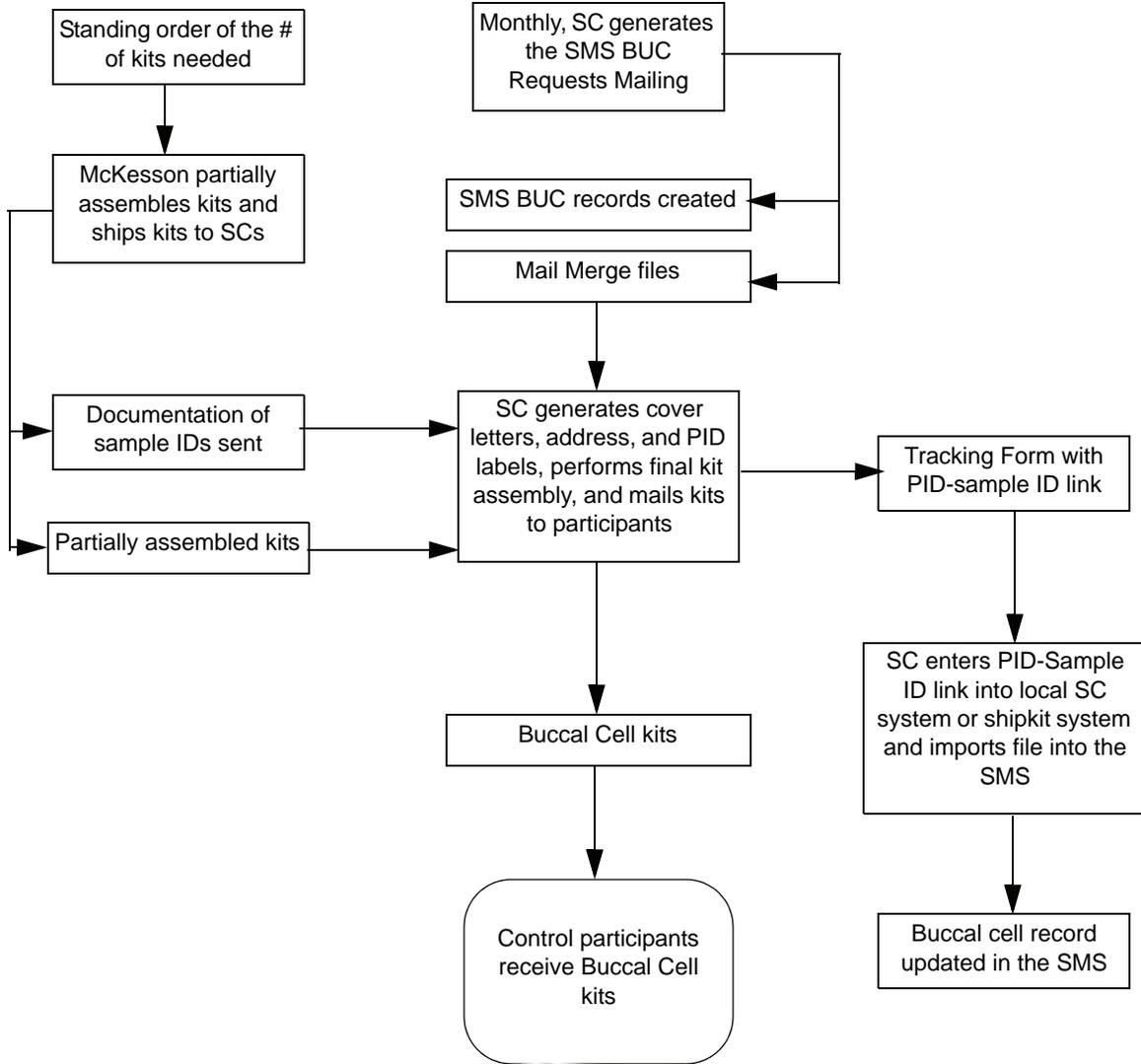
1. Weekly, retrieve an electronic file from the Biorepository that identifies buccal cell samples receipted at the Biorepository and import this file into the SMS. This file will update the SMS buccal cell record; and
2. Complete buccal cell sample non-response follow-up.

To aid in the understanding of the major components of Kit Assembly Process, refer to Exhibit 18-4 which outlines the Buccal Cell Collection Kit Assembly Process for Minnesota and Pittsburgh.

Exhibit 18-4

### PLCO Buccal Cell Collection

Kit Assembly Process  
(for Minnesota and Pittsburgh)



**Note:** Only control participants with a signed ESC received in the SMS will be eligible for the SMS BUC Directive.

## 18.6.2 Buccal Cell Collection Kits

Each month the SC will receive partially assembled kits from the Kit Assembly Company. The kit components will be packaged and labeled as described below:

### Component 1

Large Cushioned Mailer [7 1/4" x 12"] labeled with the SC's return address (to mail the kit to the participant); and

### Component 2

Clear plastic bag with side pouch (containing remaining kit materials).

The side pouch of the clear plastic bag will contain:

- ▶ Participant Directions (photocopied on light blue paper); and
- ▶ Extra sample ID label (matching the label on the collection cup inside the bag).

The clear plastic bag will contain the following:

- ▶ Small Cushioned Mailer [6" x 10"] with pre-addressed, postage-paid Biorepository address label affixed and no return address label (to mail the sample to the Biorepository);
- ▶ 1.5 oz bottle of Scope Mouthwash (for sample collection); and
- ▶ Leak proof Bitran bag [6" x 6"] (to contain potential spills during sample shipment).
- ▶ The Bitran bag will contain the following:
  - ▶ 15 ml Nalgene Cryogenic Vial (collection cup with sample ID label); and
  - ▶ Absorbent pad (to absorb potential spills during sample shipment).

**[Note:** In an effort to reduce DNA contamination, gloves must be worn whenever anyone other than the participant handles the collection cup outside of the Bitran bag.]

The SCs will generate the following materials for use in the final kit assembly:

- ▶ Participant-specific Buccal Cell Collection Kit Cover Letters;
- ▶ Participant mailing address labels; and
- ▶ PID labels.

Additional information regarding these materials is provided in [Section 18.6.6](#) (Generation of Kit, Cover Letters, Address Labels and PID Labels) of this memo.

A sample kit was provided to each SC. Since the kit may become contaminated when SC staff examine its contents, this kit is to be used for reference purposes only and is not for participant use.

### Sample ID Labels

The collection cups will be pre-labeled with a sample ID label. The label includes both an eye-readable and a bar-coded sample ID and sequence number. A red fill-line is also printed on the label to illustrate how full the collection cup should be filled with mouthwash in preparation for collecting the sample.

An extra sample ID label will also be included in the side pouch of the clear plastic kit bag. This extra sample ID label will be identical to the sample ID label on the collection cup contained in the clear plastic bag and will be used to document the sample ID assigned to a particular participant. Additional details on documenting sample ID assignment are provided in [Section 18.6.7](#) (Final Assembly of Buccal Cell Collection Kits).

*The barcode symbology used for the buccal cell sample ID labels is Code 128. SCs performing kit assembly will need a barcode reader that supports Code 128.*

### **18.6.3 Receipt of Partially Assembled Buccal Cell Collection Kits**

As described in [Section 18.6.2](#), each month the SCs will receive partially assembled buccal cell collection kits from McKesson. The kits will be sent to the SCs via UPS 2<sup>nd</sup> day ground service. The number of kits the SCs receive will be based on the number of kits the SC is scheduled to mail in the corresponding mailing month. Minnesota will receive kits approximately two months in advance of mailing to participants and Pittsburgh will receive kits approximately a month in advance.

McKesson will fax the SC's Buccal Cell Kit Shipment Notification, Receipt Verification and Reorder Form ([Appendix A-18-4](#)) to the SCs informing them that the kits have been shipped. Upon receipt of the kits, the SCs will verify that the appropriate number of kits was received. The SCs will then fax the copy of the shipment notification back to McKesson to verify that the shipment was received. Report any problems with the shipments to McKesson and copy the Buccal Cell Coordinator at the CC.

Each SC will receive a number of surplus kits to have on-hand for second kit mailings to participants. SCs will notify McKesson of the number of additional surplus kits that are needed. SCs will request additional surplus kits at least 4 weeks in advance and will use the Buccal Cell Kit Shipment Notification, Receipt Verification and Reorder Form to request the kits.

### **18.6.4 Buccal Cell Expectations**

The SMS Buccal Cell (BUC) expectations operate the same for those SCs mailing kits as those SCs using the Kit Assembly Company. Refer to [Section 18.3.4.1](#) and the Buccal Cell Systems Documentation for more information on buccal cell expectations.

### **18.6.5 Buccal Cell Requests (Directive and Mailing)**

All control participants must complete an ESC prior to collection of the buccal cell sample. Only control participants with a receipted ESC will be included in the Buccal Cell Directive. [*Pittsburgh only: refer to note in [Section 18.6.1](#)*] SC control participants will be selected for buccal cell collection kit mailing by generating the SMS/Requests/Annual/BUC/Directive followed by the Mailing. At this point, the SMS will create the buccal cell record for the participant. However, the BUC expectation will not be triggered until the SC's Shipping File is receipted. Refer to [Section 18.3.4.1](#) (Buccal Cell Expectations) for more information on BUC expectations.

**SCs will complete the Buccal Cell Requests/Directive and Mailing process once a month in order to comply with the SC Buccal Cell Kit Mailing Schedule.** This process will produce an electronic file, which will be used

to produce participant-specific Kit Cover Letters, mailing address labels and PID labels as described in [Section 18.6.6](#).

### **Buccal Cell Requests/Directives**

For information on the Buccal Cell Requests/Directives, refer to [Section 18.3.4.2](#).

### **Buccal Cell Requests/Mailing**

The Requests Mailing option must be completed after the generation of the Buccal Cell Requests Directive. This function has three purposes: 1) it creates the electronic file (BUCC file) that may be used to generate participant-specific Kit Cover Letters, mailing address labels and PID labels, 2) it creates the electronic file (BUCC file or Requests File) that may be used by the SCs to assist with the creation of the Shipping File, and 3) it prompts the SMS to create the SMS buccal cell record. Only the *latest* file generated is saved in the WPfiles/ directory as BUCC. SCs will need to develop and implement internal procedures to ensure that the BUCC file used contains the names and addresses of the participants in the appropriate Requests/Mailing group. At the same time the current BUCC file is created, an identical Requests File is also created. SCs may find it preferable to work with the current BUCC file and to only use the Request Files as archive files. Both the BUCC file and the Requests File are sorted by PID. For more information on Requests File specifications and naming conventions or BUCC files, refer to the Buccal Cell Systems Documentation. SCs will report any problems with either the Requests File or the BUCC file to PLCO User Support.

## **18.6.6 Generation of Kit Cover Letters, Address Labels and PID Labels**

The SCs will generate the BUC Requests/Mailing and may use the electronic BUCC file to generate participant-specific Kit Cover Letters, participant address labels and PID labels.

### **Kit Cover Letters**

To generate participant-specific Kit Cover Letters, the SCs will complete a word processing mail merge using both the previously NCI approved Kit Cover Letter text and the BUCC file (or Requests File) which contains participant names and addresses. Refer to [Section 18.3.3.2](#) for more information on the Kit Cover Letters. SCs are strongly encouraged to print the participant's ID (PID) on each participant's Kit Cover Letter. This will provide a useful reference during kit assembly when the SC will need to match the participant's name and address to his/her PID. If possible, the PID should be printed in a small font and towards the bottom of the Kit Cover Letter so as not to attract the participant's attention. For more information on creating merge files, refer to the SMS Upgrade Documentation or contact PLCO User Support.

### **Address Labels**

A participant mailing address label will be needed for each buccal cell collection kit. SCs may print address labels using the SMS Label option (SMS/Reports/Labels/Address/Text File) and the BUCC File. For more information on printing address labels, refer to the SMS Upgrade Documentation or contact PLCO User Support.

## PID Labels

Depending on internal SC procedures, at least one PID label (with both barcode and eye-readable PIDs) will be needed for each buccal cell collection kit assembled. SCs may print PID labels using the SMS Label option (SMS/Reports/Labels/Address/Text File) and the BUCC File. For more information on printing PID labels, refer to the SMS Upgrade Documentation or contact PLCO User Support.

### 18.6.7 Final Assembly of Buccal Cell Collection Kits

During this final phase of kit assembly, it is critical that the participant's information and identifiers be correctly linked and documented appropriately. The SCs may find it advantageous to only work with one participant's documents and buccal cell collection kit at a time, to help reduce the chances of a collection cup with an incorrectly assigned sample ID being sent to a participant.

The SCs' procedures need to incorporate the following steps:

1. Place a PID label for each selected participant on a Buccal Cell Collection Tracking Form ([Appendix A-18-5](#)). Forms Completion Specifications for the Buccal Cell Collection Tracking Form are also provided in [Appendix A-18-5](#).
2. Select one participant's documents (Kit Cover Letter and Buccal Cell Collection Tracking Form) to assemble and a partially assembled kit (clear plastic bag with pouch and large cushioned mailer).
3. Remove the extra sample ID label from the pouch of the clear plastic bag and place the sample ID label on the corresponding participant's Buccal Cell Collection Tracking Form. This will document which sample ID was assigned to a particular participant.

**[Note:** *In an effort to reduce DNA contamination, gloves must be worn whenever anyone other than the participant handles the collection cup outside of the Bitran bag.*]

4. Affix the participant's address label onto the large cushioned mailer.
5. Verify that the participant's name and address on both the large cushioned mailer and the Kit Cover Letter corresponds to the same participant whose PID label is on the Buccal Cell Collection Tracking Form.
6. While inserting both the participant's Kit Cover Letter and the plastic bag with pouch into the large cushioned mailer, verify that the following items are included in the large cushioned mailer:
  - Buccal Cell Collection Kit (clear plastic bag with side pouch); and
    - ▶ Small cushioned mailer
    - ▶ 1.5 oz bottle of Scope Mouthwash
    - ▶ Leak proof Bitran bag
    - ▶ Collection cup
    - ▶ Absorbent pad
    - ▶ Participant Directions
  - Participant-specific Kit Cover Letter.

*If possible, the SCs should not seal the large cushioned mailer until the Shipping File has been created, so that if questions arise as to the sample ID and PID assignment, the kit contents may easily be examined.*

### **18.6.8 Creation of Buccal Cell Shipping Files**

The SCs will use the completed Buccal Cell Tracking Form, the BUCC file that contains the PIDs of the corresponding participants, and either the SHIPKIT System or a local SC system, to create an electronic file (Shipping File) linking the PID to the appropriate sample ID sent to the participant. The Shipping File will contain the PID, the sample ID, the date the kit was mailed to the participant, and the date the Shipping File was created. If the current BUCC file does not contain the corresponding PIDs, the SC may use one of the archived Requests Files instead of the BUCC file. The system used to create the Shipping File needs to compare the PIDs included in the BUCC file with the PIDs scanned from the Buccal Cell Collection Form and produce error reports to alert the SC of potential errors in sample ID assignment. For more information on Shipping File specifications and naming conventions, refer to the Buccal Cell Systems Documentation. For additional details on the SHIPKIT System and error reports refer to the SHIPKIT System Documentation. *SCs using their own local SC system need to submit systems documentation to the CC.*

It is important that SCs create the Shipping File prior to mailing the corresponding kits to participants so that in the event a discrepancy between PID and sample assignment is discovered, it may be investigated and resolved prior to the kit being mailed to the participant. The date the kit was mailed to the participant may be estimated based on the SC Buccal Cell Kit Mailing Schedule (provided under separate cover). When creating the Shipping File, SCs are strongly encouraged to scan the PID and sample ID barcodes from the Buccal Cell Collection Tracking form rather than keying the identifiers.

Once the Shipping File is created, the SC will receipt the file into the SMS through SMS/Entry/Buccal/Receipt from Company. The SMS will then update the corresponding SMS buccal cell records indicating that the participants have been mailed kits. **It is at this point that the BUC Expectations are triggered for those participants.** If any difficulties are encountered or if any error reports are generated during this process, contact PLCO User Support immediately.

### **18.6.9 Mailing Buccal Cell Collection Kits to Participants**

Once the Shipping File has been created and any data discrepancies have been investigated and resolved, the SCs will seal the large cushioned mailers. Then, according to the SC Buccal Cell Kit Mailing Schedule (provided under separate cover), mail the fully assembled kits to the participants. **All participants in a given BUC Requests File will be mailed their buccal cell collection kits on the same day.** The SCs will document the date the kits are to be mailed to the participants on the Buccal Cell Collection Tracking Form.

The SCs will mail the kits to participants via the U.S. Postal Service's First Class Mail service. The postage fees associated with mailing the kits to participants are the responsibility of the SCs. The Kit Assembly Company is responsible for postage fees associated with participants mailing the buccal cell sample to the Biorepository.

### **18.6.10 Documenting Buccal Cell Sample Receipt at the Biorepository**

Procedures documenting buccal cell sample receipt at the Biorepository are the same for those SCs mailing kits as those SCs using the Kit Assembly Company. Refer to [Section 18.3.5](#) (Procedures to Document Receipt of Samples) for more information.

### **18.6.11 Buccal Cell Sample Non-response**

In addition to the information provided below on viewing the buccal cell record, the SCs will follow the buccal cell sample non-response procedures outlined in [Section 18.3.6](#). SCs responsible for mailing kits will follow different procedures from those SCs using the Kit Assembly Company when requesting a second buccal cell kit for a participant. Procedures specific to SCs mailing kits are provided in the next section.

### **18.6.12 Requesting a Second Buccal Cell Kit**

Participants will only be mailed a second buccal cell kit if they report that the original kit was lost, destroyed, or never received. Do not send more than 2 kits to a given participant. Prior to requesting (through IDirective) that a second kit be mailed to a participant, SCs should view the participant's SMS buccal cell record(s) and verify that only one kit has been mailed. The buccal cell record contains a mailing number indicator designating the number of kits that have been mailed. Although this second kit request process will often be referred to as kit remailing, participants will be mailed a new buccal cell collection kit from the SC.

If the participant reports that he/she lost or did not receive a complete buccal cell collection kit or the kit was damaged or destroyed, request that **one** more kit be mailed the participant by running the **Buccal Cell IDirective** (SMS/Requests/Annual/BUC/IDirective) followed by the Mailing. The SMS will add the participants flagged for a kit remailing when the next BUC Directive/Mailing is run. Complete all kit remail requests prior to generating the next BUC Directive/Mailing. Refer to the Buccal Cell Systems Documentation for more information.

SCs are cautioned that **both** the BUC IDirective and Mailing must be completed when requesting kit remailings. SCs may elect to keep copies of the IDirectives as remail requests are generated throughout the month and then compare them to the next full BUC Directive to make sure all remail requests have been included on the current BUC Directive. This comparison should be completed after running the BUC Directive and prior to running the Requests/Mailing.

IDirective is used only to request a second kit for participants that have already been shipped one kit through the SMS Requests/Mailing. IDirective must be used to update the BUC record and document that a second kit was mailed to the participant. Do not use BUC IDirective for requesting first-time mailings to participants.

Participants expecting a second buccal cell collection kit should be cautioned that they might not receive the second kit for approximately 1-3 months from the time the kit remailing is requested through IDirective. The time frame between requesting the second kit and mailing the kit is related to the amount of time the SC has allowed for final kit assembly and mailing, the time of

month the IDirective request is completed, and the date the next BUC Directive/Mailing file is generated.

If two kits are mailed to a participant, receipt of a sample from either kit will turn off the BUC expectation. If two kits were mailed, only **one** expectation will be listed on the Open Forms Report, the Participant Overview and included in the LDirective. From the time the remail request is added to the BUC Requests File until the second kit is mailed (and the BUC record is updated in the SMS), the BUC expectation is turned off. Once the second kit is mailed, the BUC expectation is once again triggered.

### **18.6.13 Buccal Cell Collection Reports**

Refer to [Section 18.3.9](#) for more information on buccal cell collection reports.

### **18.6.14 SC Quality Assurance Procedures for Buccal Cell Collection**

Since the buccal cell collection kit assembly process involves numerous steps, it is critical that the SCs develop, document, and implement quality assurance procedures to ensure that the participant receives the collection cup with the documented sample ID. *The SCs will submit their written procedures to the CC for review.*

# INDEX

## A

abstracting diagnostic evaluation information [8-12](#)  
abstracting non-PLCO cancer information [8-16](#)  
abstracting treatment information [8-15](#)  
adenoma [13-2](#)  
Adhoc Query [2-13](#), [13-3](#)  
Administrative Tracking Form (ATF) [4-7](#)  
adverse events, monitoring [17-57](#)  
Adverse Experience Report (AER) [10-46](#)  
Age Review Report [2-12](#), [17-50](#)  
Algorithm for Death Review [17-55](#)  
Algorithm Results Report [9-19](#), [9-19](#)  
Analytic Laboratories (Etiologic) [1-7](#)  
Ancillary Studies Subcommittee [1-5](#)  
ancillary study [1-11](#)  
Annual Follow-up Screening Tests [7-6](#)  
Annual Follow-up Screening Visits [7-5](#)  
Annual Study Update (ASU) [7-2](#), [8-5](#), [9-5](#), [9-16](#)  
ASU Directive [7-3](#)  
ASU Late Directive [6-20](#), [7-3](#)  
ASU Response Rate Report [17-53](#)  
ASU/PSH Forms Received [17-53](#)

## B

Baseline Directive [5-2](#), [6-13](#)  
Baseline Locator Form (BLF) [5-1](#), [6-10](#), [9-6](#)  
Baseline Questionnaire [5-1](#)  
Baseline Screening Tests [6-1](#)  
Baseline screening visit [6-4](#)  
Biorepository [1-7](#), [1-10](#)  
Biorepository Activity Without ESC Report [3-7](#)  
Biorepository cryovials, storing [10-29](#)  
blood collection  
    *form discrepancies* [10-47](#)  
    *non-response* [10-46](#)  
    *recommended supplies* [10-12](#)  
blood collection forms [10-8](#)  
blood draw procedure, medical complications [10-46](#)  
blood draw processing procedures [10-20](#)  
blood draw, situations when it should not be given [10-2](#)

blood processing and storage for Biorepository [10-18](#)  
blood protocol, equipment specifications [10-52](#)  
blood sample  
    *ID labels* [10-4](#)  
    *protocol* [10-1](#)  
    *shipping* [17-33](#)  
BQ/RAND Discrepancies, reporting [4-7](#), [4-8](#)  
Buccal Cell collection  
    *kits* [18-14](#)  
    *medical complications* [18-25](#)  
    *overview* [18-1](#)  
    *procedures* [18-10](#)  
    *quality assurance* [18-25](#)  
    *reports* [18-23](#)  
    *schedule* [18-13](#)  
Buccal Cell requests/directives [18-17](#)  
Buccal Cell sample non-response [18-20](#)  
Buccal Cell Summary Report [17-54](#)

## C

CA-125II blood test [10-1](#)  
Cancer Confirmation List [8-7](#), [8-22](#), [17-54](#)  
cancer incidence and mortality [17-54](#)  
Cancer Registries Request List [8-6](#)  
cancer status [8-1](#)  
    *ascertaining* [8-4](#)  
    *determination* [9-15](#)  
    *suspected* [8-7](#)  
    *suspicious* [8-4](#)  
Cancers on Death Certificates (ConDC) [9-17](#)  
Cancers on Death Certificates Report [8-6](#), [8-7](#)  
Chest X-ray Screening Examination Form [11-6](#)  
coding [17-26](#)  
computer system reports, storing [17-18](#)  
computer systems at SCs [17-5](#)  
Contact Summary Report [2-13](#)  
Control Activities Report [17-56](#)  
Count/List of MDFs [17-54](#)

## D

data collection activities  
    *management* [17-7](#)  
    *monitoring* [17-36](#)  
    *overview* [1-7](#)  
Data Export [2-13](#), [4-9](#)  
Data Export Module (XPORT) [17-6](#)  
Data Manager, responsibilities [17-2](#)  
data retrieval [17-28](#)  
data security [17-19](#)  
data transmission [17-34](#)

death certificate [1-9](#), [9-10](#), [9-12](#), [9-16](#)  
*shipment of* [9-14](#)  
Death Certificate Receipt Report [9-13](#)  
Death Documentation Sheet (DDS) [9-13](#), [9-15](#)  
Death Review Committee [9-2](#)  
death review process [9-2](#)  
death review selection criteria [9-19](#)  
DEES [17-7](#), [17-31](#)  
DEES Final Disposition Report [8-22](#)  
DEES/SMS Comparison [5-6](#)  
Departments of Motor Vehicle Administration [9-11](#)  
Diagnostic Evaluation Form [6-12](#), [8-4](#), [8-6](#)  
Diet History Questionnaire (DHQ) [6-12](#)  
*administering* [6-14](#)  
Dietary Questionnaire (DQX) [6-12](#)  
Dietary Questionnaire (DQX), shipping [17-33](#)  
Dietary Questionnaires [6-1](#), [6-12](#)  
*receiving and editing* [6-16](#)  
*shipping to NCS* [6-20](#)  
digital rectal examination procedures [12-1](#)  
DRC review [9-25](#)  
DRE [12-1](#)  
*examiner qualifications* [12-5](#)  
*quality control* [12-6](#)  
*reporting medical complications* [12-3](#)  
*reporting results* [12-4](#)  
duplicate randomization [17-58](#)  
Duplicate Report [5-6](#)

## E

editing computer data [17-31](#)  
editing data manually [17-25](#)  
eligibility [2-2](#)  
Eligibility Contact Report [17-50](#)  
Eligibility Screener [2-3](#)  
Eligibility Screener Review [2-11](#)  
Eligibility Screener Review Report [17-49](#)  
Eligibility Verification Form [2-4](#), [4-1](#)  
Enrollment Status Report [4-8](#), [17-51](#)  
Enrollment Summary Report [4-8](#)  
Epi-Info [8-10](#)  
ESC  
*administration* [18-4](#)  
*non-response* [18-9](#)  
*requests/directives* [18-6](#)  
Etiologic Studies Consent (ESC) [3-4](#), [10-2](#)  
Evista/Raloxifene [2-2](#)  
Examination Summary Report [6-7](#), [17-52](#)  
examiner training [10-51](#)  
examiners, responsibilities [17-2](#)  
exclusion criteria [2-2](#)

expectations [6-1](#)

## F

Final Complete (FCM) [17-32](#)  
Final Incomplete (FIC) [17-32](#)  
Follow-up activities [7-1](#)  
Follow-up Locator Form (FLF) [7-3](#), [9-6](#)  
form disposition, assigning [17-32](#)  
Forms and Specimens Tracking Module (FAST) [17-6](#)  
forms and specimens, receipting [17-29](#)  
FSG  
*abnormal results* [13-6](#)  
*documenting results* [13-7](#)  
*equipment specifications* [13-3](#)  
*examiner qualifications* [13-7](#)  
*interpreting findings* [13-5](#)  
*procedures* [13-1](#)  
*quality control* [13-8](#)  
*reporting complications* [13-6](#)

## H

hard copy data, losing [17-20](#)  
Health Care Financing Administration [9-11](#)  
Histopathology/Cytopathology Report [8-10](#)  
History of Malignancy Form (HOM) [9-16](#), [9-17](#)  
HSQ Status Report [17-53](#)  
HSQ Summary Report [17-53](#)

## I

ICD-9-CM codes [8-5](#)  
ICD9-CM coding [17-3](#)  
ICD-O coding [17-3](#)  
information requests [17-11](#)  
informed consent [3-1](#)  
informed consent, documenting results [3-2](#)  
initial treatment information [8-15](#)  
Institutional Review Board (IRB) [3-1](#)  
Interactive Randomization Report [4-4](#)  
Inter-Forms Edit Report [17-57](#)  
Interim Complete (ICM) [17-32](#)  
Intervention Activities Report [6-2](#), [17-56](#), [17-56](#)  
Intra-Forms Edit Report [17-57](#)

## L

Labels Module (LABELS) [17-6](#)  
Laboratory (Screening Test) [1-6](#)  
List of Participants in Tracing [17-53](#)  
List/Count Receipt MDFs [3-7](#)

## M

Main Study Consent form [3-2](#)  
Materials Distribution [17-50](#)  
Materials Distribution Report [2-12](#)  
McKesson [18-17](#)  
medical record abstract forms [8-11](#)  
Medical Record Abstractor (lead), responsibilities [17-2](#)  
Medical Record Abstractor, responsibilities [17-2](#)  
Medical Record Background Report [8-7](#), [8-9](#), [8-22](#), [17-54](#)  
Medical Record Release Authorization Form [8-9](#)  
medical records, abstracting [8-1](#)  
metastatic PLCO cancer [8-15](#)  
metastatic sites [8-17](#)  
Missing Data Form (MDF) [6-3](#), [6-3](#), [6-7](#), [6-20](#), [7-4](#), [8-2](#), [17-14](#)  
missing data, documenting [17-14](#)  
Modeling and Simulation Subcommittee [1-5](#)  
mortality data [9-1](#)  
multiple primary cancers [8-14](#)

## N

National Death Index (NDI) [9-6](#)  
National Death Index List [9-15](#)  
NCI Project Officers [1-4](#)  
NCI reporting [17-63](#)  
NCS Discrepancy Notification Fax [6-22](#)  
NDI matches, updating SMS [9-10](#)  
NDI reports [9-8](#)  
Non-Participation Status Summary [17-51](#)  
Non-respondents [6-19](#)  
non-response for cancer confirmation [8-20](#)  
Nonresponse Form [6-3](#), [6-4](#)  
nonresponse, documenting [17-15](#)  
Nosologist, responsibilities [17-3](#)

## O

Office Staff, responsibilities [17-2](#)  
Open Forms Report [3-7](#), [5-6](#), [6-7](#), [6-18](#), [8-7](#), [8-22](#), [13-3](#)  
Open Forms/Specimens Report [17-54](#)  
opscan forms editing [17-25](#)  
Organization Report [2-12](#), [17-50](#)  
Organizational Structure [1-3](#)  
Out of Window [7-4](#)  
over- and under-reporting of PLCO cancers [9-1](#)

## P

participant accrual [4-7](#)

Participant Control Record [6-4](#), [6-5](#), [7-6](#), [11-6](#)  
Participant ID [4-5](#)  
Participant Information Sheet [17-56](#)  
Participant Overview Report [3-7](#), [6-2](#), [6-18](#), [8-7](#), [8-22](#), [13-3](#), [17-52](#), [17-56](#)  
Participant Status Screen [9-12](#)  
participant transfer [17-35](#)  
participant's request to withdraw from PLCO, documenting [17-15](#)  
Participants with Cancer on Death Certificate Report [17-55](#)  
Pathology Review Request (PRR) [9-26](#)  
pathology slides  
    *collection and review* [16-1](#)  
    *labeling and receipting* [16-2](#)  
    *procuring* [16-5](#)  
    *receipting at the Central Repository* [16-4](#)  
    *shipping* [16-3](#)  
    *storing* [16-2](#)  
PCC Directive/Late Directive [3-7](#)  
Phlebotomist/Laboratory Technologist, responsibilities [17-2](#)  
phlebotomy protocol [10-9](#)  
Physician Consultants, responsibilities [17-4](#)  
Physician/Hospital Location Information Form [8-15](#)  
PLCO  
    *background of* [1-2](#)  
    *Colon Subcommittee* [1-5](#)  
    *Lung Subcommittee* [1-5](#)  
    *objectives of* [1-2](#)  
    *Ovary Subcommittee* [1-5](#)  
    *policy guidelines* [1-11](#)  
    *Prostate Subcommittee* [1-4](#)  
    *Protocol Subcommittee* [1-4](#)  
    *time schedule* [1-9](#)  
PLCO cancers  
    *mortality from* [1-2](#)  
PLCO Logo [1-11](#)  
PLCO Monitoring and Advisory Panel (MAP) [1-4](#)  
PLCO Quality Assurance Plan [17-62](#)  
PLCO Steering Committee [1-4](#)  
PLCO Study Brochure [3-1](#)  
PLCOnet [17-34](#)  
Population Profile Report [17-51](#)  
Processing Laboratory (Etiologic) [1-7](#)  
Production Edits Report for Individual Tracking [2-12](#)  
Proscar/Propecia/finasteride [2-2](#)  
Protocol Changes Consent (PCC) [3-3](#)  
Protocol Violation Form [4-6](#)  
protocol violations, documenting and resolving [17-58](#)

PSA and CA-125II results [10-47](#)  
PSA blood test [10-1](#)  
PSA/CA-125II  
    *blood processing and storage* [10-14](#)  
    *storage of* [10-16](#)  
Publication Policy [1-11](#)  
Publications Subcommittee [1-5](#)

## Q

QA Checks Report [6-7](#)  
quality assurance [8-23](#)

## R

randomization [4-1](#)  
    *batch* [4-4](#)  
    *errors* [4-6](#)  
Randomization Assignment Report [4-8](#), [17-55](#)  
randomized ineligibles, documenting and resolving [17-61](#)  
record keeping [17-17](#)  
recruitment [2-1](#)  
recruitment activities, monitoring [17-49](#)  
Recruitment Progress Report [2-11](#), [17-49](#)  
Recruitment Summary Report [2-11](#), [3-7](#), [17-49](#)  
referrals [6-11](#)  
Referrals for Exam Forms [6-7](#), [17-52](#)  
Reporting Recruitment Summary Data [2-13](#)  
Requests Module in FAST [6-19](#)  
Results Pending Report [6-7](#), [17-52](#)

## S

SC Coordinator, responsibilities [17-1](#)  
SC population status [17-51](#)  
SC Staff, training [17-4](#)  
Scheduled and Complete Presentations [2-12](#), [17-50](#)  
screening center management [17-1](#)  
screening center staffing [17-1](#)  
Screening Centers [1-6](#)  
Screening Examination Report [6-9](#), [17-54](#)  
Screening Results Report, correcting errors [6-10](#)  
Screening Test Results Report (STRR) [6-8](#), [11-7](#), [12-4](#)  
screening tests, reporting results [6-9](#)  
security of data [17-19](#)  
Session Edits for Individual Tracking [17-50](#)  
Shipment Notification Fax [6-21](#)  
shipping, specimens and documents [17-32](#)  
site visits [17-63](#)

smoking status, determined by [11-1](#)  
SMS modules [17-6](#)  
SMS Telecommunications Module (COMM), management of [17-6](#)  
SMS/DEES Synchronization Reports [5-6](#)  
Social Security Death Index (SSDI) [9-11](#)  
staff identification number [17-5](#)  
study data, processing [17-21](#)  
Study ID Assignment Report [4-8](#), [17-55](#)  
Summary of Contacts with Organizations Report [17-50](#)  
Summary of Scanned Forms Report [8-22](#)  
System Administration Module (ADM) [17-6](#)

## T

TASR [2-5](#), [2-8](#)  
TASR, possible duplicates [17-50](#)  
TASR/RAND Comparison Report [2-12](#), [4-8](#), [17-50](#)  
TNM staging [17-3](#)  
Tracing Log [17-53](#)  
Tracking and Summarizing Recruitment Module (TASR) [17-6](#)  
Tracking Potential Participants [2-4](#)  
Transmittal Log, DOX and DHQ [6-21](#)  
Transmitting Data to the Coordinating Center [5-6](#)  
transvaginal ultrasound (TVU) procedures [15-1](#)  
TVU  
    *abnormal results* [15-4](#)  
    *examination procedures* [15-3](#)  
    *examination scheduling* [15-1](#)  
    *examiner qualifications* [15-5](#)  
    *interpreting findings* [15-3](#)  
    *quality control* [15-6](#)  
    *specifications* [15-2](#)  
TVU Screening Examination Form [15-4](#)

## U

UCLA Tissue Typing Laboratory (UCLA) [10-1](#)  
unknown primary [8-17](#)  
updating cancer status [8-19](#)

## V

Vanguard blood collection [10-2](#)  
vital status ascertainment [9-5](#)  
Vital Status Confirmation List [9-15](#), [17-55](#)

## W

Westat [1-6](#)

**X**

X-ray

*abnormal results* [11-5](#)  
*equipment specifications* [11-2](#)  
*examination procedures* [11-3](#)

*examiner qualifications* [11-7](#)  
*interpretation of findings* [11-4](#)  
*procedures* [11-1](#)  
*quality control* [11-8](#)  
*reporting results* [11-7](#)

## **APPENDIX A**

### **Appendix A: Data Collection Forms And Specifications**

## **A-2-1**

### **A-2-1: Eligibility Screener (ES)**

#### **Specifications for the Eligibility Screener**

**Prostate, Lung, Colorectal and Ovarian  
Cancer Screening Trial**

Form Approved OMB #: 0925-0407  
Exp. Date: 10/02  
Version Date: 11/00

**ELIGIBILITY SCREENER**

**If you are interested in participating in the PLCO Cancer Screening Trial, please complete this questionnaire and return it to the PLCO study office.**

**Today's Date:**

_ _  /  _ _  /  _ _ _ _
Month          Day          Year

**If an address is printed above, review the information and make any corrections or additions in the box below. If there is no address above, please complete the box below in its entirety. PLEASE INCLUDE YOUR TELEPHONE NUMBER(S).**

NAME: MR./MRS./MISS/MS.	FIRST	MIDDLE	LAST	(JR., SR., etc.)
CURRENT STREET ADDRESS:				APT. NO.
CITY		STATE	ZIP	
TELEPHONE NUMBER:				
HOME: (    )		WORK: (    )		OTHER: (    )

<b>1.</b>	<b>What is your date of birth?</b>												
<table style="margin: auto;"> <tr> <td style="border-bottom: 1px solid black;"> _ _ </td> <td style="border-bottom: 1px solid black;">/</td> <td style="border-bottom: 1px solid black;"> _ _ </td> <td style="border-bottom: 1px solid black;">/</td> <td style="border-bottom: 1px solid black;">19</td> <td style="border-bottom: 1px solid black;"> _ _ </td> </tr> <tr> <td style="text-align: center;">Month</td> <td></td> <td style="text-align: center;">Day</td> <td></td> <td></td> <td style="text-align: center;">Year</td> </tr> </table>		_ _	/	_ _	/	19	_ _	Month		Day			Year
_ _	/	_ _	/	19	_ _								
Month		Day			Year								

<b>3.</b>	<b>Which of these groups best describes you? (CHECK ONE)</b>
<input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Asian <input type="checkbox"/> Pacific Islander <input type="checkbox"/> American Indian or Alaskan Native	

<b>2.</b>	<b>What is your gender?</b>
<input type="checkbox"/> Male <input type="checkbox"/> Female	

<b>3a.</b>	<b>Are you of Hispanic origin? (CHECK YES OR NO)</b>
<input type="checkbox"/> Yes <input type="checkbox"/> No	

(OVER)

**Statement of Confidentiality**

Collection of this information is authorized by the Public Health Service Act, Section 412 (42 USC 285 a-1). Rights of study participants are protected by the Privacy Act of 1974. Participation is voluntary and there are no penalties for not participating or withdrawing from the study at any time. Participation will not influence a person's relationship with any provider of medical care or any federal program such as Social Security or Medicare. The information collected in this study will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. Names and other identifiers will be separated from information provided and will not appear in any report of the study. Information provided will be combined for all study participants and reported as statistical summaries. Study records will be kept for approximately 2 years past the end of the study, and then destroyed.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974. ATTN: PRA (0925-0407). Do not return the completed form to this address.

4. Are you undergoing treatment for any type of cancer (other than basal-cell and squamous-cell skin cancer) at this time? (CHECK YES OR NO)

Yes  
 No

9. Are you currently participating in a cancer screening or cancer primary prevention study? (CHECK YES OR NO)

Yes \_\_\_\_\_  
Name of Study  
 No

5. Have you ever been told by a physician that you have any of the following types of cancer? (CHECK YES OR NO FOR EACH TYPE)

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	Colon or Rectal Cancer
<input type="checkbox"/>	<input type="checkbox"/>	Lung Cancer
<input type="checkbox"/>	<input type="checkbox"/>	Prostate Cancer ( <b>Men Only</b> )
<input type="checkbox"/>	<input type="checkbox"/>	Ovarian Cancer ( <b>Women Only</b> )

10. In the past 6 months, have you taken Proscar or Propecia (also known as finasteride) (**Men Only**)? (CHECK YES OR NO)

YES  
 NO

6. Have you had surgery to remove any of the following organs? (CHECK YES OR NO FOR EACH ORGAN)

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	The Entire Colon
<input type="checkbox"/>	<input type="checkbox"/>	One Lung
<input type="checkbox"/>	<input type="checkbox"/>	The Entire Prostate ( <b>Men Only</b> )

11. During the past three years, have you had more than one PSA blood test (for detection of prostate cancer)? (**Men Only**) (CHECK YES OR NO)

Yes  
 No

7. Have you had a hysterectomy (surgical removal of the uterus)? (**Women Only**) (CHECK YES OR NO)

Yes \_\_\_\_\_

Were both ovaries removed?

Yes (GO TO 9)  
 No (GO TO 8)

No (GO TO 8)

12. During the past three years, have you had a colonoscopy, sigmoidoscopy, or barium enema to examine the colon and rectum? (CHECK YES OR NO)

Yes  
 No

8. Have you had surgery to remove your ovaries? (**Women Only**) (CHECK YES OR NO)

Yes \_\_\_\_\_

Were both ovaries removed?

Yes  
 No

No

13. How did you first hear about the PLCO Trial? (CHECK ONE)

Mail  
 PLCO Participant  
 Friend or relative  
 Advertisement (newspaper, TV, radio, etc.)  
 Other \_\_\_\_\_  
SPECIFY

**Thank you for completing this questionnaire. Please return the questionnaire in the postage-paid envelope to:**

PLCO Screening Trial  
University  
Address  
City, State ZIP

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE ELIGIBILITY SCREENER**

The Eligibility Screener may be sent by mail and completed by the participant or it may be administered by an SC staff member. The following are specifications for the administration of the form by telephone with a sample script for introducing the screener. These specifications may also be used as a reference document for answering questions from potential participants who are completing the form themselves.

**Check Boxes Regarding Interest in the Trial:**

*Depending on the SC preference, these check boxes may or may not appear on the form. If they are present, they should be completed as follows:*

If the potential participant is interested in participating in the trial, s/he or an SC staff member should check "Yes."

If the potential participant is not interested in participating in the trial, s/he, or an SC staff member, should check "No."

**Today's Date:** Record the current month, day and year. Zero-fill month and day, if applicable.

**Name and Address Label:** If desired, the SC may affix a mailing label showing the potential participant's name and address in the space provided. These labels may be generated from the Tracking and Summarizing Recruitment Module of the SMS.

**Sample Script for Introduction of Screener:**

*"Hello, my name is \_\_\_\_\_ and I'm calling on behalf of (NAME OF SCREENING CENTER). Recently, we sent you a letter inviting you to participate in the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial being conducted with the National Cancer Institute. Did you receive our letter?"*

YES \_\_\_\_\_ "I'd like to tell you more about the study." (CONTINUE BELOW)

NO \_\_\_\_\_ "I'd like to tell you about the study." (CONTINUE BELOW)

*"The purpose of this study is to determine whether screening for the early detection of prostate, lung, colorectal and ovarian cancers can reduce deaths from these cancers. Since doctors are not sure whether these screening tests are effective at reducing cancer deaths, some of the study participants will receive screening tests, others will receive their regular medical care, and the two groups will be compared. All participants will be contacted each year and asked questions about their medical care over the previous year.*

*We would like to ask for your participation in the study. The study will provide invaluable information that may help save lives, and we hope you will agree to help. Your participation, however, is voluntary. Are you interested in participating?"*

YES \_\_\_\_\_ (CHECK THE FIRST BOX ON PAGE 1 OF SCREENER (if using check boxes) AND CONTINUE BELOW.)

*"In order to participate in the trial, you must meet certain eligibility criteria. For example, you must be between the ages of 55 and 74, and you cannot have a history of (prostate, lung, or colorectal/ovarian, lung, or colorectal) cancer. To determine whether you are eligible to participate in the trial, I would like to ask you a few ques-*

tions." For your information, (READ STATEMENT OF CONFIDENTIALITY). (CONTINUE WITH NAME AND ADDRESS VERIFICATION.)

NO \_\_\_\_\_ (CHECK THE SECOND BOX ON PAGE 1 OF SCREENER (if using check boxes), AND CONTINUE BELOW.)

### **NAME AND ADDRESS VERIFICATION:**

This section verifies the potential participant's name, address, and telephone number. If a mailing label has been affixed to the form, verify the information printed on the label, and make corrections/additions in the box. If no label is affixed to the form, complete the name and address box in its entirety. The sample script below may be used in cases where a mailing label has been affixed to the form.

*"First, I would like to verify your name, address and telephone number."*

**NAME** *"I have your name listed as (FULL NAME FROM LABEL). Is that correct?"*

Make any corrections/additions to the name in the box provided. Include title and suffix (such as Jr., Sr., etc.), if applicable. Verify all spelling.

**ADDRESS** *"I have your address listed as (ADDRESS FROM LABEL). Is that correct?"*

Make any corrections/additions to the address in the box provided. Verify all spelling.

**PHONE NUMBER** Since the telephone number may not be printed on the label, say the following:

*"What is your home telephone number, including the area code?"*

Record the number, including the area code, in the space provided. This should be the number which corresponds to the address on the mailing label.

Since the potential participant may prefer to be contacted at another number, you may say the following:

*"Do you have a work number or another contact number?"*

Record the number(s), including the area code in the space(s) provided.

### **ELIGIBILITY QUESTIONS:**

Read each question, exactly as it is written, to the potential participant and record his/her response. Do not attempt to elicit a "Don't Know" response to any question; however, if the potential participant indicates that s/he does not know the answer, record "DK" in the white space next to the question. You may, if desired, terminate the call as soon as the potential participant answers a question in a way that makes him/her ineligible for the trial, or you may complete the entire screener, regardless of the response to each question.

Specifications for each question are given below.

**QUESTION 1:** This question asks about the individual's birthdate. Record the month, day and year of the participant's birthdate. Zero-fill the month and day, if applicable.

Eligibility is determined by the potential participant's age on the day of enrollment in the study (i.e., the day s/he is randomized and assigned a Participant ID). To be eligible, the potential participant must be at least 55 years of age and less than 75 years of age on the day of enrollment. The following are examples of different situations in which a potential participant may be judged eligible or ineligible based on age:

Today's Date	Date of Birth	Age Today	Projected Enroll Date	Age at Enrollment	Eligible?
10/01/96	10/01/41	55	10/01/96	55	Yes
10/01/96	9/30/41	54	10/01/96	55	Yes
10/01/96	10/02/41	54	10/01/96	54	No
10/01/96	10/01/21	75	10/01/96	75	No
10/01/96	10/02/21	74	10/01/96	74	Yes
10/01/96	10/02/21	74	10/02/96	75	No

**QUESTION 2:** This question asks whether the respondent is male or female. Record a response to this question without asking the respondent, unless you are unable to determine his/her gender.

**QUESTION 3:** This question asks about the potential participant's race. Read the possible answers and check the one that the respondent feels best describes himself/herself. The following definitions may be used to determine race:

**White:** Includes persons having origins in any of the original people of Europe, including Spain and Portugal, and of North Africa and the Middle East. May also include white persons of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish cultures.

**Black:** Includes persons having origins in any of the black racial groups of Africa. May also include persons having origins in any of the black racial groups of Africa and who also are of Mexican, Puerto Rican, Cuban, Portuguese, South or Central American, or other Spanish cultures, including Spain.

**Asian:** Includes persons having origins in any of the original people of the Far East, Southeast Asia, or the Indian subcontinent. This area includes, for example, China, Japan, Korea, the Philippine Islands, India, Pakistan, Bangladesh, Sri Lanka, Nepal, and Bhutan.

**Pacific Islander:** Includes persons having origins in the Pacific Islands. This includes Hawaii, Samoa, Tonga, Guam, and other Pacific islands.

**American Indian/Alaskan Native:** Includes persons having origins in any of the original people of the American continents.

**QUESTION 3a:** This question asks if the participant is of Hispanic origin. The following definition may be used to determine ethnicity:

**Hispanic:** Includes persons of Mexican, Puerto Rican, Cuban, South or Central American, Portuguese, or other Spanish cultures, including Spain.

If, after hearing the above definitions, the potential participant does not know how to categorize himself/herself, or refuses to categorize himself/herself, you may note this on the Eligibility Screener next to this question; however, information on refusals or "don't know" responses will not be entered into the SMS.

**QUESTION 4:** This question asks whether the potential participant is undergoing any treatment for cancer at this time, other than basal-cell or squamous-cell skin cancer.

- If the potential participant is undergoing treatment for cancer at this time, check "Yes."
- If the potential participant underwent a course of cancer therapy in the past, but on the date s/he completed the screener was not involved in a course of cancer therapy, or if the cancer is basal-cell or squamous-cell skin cancer, check "No."
- If the potential participant does not know whether or not s/he is undergoing treatment for cancer at this time, s/he should be asked to contact his/her physician to obtain the information. If, after contacting the physician, s/he still does not know, s/he is not eligible for the trial.

**QUESTION 5:** This question asks about a history of PLCO cancers.

- If the potential participant has been told by a physician that s/he has/had colon or rectal cancer, lung cancer, prostate cancer (men only) or ovarian cancer (women only), check "Yes." Include both metastatic and primary cancer, and cancers that are in remission.
- If the potential participant says s/he had a "tumor", probe to find out whether it was "malignant" or "cancerous." If so, check "Yes."
- If the potential participant does not know whether or not s/he has been diagnosed with a PLCO cancer, s/he should be asked to contact his/her physician to obtain the information. If, after contacting the physician, s/he still does not know, s/he is not eligible for the trial.

**QUESTION 6:** This question asks about surgery to remove the entire colon, one lung, or the entire prostate (men only).

**Colon:** Another term for removal of the colon is "colectomy." We are interested in the removal of the *entire* colon. If the potential participant had his/her entire colon removed, check "Yes." If the potential participant had a partial colectomy, that is, only part of the colon was removed, check "No."

A "polypectomy," that is polyps removed from the colon, is not the same as having the colon removed. If the potential participant had a polypectomy but the colon was not removed, check "No."

**Lung:** Other terms for removal of a lung are "pneumonectomy" or "lobectomy." If the potential participant had an *entire* lung

removed, check "Yes." If the potential participant had a *partial* lobectomy, that is only part of a lung removed, check "No."

**Prostate:** Another term for removal of the prostate is "prostatectomy." We are interested in the removal of the entire prostate. If the entire prostate was removed, check "Yes." If the potential participant had a partial prostatectomy, that is, only part of the prostate was removed, check "No."

If the potential participant does not know whether or not one or more of these organs has been removed, s/he should be asked to contact his/her physician to obtain the information. If, after contacting the physician, s/he still does not know, s/he is not eligible for the trial.

**\*NOTE:** The following two questions ask about removal of the ovaries. As of October 1996, women without ovaries are eligible for the trial. It is still necessary, however, to ask these questions so that the SC will have a record of the presence or absence of the ovaries. If a woman is randomized into the trial as an intervention participant and responded on the Eligibility Screener that both ovaries have been removed, the SC must complete a Missing Data Form for the ovarian palpation and transvaginal ultrasound examinations.

**QUESTION 7:** This question asks whether the potential participant (if female) has had a hysterectomy. Note that the term hysterectomy refers to the surgical removal of the uterus and, in some cases, the fallopian tubes, but not the ovaries.

- If the woman has not had a hysterectomy, check "No" and go to Question 8.
- If the woman has had a hysterectomy, check "Yes" and ask the woman whether both ovaries were removed at the time of the surgery.
- If both entire ovaries were removed, check "Yes" and skip to Question 9.
- If neither ovary was removed, check "No" and go to Question 8.
- If one entire ovary was removed, check "No" and go to Question 8.
- If one or both ovaries were partially removed, check "No" and go to Question 8.
- If the woman does not know whether or not she has had a hysterectomy, or whether or not both her ovaries were removed, record "DK" (Don't Know) in the white space next to the question and go to Question 8.

**QUESTION 8:** This question asks whether the potential participant (if female) has had surgery to remove her ovaries. This question is only asked of women who responded "No" or "Don't Know" to Question 7.

- If the woman has not had surgery to remove her ovaries, check "No" and go to Question 9.

- If the woman has surgery to remove her ovaries, check "Yes" and ask the woman whether both ovaries were removed at the time of the surgery.
- If both entire ovaries were removed, check "Yes" and go to Question 9.
- If neither ovary was removed, check "No" and go to Question 9.
- If one entire ovary was removed, check "No" and go to Question 9.
- If one or both ovaries were partially removed, check "No" and go to Question 9.
- If the woman does not know whether or not she has had surgery to remove her ovaries, or whether or not both her ovaries were removed, record "DK" (Don't Know) in the white space next to the question. The woman should be asked to contact her physician to obtain the information. If, after contacting the physician, she still does not know, it should be assumed that her ovaries are intact, and if she is randomized to the intervention arm of the trial, she should be offered the ovarian palpation examination, transvaginal ultrasound examination, and blood draw for CA-125.

**QUESTION 9:** This question asks about whether the potential participant is currently participating in a cancer screening or primary cancer prevention study. If the potential participant is unsure of the nature of the study, probe for the name of the study or any other information the potential participant can provide about the study, such as the name of the doctor associated with the study, the location where interventions take place, etc. Record this information in the space next to the "Yes" response category.

If the participant is unable to answer the question "Yes" or "No," but is able to provide information about a study in which s/he is participating, the SC should investigate the nature of the study to determine whether or not the potential participant is eligible for the trial.

**QUESTION 10:** This question asks about the use of the medications Proscar and Propecia, in the past 6 months. Proscar (also known as finasteride) is usually prescribed for men as a treatment for benign prostatic hypertrophy (BPH), which is enlargement of the prostate. Propecia (is also finasteride, but a lower dose than Proscar) is prescribed for male pattern hair loss.

- If the potential participant is not sure of the name of his medication, ask him to check the bottle while you wait.
- If the potential participant does not know whether or not s/he has taken Proscar, Propecia, in the past 6 months, s/he should be asked to contact his/her physician to obtain the information. If, after contacting the physician, s/he still does not know, s/he is not eligible for the trial.

**QUESTION 11:** This question asks whether the potential participant (if male) has had more than one PSA blood test in the past 3 years.

- If the potential participant does not know whether or not he has had more than one PSA blood test in the past 3 years, record "DK" (Don't Know) in the white space next to the question. He should be

asked to contact his physician to obtain the information. If, after contacting the physician, he still does not know, he is not eligible for the trial.

**QUESTION 12:** This question asks whether the potential participant has had a colonoscopy, sigmoidoscopy (flexible or rigid), or barium enema in the past 3 years.

- If the potential participant does not know whether or not s/he has had a colonoscopy, sigmoidoscopy or barium enema in the past 3 years, record "DK" (Don't Know) in the white space next to the question. S/he should be asked to contact his/her physician to obtain the information. If, after contacting the physician, s/he still does not know, s/he is not eligible for the trial.

**QUESTION 13:** This question asks how the potential participant first heard about the PLCO trial. The respondent should check only one category, the one that corresponds to the first time s/he heard about the trial. This question does not affect eligibility in any way and is an optional question. An SC which is administering the questionnaire by phone or in person may omit this question when completing the form.

**After Completing the Form:**

1. Enter the screener information into the tracking system (either the Tracking and Summarizing Recruitment module of the SMS or an alternate system).
2. Review the screener to determine whether or not the potential participant is eligible for the trial (see Chapter 2 of the Manual of Operations and Procedures).
3. If a woman whose ovaries are absent is randomized into the trial as an intervention participant, complete a Missing Data form for the T0 study year indicating that the ovarian palpation and transvaginal ultrasound examinations will not be performed. The reason should be recorded as "7" (PLCO Organ Removed).
4. If the participant is randomized into the trial, file the completed Eligibility Screener in the participant's folder.
5. If the potential participant is not randomized into the trial, file the completed Eligibility Screener in a separate file of non-randomized individuals.

## **A-4-1**

### A-4-1 Eligibility Verification Form (EVF)

#### Specifications for the Eligibility Verification Form





## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE ELIGIBILITY VERIFICATION FORM (EVF)

This form is to be completed by the SC Coordinator or a staff member who has been approved to perform the eligibility verification procedures. Each of the eligibility criteria listed must be satisfied if the participant is to be randomized and enrolled in the PLCO trial. The recommended source of information which should be used when answering each question is provided in the right-most column of the form.

#### **Administrative Section:**

**Barcode:** This is the three character form identifier (EVF) in barcode format. The barcode may be read by a barcode reader (wand) during the receipt of the form into the SMS.

**Participant ID Label:** After the enrollment process is complete, a Participant ID will be assigned by the Randomization and Enrollment module. Affix the appropriate Participant ID label to the front of the form in the space provided.

**Participant Name:** Record the participant's last, first, and middle names.

**Participant Date of Birth:** Record two digits each for the month, day and year of the participant's date of birth. Zero-fill month and day of birth, if applicable.

**Participant Gender:** Record an "M" if the participant is male or an "F" if the participant is female.

**Screening Center:** Record the 2-digit SC ID.

**Satellite Center:** If the EVF is being completed at a satellite center, record the 2-digit Satellite Center ID. If the participant is not being randomized through a satellite center, record "00."

**Screening Center Staff ID:** Record the 4-digit ID number of the staff member completing the form.

#### **Part A - Eligibility Verification:**

For each of the eligibility verification questions, check "Yes" for a yes answer or "No" for a no answer. If "Yes" is checked, the potential participant is not eligible to be enrolled in the PLCO trial.

1. Is this individual younger than 55 years of age or 75 years or older? This question asks about the age of the potential participant. A participant must be between the ages of 55 and 74 on the day of enrollment in order to be eligible for the trial. Refer to the Eligibility Screener (Question 1) or the medical record for birthdate information.
2. Is this individual undergoing treatment for cancer, other than basal-cell and squamous-cell skin cancer, at this time? This question asks about current treatment for cancer, excluding basal-cell and squamous-cell skin cancer. An individual who is currently undergoing treatment for cancer or does not know whether or not s/he is undergoing treatment for cancer is not eligible for the trial. Refer to the Eligibility Screener (Question 4) or the medical record for information on current cancer treatment.
3. Has this individual been diagnosed with cancer of the prostate (men only), ovary (women only), colon, rectum or lung? This question asks about a history of PLCO cancer. An individual with a history of a PLCO cancer or one who does not know this

whether or not s/he has been diagnosed with a PLCO cancer is not eligible for the trial. Refer to the Eligibility Screener (Question 5) or the medical record for cancer history.

4. Has this individual had the entire colon, one lung, or the entire prostate (men only) surgically removed? This question asks about removal of the prostate, lung, or colon. An individual who has had the entire colon, one entire lung, or the entire prostate is not eligible for the trial. An individual who has had a partial colectomy, a partial lobectomy, or a partial prostatectomy is still eligible for the trial. An individual who does not know whether or not s/he has had one of these organs removed is not eligible for the trial. Refer to the Eligibility Screener (Question 6) or the medical record for information on such surgery.
5. Is this individual participating in another cancer screening or cancer primary prevention study? This question asks about current participation in a cancer screening or cancer primary prevention study. Refer to the Eligibility Screener (Question 9) or the medical record for this information. In some cases, the potential participant may not know whether the study is a cancer primary prevention study, and the SC staff may need to further investigate the nature of the study to determine whether the individual is eligible for the PLCO trial.
6. Has this individual taken Proscar/Propecia/finasteride (men only) in the past 6 months? This question asks about the use of the drugs Proscar and Propecia (also known as finasteride) by men in the past 6 months. An individual who has taken or does not know whether or not he has taken one of these medications in the past 6 months is not eligible for the trial. Refer to the Eligibility Screener (Question 10) or the medical record for this information.
7. Is this individual unwilling or unable to sign the trial consent form? This question asks about the potential participant's willingness/ability to sign the informed consent form for the trial. In SCs employing a single consent approach, this is the full consent form. In SCs employing a dual consent approach, this is the "forms" (the mini) consent form. This information should be obtained through in-person or mail contact with the potential participant. If the individual does not sign the consent form for any reason, s/he is not eligible to participate in the trial. The SC must have a signed consent form on file in order to check "No" for this question.
8. Has this individual had more than one PSA blood test in the past three years? This question asks about the potential participant's utilization of PSA blood tests. Any individual who has had more than one PSA blood test in the past three years or does not know whether or not he has had more than one PSA blood test in the past three years is not eligible for the trial. Refer to the Eligibility Screener (Question 11) or the medical record for this information.
9. Has this individual had a colonoscopy, sigmoidoscopy, or barium enema in the past three years? This question asks about the potential participant's utilization of colorectal screening tests, specifically colonoscopy, sigmoidoscopy (rigid or flexible), and barium enema. An individual who has had one of these tests even once in the past three years, or does not know whether or not s/he has had one of these tests in the past three years, is not eligible for the trial. Refer to the Eligibility Screener (Question 12) or the medical record for this information.

### **Part B - Randomization and Enrollment:**

Part B should be completed after entry of Part A data into the Randomization and Enrollment module of the SMS. The following information will be displayed on the screen after the participant is randomized. Copy the information onto the EVF exactly as it appears on the screen.

**Date of Randomization/Enrollment:** Record two digits each for the month, day and year of the date the participant was randomized and enrolled.

**Participant ID:** Record the Participant ID number that has been assigned.

**Randomization Group:** Check one box to indicate to which arm of the trial the participant was assigned, intervention or control.

**Name and ID of person completing the Eligibility Verification Form:** The SMS will display the 4-digit ID of the person who completed the EVF. In addition to the ID number displayed on the screen, write the name of the staff member in the space provided. If the confirmation of eligibility criteria is done by telephone from a satellite center, record the name and ID of the person who called to initiate the telephone randomization process.

**Name and ID of person completing randomization/enrollment:** Record the name (not displayed on the screen) and ID of the staff member who performed the randomization/enrollment using the SMS.

**Confirmation Number:** Record the 14-digit confirmation number that was assigned to the randomization procedure.

**After completing the form:**

1. Receipt the EVF into the Forms and Specimens Tracking module of the SMS. (Note: This is not the same as entering the data from Part A of the EVF into the Randomization and Enrollment Module. Refer the *SMS User's Guide* for information on receipting forms).
2. Generate Participant ID labels for the new participant ID.
3. File the form and the extra Participant ID labels in the participant's folder.

## **A-4-2**

### **A-4-2: Administrative Tracking Form (ATF)**

#### **Specifications for the Administrative Tracking Form**

# Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

## ADMINISTRATIVE TRACKING FORM

Screening Center: ..... |\_\_|\_\_|

Satellite Center: ..... |\_\_|\_\_|

Screening Center Staff ID: ..... |\_\_|\_\_|\_\_|\_\_|

Date Form Completed: . |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|  
MO DY YEAR

ATF

Participant ID Label

**INSTRUCTIONS:** Complete this form to document situations in which a participant was found to have been ineligible at the time of randomization.

1. Date ineligibility discovered: |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|  
MO DY YEAR

2. Reason for ineligibility: (Mark all that apply)

- 01 = Age < 55 or > = 75
- 02 = Current cancer treatment
- 03 = History of PLCO cancer → (Complete Item 2a.)
- 04 = Entire P/L/C organ removed
- 05 = Another cancer study
- 06 = Proscar/Propecia/Finasteride in the past 6 months
- 07 = Unable/unwilling to sign consent
- 08 = More than one PSA in last 3 years
- 09 = One or more colonoscopy, sigmoidoscopy, or barium enema in last 3 years

**(IF "03 = History of PLCO cancer" IS MARKED, COMPLETE ITEMS 2a. AND 3. OTHERWISE COMPLETE ONLY ITEM 3.)**

2a. History of PLCO Cancer: (MARK ALL THAT APPLY)

Type of PLCO Cancer	Cancer Confirmed by Physician or Medical Record	Date of Cancer Diagnosis MONTH - DAY - YEAR
<input type="checkbox"/> Prostate	<input type="checkbox"/> NO <input type="checkbox"/> YES	__ __  -  __ __  -  __ __ __ __
<input type="checkbox"/> Lung	<input type="checkbox"/> NO <input type="checkbox"/> YES	__ __  -  __ __  -  __ __ __ __
<input type="checkbox"/> Colorectal	<input type="checkbox"/> NO <input type="checkbox"/> YES	__ __  -  __ __  -  __ __ __ __
<input type="checkbox"/> Ovary	<input type="checkbox"/> NO <input type="checkbox"/> YES	__ __  -  __ __  -  __ __ __ __

3. Method of Discovery:

---



---



---



---



---



---



---

## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE ADMINISTRATIVE TRACKING FORM (ATF)

This form is to be completed by an SC staff member to document the randomization of an individual who did not meet eligibility criteria at the time of randomization.

Specifications for completing each item of the form are given below:

#### **Administrative Section:**

**Barcode:** This is the three character form identifier ("ATF") in barcode format. The barcode may be read by a barcode reader (wand) during the receipt of the form into the SMS.

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form.

**Screening Center:** Enter the two-digit SC ID.

**Satellite Center:** If the participant is seen at a satellite center, enter the two-digit Satellite Center ID. If the participant is not seen at a satellite center, enter "00."

**Screening Center Staff ID:** Enter your four-digit staff ID number.

**Date Form Completed:** Record the date the ATF was completed. Month and day should be zero-filled, and four digits should be recorded for the year (e.g., 02/07/1996).

#### **Information Regarding Randomized Ineligible Participant:**

1. **Date Ineligibility Discovered:** Record the date that the ineligibility was discovered by the SC staff. Month and day should be zero-filled, and four digits should be recorded for the year (e.g., 02/07/1996).
2. **Reason for Ineligibility:** The reason for ineligibility is the exclusion criterion that the participant met at the time of randomization (causing him/her to be ineligible). Check the box corresponding to the appropriate exclusion criterion. If the participant met more than one of the exclusion criteria, check all that apply. If at a later date another reason for ineligibility is discovered, this new reason should be coded in addition to the previous ones on the ATF hard copy. Be sure to mark the date in the margin and update the information in SMS. If at least one of the reasons for ineligibility is "03 = History of PLCO cancer", complete Items 2a and 3. Otherwise complete only Item 3.

2a. **History of PLCO Cancer:** Instructions for completing this table are given below:

#### **Type of PLCO Cancer:**

Complete this item if the participant is a randomized ineligible for reason of a previous PLCO cancer. Check the box corresponding to the type of PLCO cancer the participant had. If the participant had more than one PLCO cancer, check all that apply.

#### **Confirmation of PLCO Cancer by Physician or Medical Record Review:**

If the participant's previous PLCO cancer was confirmed by contacting a physician or by review of the participant's medical record, check the box for "Yes" and complete Date of Confirmation. If the participant's previous PLCO cancer was not confirmed by contacting a physician or by reviewing the medical record, check the box for "No."

**Date of Cancer Diagnosis:**

Record the month, day and year the cancer was diagnosed. If you do not have the exact day, record "99".

3. **Method of Discovery:** The purpose of the ATF is to differentiate between types of "randomized ineligibles," so the details surrounding the discovery of a randomized ineligible are important. Below are several types of situations that may involve randomization of ineligible individuals:
  1. Intervention and control individuals who were randomized in error (i.e., the participant provided information to the SC indicating his/her ineligibility, but the SC failed to exclude him/her from the trial);
  2. Intervention individuals who were randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization—at the time of screening or follow-up of screening—that the information provided had been incorrect; and
  3. Intervention and control individuals who were randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization—from a review of the baseline questionnaire—that the information provided had been incorrect.

Record the details surrounding the discovery of ineligibility. These may include descriptions of:

- how the participant completed items related to eligibility on study forms (the Eligibility Screener and/or the Baseline Questionnaire);
- conversations with the participant;
- details of screening examinations (e.g., in which removal of an organ was discovered);
- SC procedures for verifying eligibility and randomization, etc.

If additional space is needed, you may write on the back of the form or attach another sheet of paper.

**After completing the form:**

1. Receipt the form into the SMS.

If the participant met more than one exclusion criterion (i.e., more than one reason for ineligibility is marked in Item 2), enter the reasons into the SMS in ascending numerical order.
2. File the form in the participant's folder.

## **A-5-1**

A-5-1: Baseline Questionnaire - Male (BQM3)

Specifications for the Baseline Questionnaire - Male



The following questions ask about your general background, work history, and smoking history.

1. In what state or foreign country were you born?

State/Foreign Country: \_\_\_\_\_

For Office Use Only	
0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

2. Which of these groups best describes you?

- White
- Black
- Asian
- Pacific Islander
- American Indian or Alaskan Native

2a. Are you of Hispanic origin?

- No
- Yes

3. What is the highest grade or level of schooling you completed? (MARK ONLY ONE RESPONSE)

- Less than 8 years
- 8 through 11 years
- 12 years or completed high school
- Post high school training other than college (for example, vocational or technical training)
- Some college
- College graduate
- Postgraduate

4. What is your current marital status?

- Married or living as married
- Widowed
- Divorced
- Separated
- Never married

5. Which of these categories best describes your current working situation?

- Homemaker
- Working
- Unemployed
- Retired
- Extended sick leave
- Disabled
- Other (SPECIFY) \_\_\_\_\_

6. What has been your usual adult occupation? That is, at what type of occupation have you worked the longest during your adult life?

Usual adult occupation: \_\_\_\_\_

IF HOMEMAKER, GO TO QUESTION 10.

7. What were your usual activities and duties in this occupation?

Usual activities or duties: \_\_\_\_\_

8. In what type of business or industry were you usually employed in this occupation?

Business or industry: \_\_\_\_\_

9. How many years have you worked in this occupation?

\_\_\_\_\_ Number of years worked in occupation

10. Have you ever smoked cigarettes regularly for six months or longer?

- No (GO TO QUESTION 16)
- Yes

11. At what age did you start smoking cigarettes regularly? (Enter age first started smoking in the space provided, then darken the appropriate circles.)

Age In Years:

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9



21. Please complete this chart for each relative (mother, father, children, brothers, sisters, half-brothers, half-sisters) diagnosed with cancer. (DO NOT INCLUDE BASAL-CELL SKIN CANCER.) (If you have more than four relatives diagnosed with cancer, please include a separate page with this information.)

Who was diagnosed as having cancer, that is, what is his or her relationship to you?		What type of cancer did he or she have?	How old was your relative when he or she was diagnosed as having cancer?
1st RELATIVE	Relationship _____	Type of cancer _____	Age _____
2nd RELATIVE	Relationship _____	Type of cancer _____	Age _____
3rd RELATIVE	Relationship _____	Type of cancer _____	Age _____
4th RELATIVE	Relationship _____	Type of cancer _____	Age _____

22. What is or was your weight at these ages? (Enter the weight in pounds in the space provided, then darken the corresponding circles.)

Weight at Age 50?

0	0	0
1	1	1
2	2	2
3	3	3
4	4	
5	5	
6	6	
7	7	
8	8	
9	9	

Weight at Age 20?

0	0	0
1	1	1
2	2	2
3	3	3
4	4	
5	5	
6	6	
7	7	
8	8	
9	9	

Current Weight?

0	0	0
1	1	1
2	2	2
3	3	3
4	4	
5	5	
6	6	
7	7	
8	8	
9	9	

23. How tall are you? (Record your height in feet and inches in the space provided, then darken the appropriate circles.)

Feet

--

Inches

--

3
4
5
6
7

0
1
2
3
4
5
6
7
8
9
10
11

24. During the last 12 months, have you regularly used aspirin or aspirin-containing products, such as Bayer, Bufferin, or Anacin? (Please do not include aspirin-free products such as Tylenol and Panadol.)

- No (GO TO QUESTION 26)
- Yes

25. During the last 12 months, how many pills of aspirin or aspirin-containing products did you usually take per day, per week, or per month?

- 1 per day
- 2 or more per day
- 1 per week
- 2 per week
- 3-4 per week
- Less than 2 per month
- 2-3 per month

26. During the last 12 months, have you regularly used ibuprofen-containing products, such as Advil, Nuprin, or Motrin?

- No (GO TO QUESTION 28)
- Yes

27. During the last 12 months, how many pills of ibuprofen-containing products did you usually take per day, per week, or per month?

- 1 per day
- 2 or more per day
- 1 per week
- 2 per week
- 3-4 per week
- Less than 2 per month
- 2-3 per month

28. Has a doctor ever told you that you have any of the following conditions? (MARK YES OR NO FOR EACH CONDITION)

- NO YES**
- High blood pressure (hypertension)
  - Coronary heart disease/heart attack
  - Stroke
  - Emphysema
  - Chronic bronchitis
  - Diabetes
  - Colorectal polyp(s)
  - Ulcerative colitis
  - Crohn's Disease
  - Familial polyposis
  - Arthritis
  - Osteoporosis
  - Gardner's Syndrome
  - Hepatitis
  - Cirrhosis
  - Diverticulitis/diverticulosis
  - Gall bladder stones or inflammation

29. Have you ever been diagnosed as having cancer? (DO NOT INCLUDE BASAL-CELL SKIN CANCER.)

- No (GO TO QUESTION 31)
- Yes

30. Please complete this chart for each cancer. (DO NOT INCLUDE BASAL-CELL SKIN CANCER.) (If you have been diagnosed with more than 3 types of cancer, please include a separate page to record this information.)

What type of cancer did you have?		How old were you when you were diagnosed with this cancer?
1st CANCER	_____ Type of cancer	_____ Age
2nd CANCER	_____ Type of cancer	_____ Age
3rd CANCER	_____ Type of cancer	_____ Age

31. During a typical night in the last year, how many times did you usually wake up to urinate?

- Never (GO TO QUESTION 33)
- Once (GO TO QUESTION 33)
- Twice
- Three times
- More than three times

32. How old were you when you first began waking up to urinate more than once a night on a regular basis?

- Less than 30
- 30-39
- 40-49
- 50-59
- 60-69
- 70 or older

33. Has a doctor ever told you that you had a problem with your prostate?

- No
- Yes

34. Has a doctor ever told you that you had an enlarged prostate or benign prostatic hypertrophy (BPH)?

- No (GO TO QUESTION 36)
- Yes

35. How old were you when a doctor first told you that you had this problem?

- Less than 30
- 30-39
- 40-49
- 50-59
- 60-69
- 70 or older

36. Has a doctor ever told you that you had an inflamed prostate or prostatitis?

- No (GO TO QUESTION 38)
- Yes

37. How old were you when a doctor first told you that you had this problem?

- Less than 30
- 30-39
- 40-49
- 50-59
- 60-69
- 70 or older

38. Have you ever had any of the following surgical procedures of the prostate? (Darken all circles that apply.)

- Biopsy
- Transurethral resection of the prostate or TURP
- Prostatectomy for benign disease
- Prostate surgery, type unknown
- None (GO TO QUESTION 40)
- Don't know (GO TO QUESTION 40)

39. How old were you when you had a surgical procedure of the prostate the first time?

- Less than 30
- 30-39
- 40-49
- 50-59
- 60-69
- 70 or older

40. Have you had a vasectomy, that is, a sterilization procedure for men?

- No (GO TO QUESTION 42)
- Yes

41. How old were you when you had a vasectomy?

- Less than 25
- 25-34
- 35-44
- 45 or older

42. Has a doctor ever told you that you had any of the following conditions? (MARK YES OR NO FOR EACH CONDITION.)

- NO YES
- Syphilis
  - Gonorrhea

43. During the past three years, have you had a chest x-ray?

- No
- Yes, once
- Yes, more than once
- Don't know

44. During the past three years, have you had a digital rectal examination of the prostate?

- No
- Yes, once
- Yes, more than once
- Don't know

45. During the past three years, have you had a blood test for prostate cancer, for example PSA?

- No
- Yes, once
- Yes, more than once
- Don't know

PLEASE DO NOT WRITE IN THIS AREA



176212

46. During the past three years, have you had a test for blood in the stool?

- No  Yes, more than once  
 Yes, once  Don't know

47. During the past three years, have you had a colonoscopy, sigmoidoscopy, or barium enema to examine the colon and rectum?

- No  Yes, more than once  
 Yes, once  Don't know

48. What is the date you completed this questionnaire?

Date of Completion

MONTH

- January  
 February  
 March  
 April  
 May  
 June  
 July  
 August  
 September  
 October  
 November  
 December

DAY

- 0  
 1  
 2  
 3  
 4  
 5  
 6  
 7  
 8  
 9

YEAR

- 0  
 1  
 2  
 3  
 4  
 5  
 6  
 7  
 8  
 9

For Office Use Only

Estimated date

49. Who completed this questionnaire?

- Completed by study participant  
 Completed by someone else (SPECIFY RELATIONSHIP)

Thank you very much for completing this questionnaire. Please check each page carefully to make certain you have answered all the questions that apply to you; then complete the Baseline Locator Form.

FOR OFFICE USE ONLY

SCREENING CENTER ID #

- 0  
 1  
 2  
 3  
 4  
 5  
 6  
 7  
 8  
 9

SATELLITE CENTER ID #

- 0  
 1  
 2  
 3  
 4  
 5  
 6  
 7  
 8  
 9

SC STAFF ID #

- 0  
 1  
 2  
 3  
 4  
 5  
 6  
 7  
 8  
 9

METHOD OF ADMINISTRATION

(MARK ONE):

- SELF-ADMINISTERED  
 SELF-ADMINISTERED WITH ASSISTANCE  
 IN-PERSON INTERVIEW BY SC STAFF  
 IN-PERSON INTERVIEW BY OTHER (SPECIFY)  
 TELEPHONE ADMINISTERED

FORM PROCESSING

(DARKEN CIRCLES AS STEPS ARE COMPLETED):

- Form Received into SMS  
 Manual Review Completed

Data Retrieval:

- Attempted OR  None Required

Data Entry of Non-Scannable Items:

- Completed OR  None Required

Final Disposition:

- Final Complete (FCM) OR  Final Incomplete (FIC)

FOR OFFICE USE ONLY

Item 21 Relationships with Cancer

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

SEQNO	RECODE	CACODE	AGE
1	0 0	0 0 0	0 0
2	1 1	1 1 1	1 1
3	2 2	2 2 2	2 2
4	3	3 3 3	3 3
5	4	4 4 4	4 4
6	5	5 5 5	5 5
7	6	6 6 6	6 6
8	7	7 7 7	7 7
	8 8	8 8 8	8 8
	9 9	9 9 9	9 9

Item 30 Cancer Types

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	3 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	2 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	3 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	2 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	3 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	3 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	3 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

SEQNO	CACODE	AGE
1	0 0 0	0 0
2	1 1 1	1 1
3	2 2 2	2 2
4	3 3 3	3 3
5	4 4 4	4 4
6	5 5 5	5 5
7	6 6 6	6 6
8	7 7 7	7 7
	8 8 8	8
	9 9 9	9

PLEASE DO NOT WRITE IN THIS AREA



176212

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE BASELINE QUESTIONNAIRE FOR MALE PARTICIPANTS - VERSION 3 (BQM3)**

This form is to be completed by all male participants. If the participant has difficulty in the completion of the form, an SC staff member may either assist the participant in its completion or administer the questionnaire as an interview (in-person or by telephone). The boxed instructions on the questionnaire's cover page give the respondent a short set of directions for filling out the questionnaire. A statement of confidentiality is also included, which is important in clarifying the respondent's rights as a participant.

The specifications include guidelines for the completion of each question on the form, whether it is completed by the participant or some other person. The specifications also include specific guidelines for the SC staff on coding, editing or data retrieval, as appropriate. The "For Office Use Only" sections must always be completed by the SC staff according to the guidelines provided for that specific question.

General Instructions for editing and data retrieval: An attempt should be made to correct all errors or discrepant data on the questionnaire (including zero-fill errors) without contacting the participant. For any critical data items that are incomplete, unclear or marked "Don't Know" and cannot be completed without participant input, data retrieval should be attempted. Data retrieval should be directed to the participant, not the participant's physician. Any non-critical data items that are incomplete, unclear or marked "Don't Know" may be clarified with the participant through data retrieval at the discretion of the SC Coordinator. If a critical data item still cannot be completed after data retrieval is attempted, it should remain as it was recorded by the participant and not changed. If a non-critical data item cannot be completed either with or without data retrieval, it should also remain as it was recorded by the participant and not changed. All original responses, editing and recoding must be clearly documented on the form and in the SC Decision Log.

Specifications for completing the form are given below:

**COVER PAGE:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

**Participant name:** Enter the full name (first, middle, and last) of the participant. Include any titles or suffixes.

**Participant date of birth:** Enter the month, day and year of the participant's date of birth.

**SC Instructions:** This question is a critical data item. If any portion of the date of birth is incomplete or not answered, data retrieval must be attempted. Date of Birth should not be obtained from the Eligibility Screener or any source other than the participant.

**Participant telephone number:** Enter the participant's telephone number, including area code. This should be the number at which the participant would like to be contacted.

**Statement of Confidentiality Box:** The participant should read the Statement of Confidentiality. If administered by SC staff, this statement must be read to the participant.

**GENERAL BACKGROUND:**

This section of the questionnaire is concerned with the participant's general background, work history and smoking history.

**1. In what state or foreign country were you born?**

Obtain the participant's place of birth. Record the state of birth, if in the United States, or the country of birth, if in a foreign country.

*SC Instructions: Assign the appropriate numeric code in the space provided in the "For Office Use Only" box. Refer to Appendix I of the Manual of Operations and Procedures for the listing of State Codes. Canada and specific provinces in Canada should be coded as "00" (Foreign Country). Darken the circle corresponding to each number. If the participant's place of birth is recorded on the BLF but left blank on the Baseline Questionnaire, it is acceptable to complete Item 1 using the information from the Baseline Locator Form.*

**2. Which of these best describes your race or ethnic background?**

The following definitions are to be used for determining race or ethnic background:

**White:** Includes persons having origins in any of the original people of Europe, including Spain and Portugal, and of North Africa and the Middle East. May also include white persons of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish cultures.

**Black:** Includes persons having origins in any of the black racial groups of Africa. May also include persons having origins in any of the black racial groups of Africa and who also are of Mexican, Puerto Rican, Cuban, Portuguese, South or Central American, or other Spanish cultures, including Spain.

**Asian:** Includes persons having origins in any of the original people of the Far East, Southeast Asia, or the Indian subcontinent. This area includes, for example, China, Japan, Korea, the Philippine Islands, India, Pakistan, Bangladesh, Sri Lanka, Nepal, and Bhutan.

**Pacific Islander:** Includes persons having origins in the Pacific Islands. This includes Hawaii, Samoa, Tonga, Guam, and other Pacific Islands.

**American Indian or Alaskan Native:** Includes persons having origins in any of the original people of the American continents.

**2a. Are you of Hispanic origin?**

The following definition is to be used for determining ethnic background:

**Hispanic:** Includes persons of Mexican, Puerto Rican, Cuban, South or Central American, Portuguese, or other Spanish cultures, including Spain.

*SC Instructions: Questions 2 and 2a are critical data items. If these questions are incomplete or not answered, data retrieval must be attempted. If the participant refuses to categorize himself as belonging to one of the above races or ethnic groups, these items should be left blank.*

**3. What is the highest grade or level of schooling you completed?**

Obtain the highest grade completed, regardless of skipped or repeated grades. If the participant attended school in a foreign country, in an ungraded school, under a tutor, or under other special circumstances, ask the participant to give the nearest equivalent of years in a regular U.S. school. The following guidelines should be used for determining the highest grade completed:

**Less than 8 years:** The participant completed one to seven years of school.

**8 through 11 years:** The participant completed eight to eleven years of school.

**12 years or completed high school:** The participant completed 12 years of school or completed high school. This includes the participant having received a GED.

**Post high school training other than college:** The participant completed training other than college following high school. This includes secretarial school, mechanical or computer training, nursing school where only a diploma is offered, other vocational trades, or business schools outside the regular school system and attended by the participant after completion of high school.

**Some college:** The participant completed some college but did not attain a four year college degree. An Associate of Arts (AA) degree from a community college or a junior college specializing in skill training should be considered as some college.

**College graduate:** This includes a seminary in which a bachelors degree is offered, colleges of education, and nursing schools in which a bachelors degree is offered.

**Postgraduate:** Any completed post-graduate work qualifies as "post-graduate." Receiving a degree is not a criteria for this category. This also includes a Master's Degree, Post-Doctoral Degree, or some type of professional school (i.e., medical, dental, or veterinary school).

*SC Instructions: If the participant marked more than one response, the highest level of education should be kept; the remaining responses should be deleted.*

**4. What is your current marital status?**

"Current" is at the time the participant completes the questionnaire, i.e., a man who was widowed but has remarried is considered married. Separated refers to living apart because of marital discord, not circumstantial separation (such as wife living in a nursing home).

**5. Which of these categories best describes your current working situation?**

The participant is to select the category that he feels best describes his current (at the time of completing the questionnaire) situation. "Working" is working for pay (wages, salary, commission or pay-in-kind), or working without pay in a business or farm operated by a household member. Volunteer or other unpaid work for a church, charity, or similar organization is not included. Individuals who have "retired" from their usual occupation but are currently working either full or part-time for pay are considered working unless they work less than 20 hours per week.

*SC Instructions: If the participant has circled "Other (SPECIFY)," check that the verbatim response does not actually fall into a predetermined category.*

**6. What has been your usual adult occupation? That is, at what type of occupation have you worked the longest during your adult life.**

The participant's job title descriptive of the occupation worked at the longest during his adult life should be recorded. A one-word description is almost never adequate. For example, a "clerk" can be a shipping clerk, a stock clerk, or a sales clerk.

If the participant is self-employed, find out what activities the participant spends most time doing. Do not record "proprietor" as the occupation unless the participant actually spends most time in the management of the business. If the participant spends most time in the trade or craft, record that as the occupation, i.e., shoe repairman, beautician, or carpenter, as appropriate.

If the participant is a "Homemaker," go to Question 10.

*SC Instructions: Question 6 will not be coded nor entered into the Study Management System (SMS).*

**7. What were your usual activities and duties in this occupation?**

These are the activities and duties corresponding to the occupation listed in Question 6. As much specificity as possible is desired. Some examples are as follows:

- Sales Manager - supervised the sales office, coordinated the other salespeople, solicited new business.
- Machine Operator - operated a lathe machine, cut and shaped metal with a knife.

*SC Instructions: Question 7 will not be coded nor entered into the Study Management System (SMS).*

**8. In what type of business or industry were you usually employed in this occupation?**

Here we are interested in the usual type of business or industry in which the participant worked at the occupation specified in Question 6. We are specifically interested in the type of business or industry, not the name of the employer or company name. One word entries are almost never adequate. Preferably, the entry should state both a general and specific function of an industry, e.g., copper mining, fountain pen manufacturing, shoe repair service.

*SC Instructions: Question 8 will not be coded nor entered into the Study Management System (SMS).*

**9. How many years have you worked in this occupation?**

This question asks for the total number of years in the occupation specified in Question 6. If periods of time have elapsed during which the participant did not or could not work in this occupation, do not omit the earlier periods of time from the total number of years.

*SC Instructions: If the participant provides a range of years, such as "around 25 to 30 years," the median value of that range (in this case, 28 years) should be recorded.*

Question 9 will not be coded nor entered into the Study Management System (SMS).

**10. Have you ever smoked cigarettes regularly for six months or longer?**

Allow the participant to use his own definition of regular.

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted.*

**11. At what age did you start smoking cigarettes regularly?**

This is the age when the participant started smoking cigarettes regularly. For example, if the participant smoked his first cigarette at age 14 but did not smoke on a regular basis until age 21, age 21 should be recorded, not 14.

*SC Instructions: If the participant provides a range of years, such as "somewhere between age 15 and 17," the median value of that range (in this case, age 16) should be recorded. If the participant provides an age such as "in my teens," then the median age should be recorded (in this case, 15). If the age provided is in half-years, always round up. For example, age 15½ should be recorded as age 16.*

**12. Do you smoke cigarettes regularly now?**

"Now" is at the time the participant completes the questionnaire. If the participant does not consider himself a regular smoker, darken the circle for "No;" if he has stopped smoking temporarily (e.g., due to a cold) and expects to begin again, darken the circle for "Yes."

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted.*

**13. At what age did you last stop smoking cigarettes regularly?**

This question is for participants who no longer smoke cigarettes. The participant's age when he stopped smoking cigarettes regularly should be recorded.

*SC Instructions: If the participant provides a range of years, such as "between age 40 and 45," the median value of that range (in this case, age 43) should be recorded. If the participant provides an age such as "in my forties," then the median age should be recorded (in this case, 45). If the age provided is in half-years, always round up. For example, age 52½ should be recorded as age 53.*

**14. During periods when you smoked, how many cigarettes did or do you usually smoke per day?**

The answer should be the usual or average number of cigarettes smoked per day during the years in which the participant regularly smoked cigarettes.

*SC Instructions: If the participant records in "packs" of cigarettes smoked per day, convert that to the number of cigarettes per day. For example, half a pack equals 10 cigarettes, 1 pack equals 20 cigarettes, 2 packs equals 40 cigarettes, etc.*

**15. During periods when you smoked, did or do you more often smoke filter or non-filter cigarettes?**

The emphasis is on the words more often. The participant may have smoked both filtered and non-filtered cigarettes, but smoked filtered cigarettes more often.

**16. Do you now or did you ever smoke a pipe regularly for a year or longer?**

The emphasis here is on regular use for a year or longer. Allow the participant to use his own definition of regular.

**17. Do you now or did you ever smoke cigars regularly for a year or longer?**

The emphasis here is on regular use for a year or longer. Allow the participant to use his own definition of regular.

**FAMILY AND PERSONAL MEDICAL HISTORY:**

This section of the questionnaire is concerned with the participant's family medical history and personal medical history. Immediate blood relatives only (parents, children, brothers, sisters, half-brothers, and half-sisters) should be included in the family medical history.

**18. How many full and half-sisters do you have, both living and deceased?**

Include full- (two parents in common) and half- (one parent in common) sisters, living and deceased.

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**19. How many full and half-brothers do you have, both living and deceased?**

Include full- (two parents in common) and half- (one parent in common) brothers, living and deceased.

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**20. Have your parents, children, brothers, sisters, half-brothers, or half-sisters ever been diagnosed as having any type of cancer?**

We are interested in all cancers except basal-cell skin cancer. If the participant recorded "Don't Know," leave this item blank. If "Yes," Question 21 must be completed. If "No" or "Don't Know," go to Question 22.

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**21. Please complete this chart for each relative (mother, father, children, brothers, sisters, half-brothers, half-sisters) diagnosed with cancer.**

The table for Question 21 should be completed if Question 20 is "Yes."

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

The table should be completed as follows:

- **Who was diagnosed as having cancer, that is, what is his or her relationship to you?**

Specify the sex-specific relationship of the relative with cancer to the participant (for example, "son" rather than "child"). If there are more than four relatives who have cancer, additional information may be recorded on a separate sheet of paper.

*SC Instructions: If the participant has listed additional relatives who have cancer on a separate sheet of paper, label the sheet of paper with the participant's ID number, the title of the questionnaire and the question number to which the information refers. Insert the sheet of paper in the questionnaire.*

Record a sequence number (e.g., 1, 2, 3, etc.) for each chart entry in the "For Office Use Only" box located on the last page of the questionnaire. The sequence number should be entered in the column titled "SEQNO." Do not assign a sequence number or code a cancer for any relative who is not an immediate blood relative (e.g., aunt, grandfather, etc.) Darken the circle corresponding to the sequence number.

Assign the code corresponding to the relationship of the relative with cancer to the participant in the "For Office Use Only" box located on the last page of the questionnaire. A twin sister or brother should be coded as "sister" or "brother." Refer to Appendix I of the Manual of Operations and Procedures for the listing of Relationship

Codes. The relationship code should be entered in the column titled "RECODE." Darken the circle corresponding to each number.

- **What type of cancer did he or she have?**

The primary site of cancer or where it started should be recorded. Do not include relatives diagnosed with basal-cell skin cancer.

*SC Instructions: Assign the code corresponding to the type of cancer in the "For Office Use Only" box located on the last page of the questionnaire. Refer to Appendix I of the Manual of Operations and Procedures for the listing of Cancer Codes. The cancer code should be entered in the column titled "CACODE." Darken the circle corresponding to each number. If type of cancer is left blank, it should be coded as "999" (Not Ascertained). If the participant recorded "don't know," it should be coded as "998" (Don't Know). If the participant has recorded more than one cancer on the same line for one relative, assign codes as follows:*

<b>Assign Code:</b>	<b>If the participant reported:</b>
880	Prostate cancer and some other cancer
881	Lung cancer and some other cancer
882	Colorectal cancer and some other cancer
883	Ovarian cancer and some other cancer
884	More than one non-PLCO cancer
885	More than one PLCO cancer
886	Colon cancer and some other cancer
887	Rectal cancer and some other cancer

Code skin cancer and melanoma as follows:

<b>Assign Code:</b>	<b>If the participant reported:</b>
024	specific melanoma other than skin melanoma
033	skin melanoma
888	unspecified melanoma/unspecified skin cancer
Do not code	skin (non-melanoma)

*If more than eight cancers are reported for relatives (i.e., all eight coding spaces are used in the "For Office Use Only" box), contact the Coordinating Center.*

*For codes 880 - 888, enter the type of cancer verbatim into DEES.*

- **How old was your relative when he or she was diagnosed as having cancer?**

*SC Instructions: Record the age at diagnosis in the "For Office Use Only" box located on the last page of the questionnaire. The age should be entered in the column titled "AGE."*

*Assign the age 01 if the age is one year or less than one year.*

*Assign the age 99 if the age is 99 years or greater than 99 years.*

*Assign the age 00 if the participant recorded more than one age on the same line for one relative, if a specific age was not given (i.e., the respondent recorded "over 50" for the age), or if the participant recorded "don't know."*

*Darken the circle corresponding to each number. If 00 is recorded, enter the verbatim response into the DEES.*

**22. What is or was your weight at these ages? (weight at age 50?...weight at age 20?... current weight?)**

Current weight is the participant's weight at this specific time when the questionnaire is being completed. For weight at age 20 and at age 50, we are interested in the participant's average weight at each age.

*SC Instructions: The numeric entry for weight should be zero filled, if appropriate. For example, a weight of 98 pounds should be recorded as 098 pounds. A weight of 399 lbs. or greater should be recorded as 399 lbs.*

**23. How tall are you?**

This question asks for current height of the participant. Height should be recorded in feet and inches.

*SC Instructions: If the participant is exactly 6 feet tall, 6 feet, 00 inches should be recorded. If the participant reported his height to the half-inch, it should be rounded up to the nearest inch.*

**24. During the last 12 months, have you regularly used aspirin or aspirin-containing products, such as Bayer, Bufferin, or Anacin? (Please do not include aspirin-free products such as Tylenol and Panadol.)**

Regular use is emphasized and defined by the participant. This item includes baby aspirin.

*SC Instructions: If the participant recorded "No" for this item but then marked a response for Item 25 indicating use of an aspirin-containing product, this item should be recoded to "Yes."*

**25. During the last 12 months, how many pills of aspirin-containing products did you usually take per day, per week, or per month?**

Only one of the categories listed should be marked.

*SC Instructions: If the participant recorded daily use of less than one aspirin (e.g., 1/4 or 1/2 aspirin per day), or daily use of baby aspirin, code as "1 per day."*

**26. During the last 12 months, have you regularly used ibuprofen-containing products, such as Advil, Nuprin, or Motrin?**

Regular use is emphasized and defined by the participant.

*SC Instructions: If the participant recorded "No" for this item but then marked a response for Item 27 indicating use of an ibuprofen-containing product, this item should be recoded to "Yes."*

**27. During the last 12 months, how many pills of ibuprofen-containing products did you usually take per day, per week, or per month?**

Only one of the categories listed should be marked.

**28. Has a doctor ever told you that you have any of the following conditions?**

The condition must be diagnosed by a doctor; we are not interested in self-diagnosed conditions. Each condition should be recorded as either "Yes" or "No."

*SC Instructions: Definitions should not be provided for any of the conditions. Allow the participant to record his response based on his understanding of the condition. If the participant did not record responses for some of the items (e.g., he marked only the "Yes" responses but not the "No" responses) these items may be left blank since they are not critical data items. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**29. Have you ever been diagnosed as having cancer?**

We are interested in all cancers except basal-cell skin cancer. If "Yes," Question 30 must be completed. If "No," go to Question 31.

*SC Instructions: This question is a critical data item. If this question is incomplete, unclear, or not answered, data retrieval must be attempted. If the participant responds "Yes" to this item but then lists only conditions which are not coded, such as a non-melanoma skin cancer in Item 30, this item should be recoded to "No."*

**30. Please complete this chart for each cancer.**

The table for Question 30 should be completed if Question 29 is "Yes." It should be completed for initial diagnoses only, not recurrent cancers. The table should be completed as follows:

- **What type of cancer did you have?**

Record the primary site of cancer or where the cancer started. Do not include basal-cell skin cancer. If the participant has more than three cancers, additional information may be recorded on a separate sheet of paper.

*SC Instructions: If the participant has listed additional cancers on a separate sheet of paper, label the sheet of paper with the participant's ID number, the title of the questionnaire and the question number to which the information refers. Insert the sheet of paper in the questionnaire. Do not code or enter into the DEES any non-melanoma (basal-cell) skin cancers that are reported.*

*Record a sequence number (e.g., 1, 2, 3, etc.) for each primary cancer in the "For Office Use Only" box located on the last page of the questionnaire. The sequence number should be entered in the column titled "SEQNO." Darken the circle corresponding to the sequence number.*

*Assign the code corresponding to the type of cancer in the "For Office Use Only" box located on the last page of the questionnaire. Refer to Appendix I of the Manual of Operations and Procedures for the listing of Cancer Codes. The cancer code should be entered in the column titled "CACODE." Darken the circle corresponding to each number. If the participant has recorded more than one cancer on the same line, transfer the information for each additional cancer to a separate line, using additional sheets, if necessary. Then make separate entries in the "CACODE" column in the "For Office Use Only" box for each cancer listed.*

Code skin cancer and melanoma as follows:

<b>Assign Code</b>	<b>If the participant reported</b>
024	specific melanoma other than skin melanoma
033	skin melanoma
888	unspecified melanoma/unspecified skin cancer
Do not code	skin (non-melanoma)

*If the participant has recorded more than eight cancers (i.e., all eight coding spaces are used in the "For Office Use Only" box), contact the Coordinating Center.*

*For codes 880 - 888, enter the type of cancer verbatim into DEES.*

*This question is a critical data item. If the type of cancer is incomplete, unclear, or not answered, data retrieval must be attempted. If the response is "Don't know," data retrieval must be attempted.*

- **How old were you when you were diagnosed with this cancer?**

We are interested in the participant's age at initial diagnosis.

*SC Instructions: Record the age at diagnosis in the "For Office Use Only" box located on the last page of the questionnaire. The age should be entered in the column titled "AGE." Darken the circle corresponding to each number*

*This question is a critical data item. If age at diagnosis is incomplete, unclear, or not answered, data retrieval must be attempted. If the response is "Don't know," data retrieval must be attempted. Probe for the best estimate. If the participant maintains a "don't know" response, assign the age "00" and enter "don't know" as the verbatim response in DEES.*

**31. During a typical night in the last year, how many times did you usually wake up to urinate?**

The time period is the last year, the previous 12 months. The participant should use his own definition of "typical".

**32. How old were you when you first began waking up to urinate more than once a night on a regular basis?**

Emphasis is more than once a night regularly.

General specifications for Questions 33 through 37 are provided at the end of Question 37.

**33. Has a doctor ever told you that you had a problem with your prostate?**

**34. Has a doctor ever told you that you had an enlarged prostate or benign prostatic hypertrophy (BPH)?**

**35. How old were you when a doctor first told you that you had this problem?**

**36. Has a doctor ever told you that you had an inflamed prostate or prostatitis?**

**37. How old were you when a doctor first told you that you had this problem?**

Questions 33 through 37 all require that the condition be diagnosed by a doctor, and not be self-diagnosed. For the participant's age, the emphasis is on first diagnosed.

*SC Instructions: If the participant responded "No" to Item 33, then ignored the skip and responded "No" to Items 34 and 36, it is not necessary to delete the responses to Items 34 and 36. The DEES system is programmed to ignore these errors.*

**38. Have you ever had any of the following surgical procedures of the prostate?**

Here, we are asking if the participant ever had one or more surgical procedures of the prostate as listed below.

Biopsy

Transurethral resection of the prostate (TURP)

Prostatectomy for benign disease

Prostate surgery type unknown: The participant had prostate surgery but the type of surgery is unknown.

None: The participant did not have any surgical procedures of the prostate.

Don't Know: The participant does not know whether he had any prostate surgery.

*SC Instructions: This question is a critical data item. If this question is incomplete, unclear, or not answered, data retrieval must be attempted. If the response is "Don't Know," data retrieval must be attempted to confirm this response.*

**39. How old were you when you had a surgical procedure of the prostate the first time?**

The emphasis is on surgery of the prostate for the first time.

**40. Have you had a vasectomy, that is, a sterilization procedure for men?**

Here, we are interested in determining whether or not the participant had a vasectomy, which is a sterilization procedure for men. If the participant records information for two vasectomy procedures, the year of the first procedure should be recorded.

**41. How old were you when you had a vasectomy?**

We are interested in the participant's age when he had the vasectomy.

**42. Has a doctor ever told you that you had any of the following conditions?**

The question asks whether or not the participant had either syphilis or gonorrhea. The condition must be diagnosed by a doctor; we are not interested in self-diagnosed conditions. Each condition should be recorded as either "Yes" or "No."

*SC Instructions: Definitions should not be provided for any of the conditions. Allow the participant to record his response based on his understanding of the condition.*

In the next series of questions, we are only interested in examinations or procedures that have occurred within the past three years.

**43. During the *past three years*, have you had a chest X-ray?**

This does not include diagnostic procedures, such as a GI series or a CAT scan.

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

- 44. During the *past three years*, have you had a digital rectal examination of the prostate?**

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

- 45. During the *past three years*, have you had a blood test for prostate cancer, for example PSA?**

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required. If the answer to this question is "Yes", data retrieval is not required to confirm that the participant is referring to an examination received prior to randomization.*

- 46. During the *past three years*, have you had a test for blood in the stool?**

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

- 47. During the *past three years*, have you had a colonoscopy, sigmoidoscopy, or barium enema to examine the colon and rectum?**

This includes flexible sigmoidoscopy, and/or proctoscopy.

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required. If the answer to this question is "Yes", data retrieval is not required to confirm that the participant is referring to an examination received prior to randomization.*

- 48. What is the date you completed this questionnaire?**

*SC Instructions: Make sure the numbers are written in the boxes and the corresponding circles are darkened. If the question is left blank or is unclear, either contact the participant to determine the correct date, or enter the date the Baseline Questionnaire was receipted into the SMS. Darken the corresponding circles.*

*If the date of receipt is used as an estimated date, darken the circle for "Estimated Date."*

- 49. Who completed this questionnaire?**

If the questionnaire was completed by someone other than the participant, we are interested in that person's relationship to the participant.

#### **ADMINISTRATIVE SECTION (FOR OFFICE USE ONLY):**

This section is for administrative use by the SC staff. It includes SC identification, method of administration of the questionnaire, and form processing.

**Screening Center ID#:** This item is optional. If this item is completed, enter the 2-digit SC ID and darken the circle corresponding to each number.

**Satellite Center ID#:** This item is optional. If the SC has elected to track satellite center activity and the participant is seen at a satellite center, enter the 2-digit Satellite Center ID. Darken the circle corresponding to each number. If the participant is not seen at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank.

**SC Staff ID#:** If the questionnaire was administered by SC staff, enter the 4-digit staff ID number of the staff member who administered it. If the questionnaire was self-administered or administered by someone other than the SC staff, enter the 4-digit staff ID number of the staff member who edited the questionnaire. Darken the circle corresponding to each number.

**Method of Administration:** Darken the circle corresponding to the method of administration of the Baseline Questionnaire. Definitions of methods of administration are as follows:

Self Administered - The participant completed the questionnaire by himself/herself without assistance. Unless the SC staff become aware that the participant did not complete the form himself/herself without assistance, it should be assumed that the questionnaire was self administered.

Self Administered with Assistance - The participant completed the questionnaire by himself/herself (i.e. it was not administered to him/her) but required assistance from another person (relative, friend, SC staff member) to clarify one or more of the questions or to physically complete the form.

In-Person Interview by SC Staff - The questionnaire was administered to the participant in person by an SC staff member.

In-Person Interview by Other (Specify) - The questionnaire was administered to the participant in person, by someone other than an SC staff member. If known, record the relationship of the interviewer to the participant on the line provided.

Telephone Administered - The questionnaire was administered to the participant by telephone by an SC staff member.

**Form Processing:** These are the steps that should be completed in order to process the questionnaire. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data review. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-5-2**

**A-5-2: Baseline Questionnaire - Female (BQF3)**

**Specifications for the Baseline Questionnaire -  
Female**



The following questions ask about your general background, work history, and smoking history.

1. In what state or foreign country were you born?

State/Foreign Country: \_\_\_\_\_

For Office Use Only	
0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

2. Which of these groups best describes you?

- White                       Pacific Islander  
 Black                         American Indian or  
 Asian                          Alaskan Native

2a. Are you of Hispanic origin?

- No  
 Yes

3. What is the highest grade or level of schooling you completed? (MARK ONLY ONE RESPONSE)

- Less than 8 years             Some college  
 8 through 11 years         College graduate  
 12 years or completed high school    Postgraduate  
 Post high school training other than college (for example, vocational or technical training)

4. What is your current marital status?

- Married or living as married         Separated  
 Widowed                         Never married  
 Divorced

5. Which of these categories best describes your current working situation?

- Homemaker                     Extended sick leave  
 Working                          Disabled  
 Unemployed                   Other (SPECIFY)  
 Retired

6. What has been your usual adult occupation? That is, at what type of occupation have you worked the longest during your adult life?

Usual adult occupation: \_\_\_\_\_

IF HOMEMAKER, GO TO QUESTION 10.

7. What were your usual activities and duties in this occupation?

Usual activities or duties: \_\_\_\_\_

8. In what type of business or industry were you usually employed in this occupation?

Business or industry: \_\_\_\_\_

9. How many years have you worked in this occupation?

\_\_\_\_\_ Number of years worked in occupation

10. Have you ever smoked cigarettes regularly for six months or longer?

- No (GO TO QUESTION 16)  
 Yes

11. At what age did you start smoking cigarettes regularly? (Enter age first started smoking in the space provided, then darken the appropriate circles.)

Age In Years:

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

12. Do you smoke cigarettes regularly now?

- No
- Yes (GO TO QUESTION 14)

13. At what age did you last stop smoking cigarettes regularly? (Enter age last stopped smoking in the space provided, then darken the appropriate circles.)

Age In Years:

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

14. During periods when you smoked, how many cigarettes did or do you usually smoke per day?

- 1-10
- 11-20
- 21-30
- 31-40
- 41-60
- 61-80
- 81 or more

15. During periods when you smoked, did or do you more often smoke filter or non-filter cigarettes?

- Filter more often
- Non-filter more often
- Both about equally

16. Do you now or did you ever smoke a pipe regularly for a year or longer?

- Never smoked a pipe
- Did smoke a pipe but currently do not smoke
- Currently do smoke a pipe

17. Do you now or did you ever smoke cigars regularly for a year or longer?

- Never smoked cigars
- Did smoke cigars but currently do not smoke
- Currently do smoke cigars

The following questions ask about your family medical history and your personal medical history.

18. How many full and half-sisters do you have, both living and deceased?

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11 or more

19. How many full and half-brothers do you have, both living and deceased?

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11 or more

20. Have your parents, children, brothers, sisters, half-brothers, or half-sisters ever been diagnosed as having any type of cancer? (DO NOT INCLUDE BASAL-CELL SKIN CANCER)

- No (GO TO QUESTION 22)
- Yes

21. Please complete this chart for each relative (mother, father, children, brothers, sisters, half-brothers, half-sisters) diagnosed with cancer. (DO NOT INCLUDE BASAL-CELL SKIN CANCER.) (If you have more than four relatives diagnosed with cancer, please include a separate page with this information.)

Who was diagnosed as having cancer, that is, what is his or her relationship to you?	Relationship	What type of cancer did he or she have?	Type of cancer	How old was your relative when he or she was diagnosed as having cancer?	Age
1st RELATIVE	Relationship	Type of cancer	Type of cancer	Age	Age
2nd RELATIVE	Relationship	Type of cancer	Type of cancer	Age	Age
3rd RELATIVE	Relationship	Type of cancer	Type of cancer	Age	Age
4th RELATIVE	Relationship	Type of cancer	Type of cancer	Age	Age

PLEASE DO NOT WRITE IN THIS AREA

■ ■ ○ ○ ○ ○ ○ ○ ■ ■ ■ ■ ■ ■ ○ ■ ■ ○ ○ ○ ○ ○ ○

188171

22. What is or was your weight at these ages? (Enter the weight in pounds in the space provided, then darken the corresponding circles.)

Weight at Age 50?	Weight at Age 20? (Exclude weight during pregnancy.)	Current Weight?
0 0 0	0 0 0	0 0 0
1 1 1	1 1 1	1 1 1
2 2 2	2 2 2	2 2 2
3 3 3	3 3 3	3 3 3
4 4 4	4 4 4	4 4 4
5 5 5	5 5 5	5 5 5
6 6 6	6 6 6	6 6 6
7 7 7	7 7 7	7 7 7
8 8 8	8 8 8	8 8 8
9 9 9	9 9 9	9 9 9

23. How tall are you? (Record your height in feet and inches in the space provided, then darken the appropriate circles.)

Feet	Inches
	0
	1
	2
3	3
4	4
5	5
6	6
7	7
	8
	9
	10
	11

24. During the last 12 months, have you regularly used aspirin or aspirin-containing products, such as Bayer, Bufferin, or Anacin? (Please do not include aspirin-free products such as Tylenol and Panadol.)

- No (GO TO QUESTION 26)  
 Yes

30. Please complete this chart for each cancer. (DO NOT INCLUDE BASAL-CELL SKIN CANCER.) (If you have been diagnosed with more than 3 types of cancer, please include a separate page to record this information.)

What type of cancer did you have?	How old were you when you were diagnosed with this cancer?
1st CANCER Type of cancer _____	Age _____
2nd CANCER Type of cancer _____	Age _____
3rd CANCER Type of cancer _____	Age _____

25. During the last 12 months, how many pills of aspirin or aspirin-containing products did you usually take per day, per week, or per month?

- 1 per day                       3-4 per week  
 2 or more per day         Less than 2 per month  
 1 per week                    2-3 per month  
 2 per week

26. During the last 12 months, have you regularly used ibuprofen-containing products, such as Advil, Nuprin, or Motrin?

- No (GO TO QUESTION 28)  
 Yes

27. During the last 12 months, how many pills of ibuprofen-containing products did you usually take per day, per week, or per month?

- 1 per day                       3-4 per week  
 2 or more per day         Less than 2 per month  
 1 per week                    2-3 per month  
 2 per week

28. Has a doctor ever told you that you have any of the following conditions? (MARK YES OR NO FOR EACH CONDITION)

- |                       |                       |                                     |
|-----------------------|-----------------------|-------------------------------------|
| <input type="radio"/> | <input type="radio"/> | High blood pressure (hypertension)  |
| <input type="radio"/> | <input type="radio"/> | Coronary heart disease/heart attack |
| <input type="radio"/> | <input type="radio"/> | Stroke                              |
| <input type="radio"/> | <input type="radio"/> | Emphysema                           |
| <input type="radio"/> | <input type="radio"/> | Chronic bronchitis                  |
| <input type="radio"/> | <input type="radio"/> | Diabetes                            |
| <input type="radio"/> | <input type="radio"/> | Colorectal polyp(s)                 |
| <input type="radio"/> | <input type="radio"/> | Ulcerative colitis                  |
| <input type="radio"/> | <input type="radio"/> | Crohn's Disease                     |
| <input type="radio"/> | <input type="radio"/> | Familial polyposis                  |
| <input type="radio"/> | <input type="radio"/> | Arthritis                           |
| <input type="radio"/> | <input type="radio"/> | Osteoporosis                        |
| <input type="radio"/> | <input type="radio"/> | Gardner's Syndrome                  |
| <input type="radio"/> | <input type="radio"/> | Hepatitis                           |
| <input type="radio"/> | <input type="radio"/> | Cirrhosis                           |
| <input type="radio"/> | <input type="radio"/> | Diverticulitis/diverticulosis       |
| <input type="radio"/> | <input type="radio"/> | Gall bladder stones or inflammation |

29. Have you ever been diagnosed as having cancer? (DO NOT INCLUDE BASAL-CELL SKIN CANCER)

- No (GO TO QUESTION 31)  
 Yes

31. How old were you when you had your first menstrual period?

- Less than 10       14–15  
 10–11       16 or older  
 12–13

32. How old were you when you had your last period?

- Less than 40       50–54  
 40–44       55 or older  
 45–49

33. Did your periods stop because of natural menopause, surgery, radiation, or drug therapy?

- Natural menopause       Radiation  
 Surgery       Drug therapy

34. Have you ever tried to become pregnant for a year or more without success?

- No  
 Yes

35. Have you ever been pregnant?

- No (GO TO QUESTION 43)  
 Yes  
 Don't know (GO TO QUESTION 43)

36. How old were you when you first became pregnant?

- Less than 15       30–34  
 15–19       35–39  
 20–24       40–44  
 25–29       45 or older

37. How many times have you been pregnant? Please include stillbirths, miscarriages, abortions, tubal or ectopic pregnancies, and live births.

- 1       3–4  
 2       5–9  
 10 or more

38. How many of your pregnancies resulted in a stillbirth?

- 0  
 1  
 2 or more

39. How many of your pregnancies resulted in a miscarriage or an abortion?

- 0  
 1  
 2 or more

40. How many of your pregnancies resulted in a pregnancy in one of your tubes, that is, a tubal or ectopic pregnancy?

- 0  
 1  
 2 or more

41. How many of your pregnancies resulted in a live birth? (If none, record "00" in the space provided, darken the corresponding circles, and go to Question 43.)

# Pregnancies Resulting in a Live Birth

0	0
1	1
2	2
	3
	4
	5
	6
	7
	8
	9

42. What was your age at the birth of your first child?

- Less than 16       30–34  
 16–19       35–39  
 20–24       40 or older  
 25–29

43. Did you ever take birth control pills for birth control or to regulate menstrual periods?

- No (GO TO QUESTION 46)  
 Yes

44. How old were you when you first started taking birth control pills?

- Less than 30       50–59  
 30–39       60 or older  
 40–49

45. For how many total years did you take birth control pills?

- 10 years or more       2–3 years  
 6–9 years       One year or less  
 4–5 years

46. Have you had a tubal ligation, that is, have you had your tubes tied?

- No  
 Yes  
 Don't know

47. Have you had a hysterectomy, that is, have you had your uterus or womb removed?
- No (GO TO QUESTION 49)
- Yes
- Don't know (GO TO QUESTION 49)
48. What was your age when you had your uterus or womb removed?
- Less than 40                       50–54
- 40–44                                 55 or older
- 45–49
49. Have you ever had one or both of your ovaries removed?
- No (GO TO QUESTION 51)
- Yes
- Don't know (GO TO QUESTION 51)
50. What exactly was removed?
- One ovary–partial                       Both ovaries–total
- One ovary–total                         Don't know
- Both ovaries–partial
51. Sometimes women take female hormones such as estrogen or progesterone around the time of menopause. Have you ever used female hormones (tablets, pills, or creams) for menopause?
- No (GO TO QUESTION 54)
- Yes
- Don't know (GO TO QUESTION 54)
52. Are you currently using female hormones?
- No
- Yes
53. For how many total years did you take female hormones?
- 10 years or more                       2–3 years
- 6–9 years                                 One year or less
- 4–5 years
54. Have you ever been told by a doctor that you had any of the following conditions? (MARK YES OR NO FOR EACH CONDITION)
- NO      YES**
- Benign or fibrocystic breast disease
- Benign ovarian tumor or cyst
- Endometriosis
- Uterine fibroid tumors

55. During the past three years, have you had a chest x-ray?
- No     Yes, more than once
- Yes, once                                       Don't know
56. During the past three years, have you had a mammogram?
- No     Yes, more than once
- Yes, once                                       Don't know
57. During the past three years, have you had a pap smear?
- No     Yes, more than once
- Yes, once                                       Don't know
58. During the past three years, have you had a pelvic examination?
- No     Yes, more than once
- Yes, once                                       Don't know
59. During the past three years, have you had an ultrasound or scan of your ovaries?
- No     Yes, more than once
- Yes, once                                       Don't know
60. During the past three years, have you had a blood test for ovarian cancer, for example CA-125?
- No     Yes, more than once
- Yes, once                                       Don't know
61. During the past three years, have you had a test for blood in the stool?
- No     Yes, more than once
- Yes, once                                       Don't know

PLEASE DO NOT WRITE IN THIS AREA



188171

62. During the past three years, have you had a colonoscopy, sigmoidoscopy, or barium enema to examine the colon and rectum?
- No  Yes, more than once  
 Yes, once  Don't know

64. Who completed this questionnaire?
- Completed by study participant  
 Completed by someone else (SPECIFY RELATIONSHIP)

63. What is the date you completed this questionnaire?

Date of Completion

**MONTH**

- January  
 February  
 March  
 April  
 May  
 June  
 July  
 August  
 September  
 October  
 November  
 December

**DAY**

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

**YEAR**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**For Office Use Only**

Estimated Date

Thank you very much for completing this questionnaire. Please check each page carefully to make certain you have answered all the questions that apply to you; then complete the Baseline Locator Form.

**FOR OFFICE USE ONLY**

**SCREENING CENTER ID #**

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

**SATELLITE CENTER ID #**

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

**SC STAFF ID #**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**METHOD OF ADMINISTRATION**

**(MARK ONE):**

- SELF-ADMINISTERED  
 SELF-ADMINISTERED WITH ASSISTANCE  
 IN-PERSON INTERVIEW BY SC STAFF  
 IN-PERSON INTERVIEW BY OTHER (SPECIFY)  


---

  
 TELEPHONE ADMINISTERED

**FORM PROCESSING**

**(DARKEN CIRCLES AS STEPS ARE COMPLETED):**

- Form Received into SMS  
 Manual Review Completed

**Data Retrieval:**

- Attempted OR  None Required

**Data Entry of Non-Scannable Items:**

- Completed OR  None Required

**Final Disposition:**

- Final Complete (FCM) OR  Final Incomplete (FIC)



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE BASELINE QUESTIONNAIRE FOR FEMALE PARTICIPANTS - VERSION 3 (BQF3)**

This form is to be completed by all female participants. If the participant has difficulty in the completion of the form, an SC staff member may either assist the participant in its completion or administer the questionnaire as an interview (in-person or by telephone). The boxed instructions on the questionnaire's cover page give the respondent a short set of directions for completing the questionnaire. A statement of confidentiality is also included, which is important in clarifying the respondent's rights as a participant.

The specifications include guidelines for the completion of each question on the form, whether it is completed by the participant or by some other person. The specifications also include specific guidelines for the SC staff on coding, editing or data retrieval, as appropriate. The "For Office Use Only" sections must always be completed by the SC staff according to the guidelines provided for that specific question.

General Instructions for editing and data retrieval: An attempt should be made to correct all errors or discrepant data on the questionnaire (including zero-fill errors) without contacting the participant. For any critical data items that are incomplete, unclear or marked "Don't Know" and cannot be completed without participant input, data retrieval should be attempted. Data retrieval should be directed to the participant, not the participant's doctor. Any non-critical data items that are incomplete, unclear or marked "Don't Know" may be clarified with the participant through data retrieval at the discretion of the SC Coordinator. If a critical data item still cannot be completed after data retrieval is attempted, it should remain as it was recorded by the participant and not changed. If a non-critical data item cannot be completed either with or without data retrieval, it should also remain as it was recorded by the participant and not changed. All original responses, editing and recoding must be clearly documented on the form and in the SC Decision Log.

Specifications for completing the form are given below:

**COVER PAGE:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

**Participant name:** Enter the full name (first, middle, and last) of the participant. Include any titles or suffixes.

**Participant date of birth:** Enter the month, day and year of the participant's date of birth.

**SC Instructions:** This question is a critical data item. If any portion of the date of birth is incomplete or not answered, data retrieval must be attempted. Date of birth should not be obtained from the Eligibility Screener or any source other than the participant.

**Participant telephone number:** Enter the participant's telephone number, including area code. This should be the number at which the participant would like to be contacted.

**Statement of Confidentiality Box:** The participant should read the Statement of Confidentiality. If administered by SC staff, this statement must be read to the participant.

**GENERAL BACKGROUND:**

This section of the questionnaire is concerned with the participant's general background, work history and smoking history.

**1. In what state or foreign country were you born?**

Obtain the participant's place of birth. Record the state of birth, if in the United States, or the country of birth, if in a foreign country.

*SC Instructions: Assign the appropriate numeric code in the space provided in the "For Office Use Only" box. Refer to Appendix I of the Manual of Operations and Procedures for the list of State Codes. Canada and specific provinces in Canada, should be codes as "00" (Foreign Country). Darken the circle corresponding to each number.*

*If the participant's place of birth is recorded on the BLF but left blank on the Baseline Questionnaire, it is acceptable to complete Item 1 using the information from the Baseline Locator Form.*

**2. Which of these groups best describes you?**

The following definitions are to be used for determining race or ethnic background:

**White:** Includes persons having origins in any of the original people of Europe, including Spain and Portugal, and of North Africa and the Middle East. May also include white persons of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish cultures.

**Black:** Includes persons having origins in any of the black racial groups of Africa. May also include persons having origins in any of the black racial groups of Africa and who also are of Mexican, Puerto Rican, Cuban, Portuguese, South or Central American, or other Spanish cultures, including Spain.

**Asian:** Includes persons having origins in any of the original people of the Far East, Southeast Asia, or the Indian subcontinent. This area includes, for example, China, Japan, Korea, the Philippine Islands, India, Pakistan, Bangladesh, Sri Lanka, Nepal, and Bhutan.

**Pacific Islander:** Includes persons having origins in the Pacific Islands. This includes Hawaii, Samoa, Tonga, Guam, and other Pacific Islands.

**American Indian or Alaskan Native:** Includes persons having origins in any of the original people of the American continents.

**2a. Are you of Hispanic origin?**

The following definition is to be used for determining ethnic background:

Hispanic: Includes persons of Mexican, Puerto Rican, Cuban, South or Central American, Portuguese, or other Spanish cultures, including Spain.

*SC Instructions: Questions 2 and 2a are critical data items. If these questions are incomplete or not answered, data retrieval must be attempted. If the participant refuses to categorize himself as belonging to one of the above races or ethnic groups, these items should be left blank.*

**3. What is the highest grade or level of schooling you completed?**

Obtain the highest grade completed, regardless of skipped or repeated grades. If the participant attended school in a foreign country, in an ungraded school, under a tutor, or under other special circumstances, ask the participant to give the nearest equivalent of years in a regular U.S. school. The following guidelines should be used for determining the highest grade completed:

**Less than 8 years:** The participant completed one to seven years of school.

**8 through 11 years:** The participant completed eight to eleven years of school.

**12 years or completed high school:** The participant completed 12 years of school or completed high school. This includes the participant having received a GED.

**Post high school training other than college:** The participant completed training other than college following high school. This includes secretarial school, mechanical or computer training, nursing school where only a diploma is offered, other vocational trades, or business schools outside the regular school system and attended by the participant after completion of high school.

**Some college:** The participant completed some college but did not attain a four year college degree. An Associate of Arts (AA) degree from a community college or a junior college specializing in skill training should be considered as some college.

**College graduate:** This includes a seminary in which a bachelors degree is offered, colleges of education, and nursing schools in which a bachelors degree is offered.

**Postgraduate:** Any completed post-graduate work qualifies as "post-graduate." Receiving a degree is not a criteria for this category. This also includes a Master's Degree, Post-Doctoral Degree, or some type of professional school (i.e., medical, dental, or veterinary school).

*SC Instructions: If the participant marked more than one response, the highest level of education should be kept; the remaining responses should be deleted.*

**4. What is your current marital status?**

"Current" is at the time the participant completes the questionnaire, i.e., a woman who was widowed but has remarried is considered married. Separated refers to living apart because of marital discord, not circumstantial separation (such as husband living in a nursing home).

**5. Which of these categories best describes your current working situation?**

The participant is to select the category that she feels best describes her current (at the time of completing the questionnaire) situation. "Working" is working for pay (wages, salary, commission or pay-in-kind), or working without pay in a business or farm operated by a household member. Volunteer or other unpaid work for a church, charity, or similar organization is not included. Individuals who have "retired" from their usual occupation but are currently working either full or part-time for pay are considered working unless they work less than 20 hours per week.

*SC Instructions: If the participant has circled "Other (SPECIFY)," check that the verbatim response does not actually fall into a predetermined category.*

**6. What has been your usual adult occupation? That is, at what type of occupation have you worked the longest during your adult life.**

The participant's job title descriptive of the occupation worked at the longest during her adult life should be recorded. A one-word description is almost never adequate. For example, a "clerk" can be a shipping clerk, a stock clerk, or a sales clerk.

If the participant is self-employed, find out what activities the participant spends most time doing. Do not record "proprietor" as the occupation unless the participant actually spends most time in the management of the business. If the participant spends most time in the trade or craft, record that as the occupation, i.e., seamstress, beautician, or child care provider, as appropriate.

If the participant is a "Homemaker," go to Question 10.

*SC Instructions: Question 6 will not be coded nor entered into the Study Management System (SMS).*

**7. What were your usual activities and duties in this occupation?**

These are the activities and duties corresponding to the occupation listed in Question 6. As much specificity as possible is desired. Some examples are as follows:

- Sales Manager - supervised the sales office, coordinated the other salespeople, solicited new business.
- School Teacher - taught first grade, prepared lesson plans, assisted the principal in major school projects.

*SC Instructions: Question 7 will not be coded nor entered into the Study Management System (SMS).*

**8. In what type of business or industry were you usually employed in this occupation?**

Here we are interested in the usual type of business or industry in which the participant worked at the occupation specified in Question 6. We are specifically interested in the type of business or industry, not the name of the employer or company name. One word entries are almost never adequate. Preferably, the entry should state both a general and specific function of an industry, e.g., shoe repair service, retail bookstore, wholesale grocery, or road construction.

*SC Instructions: Question 8 will not be coded nor entered into the Study Management System (SMS).*

**9. How many years have you worked in this occupation?**

This question asks for the total number of years in the occupation specified in Question 6. If periods of time have elapsed during which the participant did not or could not work in this occupation, do not omit the earlier periods of time from the total number of years.

*SC Instructions: If the participant provides a range of years, such as "around 25 to 30 years," the median value of that range (in this case, 28 years) should be recorded.*

*Question 9 will not be coded nor entered into the Study Management System (SMS).*

**10. Have you ever smoked cigarettes regularly for six months or longer?**

Allow the participant to use her own definition of regular.

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted.*

**11. At what age did you start smoking cigarettes regularly?**

This is the age when the participant started smoking cigarettes regularly. For example, if the participant smoked her first cigarette at age 14 but did not smoke on a regular basis until age 21, age 21 should be recorded, not 14.

*SC Instructions: If the participant provides a range of years, such as "somewhere between age 15 and 17," the median value of that range (in this case, age 16) should be recorded. If the participant provides an age such as "in my teens," then the median age should be recorded (in this case, 15). If the age provided is in half-years, always round up. For example, age 15½ should be recorded as age 16.*

**12. Do you smoke cigarettes regularly now?**

"Now" is at the time the participant completes the questionnaire. If the participant does not consider herself a *regular* smoker, darken the circle for "No;" if she has stopped smoking temporarily (e.g., due to a cold) and expects to begin again, darken the circle for "Yes."

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted.*

**13. At what age did you last stop smoking cigarettes regularly?**

This question is for participants who no longer smoke cigarettes. The participant's age when she stopped smoking cigarettes regularly should be recorded.

*SC Instructions: If the participant provides a range of years, such as "between age 40 and 45," the median value of that range (in this case, age 43) should be recorded. If the participant provides an age such as "in my forties," then the median age should be recorded (in this case, 45). If the age provided is in half-years, always round up. For example, age 52½ should be recorded as age 53.*

**14. During periods when you smoked, how many cigarettes did or do you usually smoke per day?**

The answer should be the usual or average number of cigarettes smoked per day during the years in which the participant regularly smoked cigarettes.

*SC Instructions: If the participant records in "packs" of cigarettes smoked per day, convert that to the number of cigarettes per day. For example, half a pack equals 10 cigarettes, 1 pack equals 20 cigarettes, 2 packs equals 40 cigarettes, etc.*

**15. During periods when you smoked, did or do you more often smoke filter or non-filter cigarettes?**

The emphasis is on the words *more often*. The participant may have smoked both filtered and non-filtered cigarettes, but smoked filtered cigarettes more often.

**16. Do you now or did you ever smoke a pipe regularly for a year or longer?**

The emphasis here is on regular use for a year or longer. Allow the participant to use her own definition of regular.

**17. Do you now or did you ever smoke cigars regularly for a year or longer?**

The emphasis here is on *regular* use for a year or longer. Allow the participant to use her own definition of regular.

**FAMILY AND PERSONAL MEDICAL HISTORY:**

This section of the questionnaire is concerned with the participant's family medical history and personal medical history. Immediate blood relatives only (parents, children, brothers, sisters, half-brothers, and half-sisters) should be included in the family medical history.

**18. How many full and half-sisters do you have, both living and deceased?**

Include full- (two parents in common) and half- (one parent in common) sisters, living and deceased.

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**19. How many full and half-brothers do you have, both living and deceased?**

Include full- (two parents in common) and half- (one parent in common) brothers, living and deceased.

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**20. Have your parents, children, brothers, sisters, half-brothers, or half-sisters ever been diagnosed as having any type of cancer?**

We are interested in all cancers *except* basal-cell skin cancer. If the participant recorded "Don't Know," leave this item blank. If "Yes," Question 21 must be completed. If "No" or "Don't Know," go to Question 22.

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**21. Please complete this chart for each relative (mother, father, children, brothers, sisters, half-brothers, half-sisters) diagnosed with cancer.**

The table for Question 21 should be completed if Question 20 is "Yes."

*SC Instructions: If the participant is adopted and has no information regarding blood relatives, this item should be left blank. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

The table should be completed as follows:

- **Who was diagnosed as having cancer, that is, what is his or her relationship to you?**

Specify the sex-specific relationship of the relative with cancer to the participant (for example, "son" rather than "child"). If there are more than four relatives who have cancer, additional information may be recorded on a separate sheet of paper.

*SC Instructions: If the participant has listed additional relatives who have cancer on a separate sheet of paper, label the sheet of paper with the participant's ID number, the title of the questionnaire and the question number to which the information refers. Insert the sheet of paper in the questionnaire.*

*Record a sequence number (e.g., 1, 2, 3, etc.) for each chart entry in the "For Office Use Only" box located on the last page of the questionnaire. The sequence number should be entered in the column titled "SEQNO." Do not assign a sequence number or code a cancer for any relative who is not an immediate blood relative (e.g., aunt, grandfather, etc.). Darken the circle corresponding to the sequence number.*

*Assign the code corresponding to the relationship of the relative with cancer to the participant in the "For Office Use Only" box located on the last page of the questionnaire. A twin sister or brother should be coded as "sister" or "brother." Refer to Appendix I of the Manual of Operations and Procedures for the listing of Relationship*

*Codes. The relationship code should be entered in the column titled "RECODE." Darken the circle corresponding to each number.*

- **What type of cancer did he or she have?**

The primary site of cancer or where it started should be recorded. Do not include relatives diagnosed with basal-cell skin cancer.

*SC Instructions: Assign the code corresponding to the type of cancer in the "For Office Use Only" box located on the last page of the questionnaire. Do not code or enter into the DEES any non-melanoma skin cancers that are reported. Refer to Appendix I of the Manual of Operations and Procedures for the listing of Cancer Codes. The cancer code should be entered in the column titled "CACODE." Darken the circle corresponding to each number. If the type of cancer is left blank, it should be coded as "999" (Not Ascertained). If the participant recorded "don't know" it should be coded as "998" (Don't Know). If the participant has recorded more than one cancer on the same line for one relative, assign codes as follows:*

<b><u>Assign Code:</u></b>	<b><u>If the participant reported:</u></b>
880	Prostate cancer and some other cancer
881	Lung cancer and some other cancer
882	Colorectal cancer and some other cancer
883	Ovarian cancer and some other cancer
884	More than one non-PLCO cancer
885	More than one PLCO cancer
886	Colon cancer and some other cancer
887	Rectal cancer and some other cancer

Code skin cancer and melanoma as follows:

<b><u>Assign Code:</u></b>	<b><u>If the participant reported:</u></b>
024	specific melanoma other than skin melanoma
033	skin melanoma
888	unspecified melanoma/unspecified skin cancer
Do not code	skin (non-melanoma)

*If more than eight cancers are reported for relatives (i.e., all eight coding spaces are used in the "For Office Use Only" box), contact the Coordinating Center.*

*For codes 880 - 888, enter the type of cancer verbatim into DEES.*

- **How old was your relative when he or she was diagnosed as having cancer?**

*SC Instructions: Record the age at diagnosis in the "For Office Use Only" box located on the last page of the questionnaire. The age should be entered in the column titled "AGE."*

*Assign the age 01 if the age is one year or less than one year.*

*Assign the age 99 if the age is 99 years or greater than 99 years.*

*Assign the age 00 if the participant recorded more than one age on the same line for one relative, if a specific age was not given (i.e., the respondent recorded "over 50" for the age), or if the participant recorded "don't know."*

*Darken the circle corresponding to each number. If 00 is recorded, enter the verbatim response into the DEES.*

**22. What is or was your weight at these ages?....(current weight?....weight at age 20?....weight at age 50?)**

Current weight is the participant's weight at this specific time when the questionnaire is being completed. For weight at age 20 and at age 50, we are interested in the participant's average weight at each age. This does not include pregnancy weight.

*SC Instructions: The numeric entry for weight should be zero filled, if appropriate. For example, a weight of 98 pounds should be recorded as 098 pounds. A weight of 399 lbs. or greater should be recorded as 399 lbs.*

**23. How tall are you?**

This question asks for current height of the participant. Height should be recorded in feet and inches.

*SC Instructions: If the participant is exactly 5 feet tall, 5 feet, 00 inches should be recorded. If the participant reported her height to the half inch, it should be rounded up to the nearest inch.*

**24. During the last 12 months, have you regularly used aspirin or aspirin-containing products, such as Bayer, Bufferin, or Anacin? (Please do not include aspirin-free products such as Tylenol and Panadol.)**

*Regular* use is emphasized and defined by the participant. This item includes baby aspirin.

*SC Instructions: If the participant recorded "No" for this item, but then marked a response for Item 25 indicating use of an aspirin-containing product, this item should be recoded to "Yes."*

**25. During the last 12 months, how many pills of aspirin-containing products did you usually take per day, per week, or per month?**

Only one of the categories listed should be marked.

*SC Instructions: If the participant recorded daily use of less than one aspirin (e.g., 1/4 or 1/2 aspirin per day), or daily use of baby aspirin, code as "1 per day".*

**26. During the last 12 months, have you regularly used ibuprofen-containing products, such as Advil, Nuprin, or Motrin?**

*Regular* use is emphasized and defined by the participant.

*SC Instructions: If the participant recorded "No" for this item, but then marked a response for Item 27 indicating use of an ibuprofen-containing product, this item should be recoded to "Yes."*

**27. During the last 12 months, how many pills of ibuprofen-containing products did you usually take per day, per week, or per month?**

Only one of the categories listed should be marked.

**28. Has a doctor ever told you that you have any of the following conditions?**

The condition must be diagnosed by a doctor; we are not interested in self-diagnosed conditions. Each condition should be recorded as either "Yes" or "No."

*SC Instructions: Definitions should not be provided for any of the conditions. Allow the participant to record her response based on her understanding of the condition.*

If the participant did not record responses for some of the items (e.g., she marked only the "Yes" responses but not the "No" responses) these items may be left blank since they are not critical data items. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."

**29. Have you ever been diagnosed as having cancer?**

We are interested in all cancers except basal-cell skin cancer. If "Yes," Question 30 must be completed. If "No," go to Question 31.

*SC Instructions: This question is a critical data item. If this question is incomplete, unclear, or not answered, data retrieval must be attempted. If the participant responds "Yes" to this item but then lists only conditions that are not coded such as a non-melanoma skin cancer in Item 30, this item should be recoded to "No".*

**30. Please complete this chart for each cancer.**

The table for Question 30 should be completed if Question 29 is "Yes." It should be completed for initial diagnoses only, not recurrent cancers. The table should be completed as follows:

- **What type of cancer did you have?**

Record the primary site of cancer or where the cancer started. Do not include basal-cell skin cancer. If the participant has more than three cancers, additional information may be recorded on a separate sheet of paper.

*SC Instructions: If the participant has listed additional cancers on a separate sheet of paper, label the sheet of paper with the participant's ID number, the title of the questionnaire and the question number to which the information refers. Insert the sheet of paper in the questionnaire. Do not code or enter into the DEES any non-melanoma skin cancers that are reported.*

*Record a sequence number (e.g., 1, 2, 3, etc.) for each primary cancer in the "For Office Use Only" box located on the last page of the questionnaire. The sequence number should be entered in the column titled "SEQNO." Darken the circle corresponding to the sequence number.*

*Assign the code corresponding to the type of cancer in the "For Office Use Only" box located on the last page of the questionnaire. Refer to Appendix I of the Manual of Operations and Procedures for the listing of Cancer Codes. The cancer code should be entered in the column titled "CACODE." Darken the circle corresponding to each number. If the participant has recorded more than one cancer on the same line, transfer the information for each additional cancer to a separate line, using additional sheets, if necessary. Then make separate entries in the "CACODE" column in the "For Office Use Only" box for each cancer listed.*

*Code skin cancer and melanoma as follows:*

<b><u>Assign Code:</u></b>	<b><u>If the participant reported:</u></b>
024	specific melanoma other than skin melanoma
033	skin melanoma
888	unspecified melanoma/unspecified skin cancer
Do not code	skin (non-melanoma)

*If the participant has recorded more than eight cancers (i.e., all eight coding spaces are used in the "For Office Use Only" box), contact the Coordinating Center.*

*For codes 880 - 888, enter the type of cancer verbatim into DEES.*

*This question is a critical data item. If the type of cancer is incomplete, unclear, or not answered, data retrieval must be attempted. If the response is "Don't Know," data retrieval must be attempted.*

• **How old were you when you were diagnosed with this cancer?**

We are interested in the participant's age at initial diagnosis.

*SC Instructions: Record the age at diagnosis in the "For Office Use Only" box located on the last page of the questionnaire. The age should be entered in the column titled "AGE." Darken the circle corresponding to each number.*

*This question is a critical data item. If age at diagnosis is incomplete, unclear, or not answered, data retrieval must be attempted. If the response is "Don't Know," data retrieval must be attempted. Probe for the best estimate. If the participant maintains a "don't know" response, assign the age "00" and enter "don't know" as the verbatim response in DEES.*

**31. How old were you when you had your first menstrual period?**

**32. How old were you when you had your last period?**

*SC Instructions: If a woman records that she is still menstruating, code this item as "55 or older" and skip Item 33.*

**33. Did your periods stop because of natural menopause, surgery, radiation, or drug therapy?**

*SC Instructions: If a woman records that she is still menstruating in Item 32, this item should be skipped. This will cause a DEES "BLANK" error to be generated, and the form should be finalized as "FIC."*

**34. Have you ever tried to become pregnant for a year or more without success?**

Here, we are asking whether the participant had tried to become pregnant for a year or more without success. We are not asking about problems retaining a pregnancy.

**35. Have you ever been pregnant?**

This includes live births, stillbirths, miscarriages and abortions.

**36. How old were you when you first became pregnant?**

This includes live births, stillbirths, miscarriages or abortions.

General specifications for Questions 37 through 40 are provided at the end of Question 40.
--

**37. How many times have you been pregnant? Please include stillbirths, miscarriages, abortions, tubal or ectopic pregnancies, and live births.**

**38. How many of your pregnancies resulted in a stillbirth?**

**39. How many of your pregnancies resulted in a miscarriage or an abortion?**

**40. How many of your pregnancies resulted in a pregnancy in one of your tubes, that is, a tubal or ectopic pregnancy?**

Questions 37 through 40 are concerned with the number of pregnancies, not the number of different births, since one pregnancy can result in a multiple birth, i.e., twins. Definitions are as follows:

**Stillbirth** - Babies born dead (no signs of life) *after* the seventh month of pregnancy.

**Miscarriage** - The spontaneous loss of the fetus before it can survive outside the mother's womb, usually occurring before the seventh month of pregnancy. Miscarriages are also referred to as spontaneous abortions.

**Abortion** - An intentional removal of the fetus before the stage of viability.

**Tubal or other ectopic pregnancy** - A pregnancy which occurs outside the uterus and cannot result in a live birth.

**Live birth** - Babies born alive or with vital signs of life.

**41. How many of your pregnancies resulted in a live birth?**

A live birth is defined as "babies born alive or with vital signs of life." The number recorded should be the *number of pregnancies* that resulted in at least one live birth, not the actual number of babies born (in the case of multiple births). If the participant had at least one live birth, Question 42 should be completed, otherwise go to Question 43.

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted. If the response is "Don't Know," data retrieval must be attempted.*

**42. What was your age at the birth of your first child?**

This question pertains to those participants who had a live birth only (the participant did not record "00" in Question 41).

**43. Did you ever take birth control pills for birth control or to regulate menstrual periods?**

Here, we are interested in whether the participant ever took oral contraceptives for birth control or to regulate menstrual periods. We are not interested in the use of birth control pills for menopause.

**44. How old were you when you first started taking birth control pills?**

We are interested in the participant's age when she first began taking birth control pills for birth control or to regulate menstrual periods.

**45. For how many total years did you take birth control pills?**

If an oral contraceptive was started and stopped over time, the respondent should add together all periods of use.

**46. Have you had a tubal ligation, that is, have you had your tubes tied?**

A tubal ligation is the tying off, cutting, burning (cauterizing), or clipping both Fallopian tubes so that no ovum can pass from the ovaries to the uterus.

**47. Have you had a hysterectomy, that is, have you had your uterus or womb removed?**

Note that the question asks about partial or complete removal of these organs (uterus, ovaries and Fallopian tubes).

**48. What was your age when you had your uterus or womb removed?**

We are interested in the participant's age at the time of her hysterectomy.

**49. Have you ever had one or both of your ovaries removed?**

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted. If the response is "Don't Know," data retrieval must be attempted.*

**50. What exactly was removed?**

*SC Instructions: This question is a critical data item. If this question is incomplete or not answered, data retrieval must be attempted. If the response is "Don't Know," data retrieval must be attempted.*

*If the participant darkened the circles next to "one ovary-partial" and "one ovary-total," both responses should be deleted and the circle next to "Both ovaries-partial" should be darkened.*

**51. Sometimes women take female hormones such as estrogen or progesterone around the time of menopause. Have you ever used female hormones (tablets, pills, or creams) for menopause?**

Here we are asking about hormones given for menopause or menopausal symptoms, such as hot flashes.

**52. Are you currently using female hormones?**

Here, we are asking if the participant is using female hormones at the present time.

**53. For how many total years did you take female hormones?**

If a medication was started and stopped over time, the respondent should add together all periods of use.

**54. Have you ever been told by a doctor that you had any of the following conditions?**

The condition must be diagnosed by a doctor; we are not interested in self-diagnosed conditions. Each condition should be recorded as either "Yes" or "No."

*SC Instructions: Definitions should not be provided for any of the conditions. Allow the participant to record her response based on her understanding of the condition. If the participant did not record responses for some of the items (e.g., she marked only the "Yes" responses but not the "No" responses) these items may be left blank since they are not critical data items. This will cause DEES "BLANK" errors to be generated, and the form should be finalized as "FIC."*

In the next series of questions, we are only interested in examinations or procedures that have occurred within the past three years.

**55. During the *past three years*, have you had a chest X-ray?**

This does not include diagnostic procedures, such as a GI series or a CT scan.

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

**56. During the *past three years*, have you had a mammogram?**

This includes mammograms performed for any reason.

**57. During the *past three years*, have you had a PAP smear?**

The definition of a PAP smear is a test for cervical cancer. It might also be called a cancer smear or cancer stain.

**58. During the *past three years*, have you had a pelvic examination?**

A pelvic examination is defined as a routine gynecologic exam, with or without a PAP smear.

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

**59. During the *past three years*, have you had an ultrasound or scan of your ovaries?**

This includes an abdominal ultrasound or a transvaginal ultrasound.

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

**60. During the *past three years*, have you had a blood test for ovarian cancer, for example, CA-125?**

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

**61. During the *past three years*, have you had a test for blood in the stool?**

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

**62. During the *past three years*, have you had a colonoscopy, sigmoidoscopy, or barium enema to examine the colon and rectum?**

This includes flexible sigmoidoscopy, and/or proctoscopy.

*SC Instructions: This question is a critical data item. If the response to this question is unclear or if the question is left blank, data retrieval must be attempted. If the response is "Don't Know," data retrieval is not required.*

**63. What is the date you completed this questionnaire?**

*SC Instructions: Make sure the numbers are written in the boxes and the corresponding circles are darkened. If the question is left blank or is unclear, either contact the participant to determine the correct date, or enter the date the Baseline Questionnaire was receipted into the SMS. Darken the corresponding circles.*

*If the date of receipt is used as an estimated date, darken the circle for "Estimated Date."*

**64. Who completed this questionnaire?**

If the questionnaire was completed by someone other than the participant, we are interested in that person's relationship to the participant.

**ADMINISTRATIVE SECTION (FOR OFFICE USE ONLY):**

This section is for administrative use by the SC staff. It includes SC identification, method of administration of the questionnaire, and form processing.

**Screening Center ID#:** This item is optional. If this item is completed, enter the 2-digit SC ID and darken the circle corresponding to each number.

**Satellite Center ID#:** This item is optional. If the SC has elected to track satellite center activity and the participant is seen at a satellite center, enter the 2-digit Satellite Center ID. Darken the circle corresponding to each number. If the participant is not seen at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank.

**SC Staff ID#:** If the questionnaire was administered by SC staff, enter the 4-digit staff ID number of the staff member who administered it. If the questionnaire was self-administered or administered by someone other than the SC staff, enter the 4-digit staff ID number of the staff member who edited the questionnaire. Darken the circle corresponding to each number.

**Method of Administration:** Darken the circle corresponding to the method of administration of the Baseline Questionnaire. Definitions of methods of administration are as follows:

- **Self Administered** - The participant completed the questionnaire by himself/herself without assistance. Unless the SC staff become aware that the participant did not complete the form himself/herself without assistance, it should be assumed that the questionnaire was self administered.
- **Self Administered with Assistance** - The participant completed the questionnaire by himself/herself (i.e. it was not administered to him/her) but required assistance from another person (relative, friend, SC staff member) to clarify one or more of the questions or to physically complete the form.
- **In-Person Interview by SC Staff** - The questionnaire was administered to the participant in person by an SC staff member.
- **In-Person Interview by Other (Specify)** - The questionnaire was administered to the participant in person, by someone other than an SC staff member. If known, record the relationship of the interviewer to the participant on the line provided.
- **Telephone Administered** - The questionnaire was administered to the participant by telephone by an SC staff member.

**Form Processing:** These are the steps that should be completed in order to process the questionnaire. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data review. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-5-3**

### A-5-3: Baseline Locator Form (BLF)

#### Specifications for the Baseline Locator Form

# Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

Participant ID Label

Form Approved OMB #: 0925-0407  
Exp. Date: 10/02  
Version Date: 10/96



BLF

## BASELINE LOCATOR FORM

Today's Date: |\_|\_|/|\_|\_|/|\_|\_|\_|\_|  
MONTH DAY YEAR

<b>1.</b>	<b>What is your full name?</b>			
<small>TITLE</small>	<small>FIRST</small>	<small>MIDDLE</small>	<small>LAST</small>	<small>SUFFIX</small>

<b>2.</b>	<b>Are you known by any other last name (please include your maiden name and any previous married names)?</b>	
<small>MAIDEN NAME</small>	<small>OTHER LAST NAME</small>	

<b>3.</b>	<b>What is your place of birth?</b>	
<small>CITY</small>	<small>STATE OR FOREIGN COUNTRY</small>	

<b>4.</b>	<b>What is your Social Security Number?</b>	
_ _ _ - _ _ - _ _ _ _		
<div style="border: 1px solid black; padding: 5px;"> <p>The National Institutes of Health is requesting your Social Security Number under Public Health Service Act 42 USC 285a. The primary use of this information is for researchers to locate you in the future if they are unable to locate you at your home address, and to search vital records in a followup study conducted in the future. Additional disclosures of information may be: to HHS contractors, grantees, and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected; to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual; and as otherwise required by Law. <b>Furnishing your Social Security Number is voluntary, and you will not be denied any federal right, benefit, or privilege by your refusal to disclose it.</b></p> </div>		

<b>5.</b>	<b>What is your current primary home address and telephone number?</b>		
<small>STREET ADDRESS</small>		<small>APT. NO.</small>	
<small>CITY</small>	<small>STATE</small>	<small>ZIP</small>	
<small>TELEPHONE NUMBER:</small>			
(      )			

<b>6.</b>	<b>What is your work telephone number? (IF NOT APPLICABLE, CHECK HERE <input type="checkbox"/> AND GO TO QUESTION 7)</b>		
<small>TELEPHONE NUMBER:</small>			
(      )			

(OVER)



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE BASELINE LOCATOR FORM (BLF)**

This form is self-administered. It is to be completed at the baseline visit by both intervention and control participants. The reporting window for completion of this form is from the participant's randomization date to one month past the participant's randomization date. The delinquency period for this form is from one month past the participant's randomization date to three months past the randomization date (see Chapter 5 of the Manual of Operations and Procedures).

Specifications for completing each item of the form are given below:

**Completed by Screening Center (in advance of administration/mailing):**

**Barcode:** This is the three-character form identifier (BLF) in barcode format. The barcode may be read by a barcode reader (wand) during the receipt of the form into the SMS.

**Participant ID:** Affix a Participant ID label to the space provided at the top of the form.

**Completed by Participant:**

**Today's Date:** This is the date the form is completed. Instruct the participant to enter the month, day, and year. Month and day should be zero filled, if applicable.

1. **What is your full name?** Instruct the participant to record his/her title (Dr., Mr., Ms., Mrs., Miss) first, middle, last name and suffix (Jr., Sr., III, Esq.).
2. **Are you known by any other last name (please include your maiden name and any previous married names)?** Instruct the participant to record any other last names such as a maiden name or any previous married names.
3. **What is your place of birth?** Instruct the participant to record the city, and state of birth. If born outside of the United States, instruct the participant to record the name of the country of his/her birth.
4. **What is your Social Security Number?** Instruct the participant to record his/her social security number in the boxes provided.

Box explaining request for Social Security Number: If the form is administered by SC staff, this statement should be read to the participant.

5. **What is your current primary home address and telephone number?** The current primary home address is the participant's usual residence. Instruct the participant to record his/her full address, including street, apartment number (if applicable), city, state, and zip code. Instruct the participant to record the telephone number, including area code at his/her primary home.
6. **What is your work telephone number?** If the participant is employed outside the home or has a business at home, instruct him/her to record a telephone number, including area code, which could be used to contact him/her at work. Assure the participant that we will not contact him/her at work unless we are unable to contact him/her at the home telephone number or by mail after repeated attempts. If the participant does not have a work telephone number, instruct him/her to place a check (÷) in the box and go to Question 7.

7. **If you have a vacation home or other residence, what is that address, telephone number and time of year of residence?** The participant may spend part of the year at another residence, or have a vacation home in another area where he/she spends a certain time of year. Instruct the participant to record the full address, including street, apartment number, city, state and zip code of the vacation home or other residence. Instruct the participant to record the telephone number, including area code this home/residence. Instruct the participant to indicate the months of the year that s/he is at this residence. If possible, the participant should record the exact dates that s/he is at this residence (e.g., From: March 1 To: October 1).

If the participant does not have a vacation home/other residence, instruct him/her to place a check (+) in the box and go to Question 8.

8. **What is your mother's maiden name and place of birth?** Instruct the participant to record his/her mother's maiden name and the city, and state of her birth. If the participant's mother was born outside of the United States, instruct the participant to record the name of the country of her birth.
9. **What are the names of two adults who live in your household and what is their relationship to you?** (Include your spouse, partner, children, relatives, and/or roommates.) Instruct the participant to record the names of two adults living in the same home as the participant, and their relationship to the participant. If only one other adult is living with the participant, s/he should record that person's name and their relationship to the respondent. If no adults aside from the participant, live in the participant's household, instruct the participant to place a check (+) in the box and go to Question 10.
10. **What is the name, address and telephone number of your current primary care physician or clinic?** Instruct the participant that if the source of his/her health care is a clinic, we are interested in the name of the doctor at the clinic. Instruct the participant to record the full name of the physician (and clinic, if applicable), the full street address, including suite or office number, the city, state, and zip code, and full telephone number, including area code, in the space provided.

If the participant does not have a current source of primary care, such as a physician or clinic, instruct him/her to place a check (+) in the box and go to Question 11.

11. **It would be of great help to us if you could provide us with the names and addresses of two people who could give us your new address should you move. We would only contact these people if we were unable to reach you at your home address. It would be helpful to get the names of people who do not live with you.** This information will be used by the Screening Centers to trace a participant if s/he cannot be contacted at his/her residential address(es). Instruct the participant to provide the names of two people who do not live with the participant, and who could give us the new address if the participant were to move.

Instruct the participant to record the full name, street address including apartment number, city, state, zip code, and telephone number including area code, of each contact in the space provided. Instruct the participant to record the relationship of each contact to him/her in the space provided.

**After completing the form:**

- If this form is administered by SC staff, thank the participant for completing the form.
- If completed by the participant at the SC, s/he should return it to the designated SC staff member or location.

- If being completed at home, the participant should mail this form to the SC in the envelope provided.

**Upon receiving the form at the SC:**

- Review the form for completeness and legibility.
- The state information in Questions 3, 5, 7, 8, 10, and 11 must be entered into the SMS as two character state abbreviations such as "MO," "MN," "HI," etc. For ease of receipt into the SMS, you may wish to write these codes in another color ink directly on the Baseline Locator Form, next to the state name provided by the participant, or you may wish to use the lookup table provided with the SMS receipt screen. The valid state codes are given in Appendix I of the Manual of Operations and Procedures.
- The relationship information in Questions 9 and 11 must be entered into the SMS as 2-digit codes such as "01" for mother, "02" for father, etc. For ease of receipt into the SMS, you may wish to write these codes in another color ink directly on the Baseline Locator Form, next to the relationship recorded by the participant, or you may wish to use the lookup table provided with the SMS receipt screen. The valid relationship codes are given in Appendix I of the Manual of Operations and Procedures. For relationships that do not appear in the list of codes in Appendix I (e.g., step-son, step-daughter, step-brother, brother-in-law, mother-in-law, etc.) use the code for "Other" (88).
- Receipt the form into the SMS.
- File the form in the participant's folder.

## **A-6-1**

### A-6-1: Participant Control Record (PCR)

#### Specifications for the Participant Control Record

## Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

### PARTICIPANT CONTROL RECORD

Satellite Center..... |\_\_|\_\_|

Study Year: T0, T1, T2, T3, T4, or T5 .....T |\_\_|

Visit Number: 1, 2, or 3 ..... |\_\_|

Date of Examination: |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|  
Month Day Year

Participant ID Label

Examination Type	Not Done (ND)/Result Pending (RP)	Exam Result	Level of Referral	Examiner ID
BCF3/BFF/Vanguard – UCLA Blood Collection				
BCF3/BFF/Vanguard – Biorepository Blood Collection				__ __ __
XRY2 - Chest X-Ray				__ __ __
TVU2 - Transvaginal Ultrasound				__ __ __
DRE2 - Digital Rectal Examination of the Prostate				__ __ __
FSG2 - Flexible Sigmoidoscopy				__ __ __
XRQ2 - Chest X-Ray - QA				__ __ __
TVQ2 - Transvaginal Ultrasound - QA				__ __ __
DRQ2 - Digital Rectal Examination - QA				__ __ __
FSQ2 - Flexible Sigmoidoscopy - QA				__ __ __

**Screening Visit Total:** Time In: \_\_ \_\_ : \_\_ \_\_ am/pm Time Out: \_\_ \_\_ : \_\_ \_\_ am/pm

Exam Result Codes	Level of Referral
AS = Positive Screen	1 = Significant Abnormality, Referral
AN = Negative Screen, Other Abnormalities	2 = Moderate Abnormality, Referral
NG = Negative Screen, No Abnormalities	3 = Slight Variation from Normal, No Referral
IN = Inadequate	4 = Normal, Result Not Available, No Referral
CM = Complete, (For BCF3/BFF/Vanguard – Biorepository only)	
PC = Partial Complete, (For BCF3/BFF/Vanguard – Biorepository only)	

## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE PARTICIPANT CONTROL RECORD (PCR)

The Participant Control Record (PCR) will be used to track the status of each screening test, the level of referral assigned to the test, and the examiner ID. In addition, total screening visit time will be collected on this form. A separate PCR form should be completed for each visit the participant makes to the SC for screening. The PCR may accompany the participant as s/he goes from one examination to the next, and may be completed, in part, by each examiner. The SC Coordinator has overall responsibility for the accurate completion of the PCR.

The order of the examinations will be dictated by protocol restrictions, (i.e., the blood must be drawn prior to the DRE for men, and the transvaginal ultrasound must be performed prior to the flexible sigmoidoscopy at the T0 screening visit for women) rather than the order in which the tests are listed on the PCR. At the end of the visit, before the participant leaves the SC, the SC staff member will review the PCR and reschedule screening tests and make referrals as needed.

Specifications for completing each item of the form are given below:

#### **Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided at the top of the form.

**Satellite Center:** If the participant is seen at a satellite center for the PLCO Trial, enter the 2-digit Satellite Center ID. If the participant is not seen at a satellite center, enter "00" or leave blank.

**Study Year:** Enter the code corresponding to the study year, from T0 to T5.

**Visit Number:** Record the number of visits the participant has made to the SC, including this visit. There should be no more than three visits to the SC in a study year.

**Date:** Record the date of the screening center visit. Month and day should be zero filled (e.g., 02/07). Record all four digits for the year.

#### **Screening Visit Information:**

**Activities:** Each examination, including each quality assurance examination, is listed on the form. The Examiner or another SC staff member will complete this section of the PCR as follows:

**Not Done (ND)/Result Pending (RP):** For each examination, except the QA examinations (XRQ2, TVQ2, DRQ2, FSQ2), if the examination was not done (i.e., the participant did not enter the exam room and the exam was not begun in any way), record "ND" in this space.

Please note that the entire row (all columns) should be left blank for:

- QA exams that are not done;
- Exams that are not done on second and third visits.

For each examination, including any QA examinations that were performed, if the result of the examination is not available by the end of the visit, record "RP." If Item B.8 on the Blood Collection Form is coded "Adequate," the BCF3/BFF – UCLA Blood Collection exam should be coded "RP" since the result of this test will not be

available immediately. In SCs where films are not interpreted immediately, the chest x-ray and/or the transvaginal ultrasound may also be coded "RP."

**Exam Result:** For each exam that was not coded ND or RP, enter a code corresponding to the result of the examination.

The exam result codes are as follows:

- AS =Positive Screen;
- AN =Negative Screen, Other Abnormalities;
- NG =Negative Screen, No Abnormalities;
- IN =Inadequate.

For each examination, except the blood draw, the result is obtained from the Examination Results section of the specific screening examination form. For the blood draw results received from UCLA, code as follows:

- AS = Positive Screen (UCLA Blood Collection Only);
- AN = Negative Screen, Other Abnormalities (UCLA Blood Collection Only);
- NG = Negative Screen, No Abnormalities (UCLA Blood Collection Only);
- IN = Inadequate. If Item B.8 of the Blood Collection Form is coded "Inadequate," the result of the BCF3/BFF – UCLA Blood Collection should be coded "IN" on the PCR. The blood result code should also be "IN" if a sample was drawn from a participant with a PLCO cancer or participants without ovaries or a prostate gland;
- CM = Complete (Biorepository Blood Collection only). This code should be used if all of the required tubes have been drawn. This information can be found in Item C.14 on the Blood Collection Form (BCF3) and item C.10 on the T4/T5 Blood Collection Form (BFF);
- PC = Partial Complete (Biorepository Blood Collection only). This code should be used if only part of the biorepository requirement was met - one or more of the required tubes was not drawn. This information can be found in Item C.14 on the Blood Collection Form (BCF3) and item C.10 on the T4/T5 Blood Collection Form (BFF).

**Level of Referral:** The level of referral indicates the severity of the findings and whether or not the SC recommends that the participant be referred for follow-up.

For each exam with a result entered in the "Exam Result" column, except the BCF3/BFF - Biorepository Blood Collection, enter a level of referral. You may leave this column blank for exams marked ND and RP. Assign level of referral as follows:

**1 = Significant Abnormality, Referral:** This code indicates that a significant abnormality was detected and the participant should be referred for immediate follow-up. This code must be used in conjunction with all exam results of "AS." It may also be used in cases where the exam result is not suspicious for a PLCO cancer (AN or IN), but a significant abnormality, that requires follow-up, was detected.

**2 = Moderate Abnormality, Referral:** This code indicates that a moderate abnormality (i.e., one that does not necessarily require immediate follow-up) was detected, and the participant should be referred for follow-up. This code may be used in cases where the exam result is AN or IN and an abnormality for which the SC recommends follow-up, was detected.

**3 = Slight Variation from Normal, No Referral:** This code indicates that a slight abnormality was detected (such as a hemorrhoid) and the SC feels that it does not require any special follow-up by the participant. This code may be used in cases where the exam result is AN or IN.

**4 = Normal/Result Not Available, No Referral:** This code indicates that no abnormality was detected, and no referral is necessary. This code may be used in cases where the exam result is NG or IN. It is not necessary to record a "4" on the hardcopy PCR for exams coded "ND" or "RP." This code should also be used if the blood sample was inadvertently drawn from a participant with a PLCO cancer or without ovaries or a prostate gland. A referral code of 4 will be recorded automatically by the system when a Missing Data Form is received for an exam that was coded "ND."

**Staff ID:** Enter the 4-digit staff ID number of the Examiner/Consultant who interpreted the examination findings and assigned the final result. For all exams except blood collection, if the final result has not been assigned during the screening visit (i.e., activity status "RP"), the staff ID should be left blank. For blood collection, the phlebotomist's staff ID should be recorded.

**Please note:** if the participant is a male, all items for the "female" exams (TVU2 and TVQ2) will always be left blank. If the participant is a female, all items for the "male" exams (DRE2, DRQ2) will always be left blank. For study years T1 through T4, the row for flexible sigmoidoscopy should be left blank.

**Screening Visit Total:** This item documents the total time the participant spent at the SC, including wait time. The PLCO protocol stipulates that a screening visit should take no more than two hours to complete. Times must be entered in a 12-hour clock format.

**Time In:** This item documents the time the participant arrived at the SC. Record the codes for the hour and minute, and circle the time of day (am or pm) that the participant arrived at the SC.

**Time Out:** This item documents the time the participant left the SC. Record the codes for the hour and minute, and circle the time of day (am or pm) that the participant left the SC.

At the end of the visit, before the participant leaves the SC, review the PCR to be sure all required tests were done. If you entered a code "ND" or "IN" and the participant is willing to reschedule the examination, arrange for an appointment to be made for the participant to have the test done/repeated. Be sure that the test is scheduled for a date that is within the reporting window (within one month of the randomization anniversary date, but not later than three months past the randomization anniversary date). The rescheduled date should be entered into the SC's appointment scheduling system.

**After completing the form:**

- Prior to receipting/scanning the form, verify that the study year and the visit number were correctly recorded.
- Receipt the form into the SMS. This may be accomplished via keyed data entry into the SMS or via update of the examination data from DEES to SMS. (Refer to the *SMS User's Guide/SMS Upgrade Documentation* and the *DEES User's Guide/DEES Upgrade Documentation* for additional information).
- File the form in the participant's study file.

- If changes are made to the results after the visit, it is not necessary to update the hardcopy PCR. All changes will be reflected on the PCR in the system.

## **A-6-2**

### A-6-2: Dietary Questionnaire (DQX)

#### Specifications for the Dietary Questionnaire

# PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER SCREENING TRIAL

## DIETARY QUESTIONNAIRE

### STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized by the Public Health Service Act, Section 412 (42 USC 285 a-1). Rights of study participants are protected by the Privacy Act of 1974. Participation is voluntary and there are no penalties for not participating or withdrawing from the study at any time. Participation will not influence a person's relationship with any provider of medical care or any Federal program such as Social Security or Medicare. The information collected in this study will be kept confidential and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. Names and other identifiers will be separated from information provided and will not appear in any report of the study. Information provided will be combined for all study participants and reported as statistical summaries. Study records will be kept for approximately 2 years past the end of the study, and then destroyed.

### For Office Use Only

#### Form Processing

- Form Received into SMS
- Manual Review Completed

#### Data Retrieval

- Completed by Center
- Completed by NOVA
- None required

Public reporting burden for this collection of information is estimated to average 35 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.



102336

This form asks about your usual food intake.  
 It takes about 35 minutes to complete. Please follow these instructions:

- Answer each question as best you can—estimate if you aren't sure.
- Use only a No. 2 pencil.
- Be certain to completely blacken in each of your answers, and erase completely if you make any changes.

CORRECT MARK: ●

INCORRECT MARKS: ✗ ⊖ ○

1. SEX

<input type="radio"/> Male	<input type="radio"/> Female
----------------------------	------------------------------

3. What is the date you are completing this questionnaire?

DATE		
MO.	DAY	YR.
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

2. What is your date of birth?

DATE		
MO.	DAY	YR.
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

4. This section is about your usual eating habits over the past year.

- Mark the column to show how often, on the average, you ate the food during the past year.
- Please BE CAREFUL which column you put your answer in.
- Please DO NOT SKIP any foods. If you never eat a food, mark "Never."

EXAMPLE: This person ate rice about twice per month and never ate winter squash.

TYPE OF FOOD	HOW OFTEN									
	NEVER	SERVINGS								
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY
Rice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>					
Winter squash, baked squash	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

TYPE OF FOOD	HOW OFTEN									
	NEVER	SERVINGS								
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY
<b>FRUITS (do not count fruit juices)</b>										
Fresh apples (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh apples (rest of year)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Applesauce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh pears (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh pears (rest of year)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bananas	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh peaches or nectarines (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Canned peaches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh plums (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cantaloupe (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Watermelon (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh strawberries (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh or frozen strawberries (rest of year)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



102336

TYPE OF FOOD	HOW OFTEN									
	NEVER	SERVINGS								
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY
<b>FRUITS (continued)</b>										
Fresh oranges (in season)	<input type="checkbox"/>									
Fresh oranges (rest of year)	<input type="checkbox"/>									
Fresh grapefruit (in season)	<input type="checkbox"/>									
Fresh grapefruit (rest of year)	<input type="checkbox"/>									
Grapes	<input type="checkbox"/>									
Apricots, fresh, dried, or canned	<input type="checkbox"/>									
Raisins	<input type="checkbox"/>									
Prunes	<input type="checkbox"/>									
Canned pineapple	<input type="checkbox"/>									
Canned fruit cocktail or mixed fruits	<input type="checkbox"/>									

<b>VEGETABLES</b>										
String beans, green beans	<input type="checkbox"/>									
Peas	<input type="checkbox"/>									
Sweet corn (in season)	<input type="checkbox"/>									
Sweet corn (rest of year)	<input type="checkbox"/>									
Summer squash, like zucchini or yellow crookneck	<input type="checkbox"/>									
Winter squash, like acorn, butternut	<input type="checkbox"/>									
Broccoli	<input type="checkbox"/>									
Cauliflower	<input type="checkbox"/>									
Brussel sprouts	<input type="checkbox"/>									
Spinach (raw)	<input type="checkbox"/>									
Spinach (cooked)	<input type="checkbox"/>									
Mustard greens, turnip greens, collards, kale, swiss chard	<input type="checkbox"/>									
Mixed vegetables, cooked	<input type="checkbox"/>									
Cole slaw, cabbage, sauerkraut	<input type="checkbox"/>									

TYPE OF FOOD	HOW OFTEN									
	NEVER	SERVINGS								
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY
<b>VEGETABLES (continued)</b>										
Carrots, cooked	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carrots, raw	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Head lettuce, like iceberg (as part of a salad)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Leaf lettuce, like romaine (as part of a salad)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Green pepper	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cucumber	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Celery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beets	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh tomatoes (in season)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fresh tomatoes (rest of year)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Canned tomatoes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tomato sauce or spaghetti sauce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ketchup, red chili sauce, taco sauce, or salsa picante	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Onions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Garlic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
French fries and fried potatoes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potatoes prepared in other ways, like boiled, baked, mashed, or potato salad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sweet potatoes, yams	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tofu or soybeans	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chili with beans	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other beans, such as baked beans, pintos, kidney, limas, and lentils	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vegetable and tomato soups, including vegetable beef, minestrone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other soups	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



For the questions on pages 6 through 11, please estimate the average serving size you ate during the past year.

- Mark the column to show HOW OFTEN, on the average, you ate the food during the past year.
- Mark the column on the right to show HOW MUCH your average serving size is (estimate small, medium, or large, based on the medium serving shown for each type of food).
- Please BE CAREFUL which column you put your answer in.
- Please DO NOT SKIP any foods. If you never eat a food, mark "Never."

**EXAMPLE:** This person ate fried chicken about 2 times per month and usually ate more than 2 small pieces or 1 large piece.

TYPE OF FOOD	HOW OFTEN										HOW MUCH			
	SERVINGS										YOUR SERVING SIZE			
	NEVER	LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY	SMALL	MEDIUM	LARGE	
Fried chicken	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	2 small or 1 large pc	<input type="radio"/>	<input checked="" type="radio"/>						

TYPE OF FOOD	HOW OFTEN										HOW MUCH			
	SERVINGS										YOUR SERVING SIZE			
	NEVER	LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY	SMALL	MEDIUM	LARGE	
<b>CEREALS, BREADS, GRAINS, PASTA</b>														
Cooked cereal or grits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium bowl	<input type="radio"/>	<input type="radio"/>
High fiber cereals, such as Fiber One, All Bran, 100% Bran, or unprocessed bran	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium bowl	<input type="radio"/>	<input type="radio"/>
Other fiber cereals, such as Raisin Bran, Corn Bran, Grape Nuts, Wheaties, Shredded Wheat, granola, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium bowl	<input type="radio"/>	<input type="radio"/>
Highly fortified cereals, such as Total, Just Right, or Product 19	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium bowl	<input type="radio"/>	<input type="radio"/>
Other cold cereals, such as corn flakes, Rice Krispies, Cheerios	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium bowl	<input type="radio"/>	<input type="radio"/>
Milk on cereal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1/2 cup	<input type="radio"/>	<input type="radio"/>
Sugar added to cereal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 teaspoons	<input type="radio"/>	<input type="radio"/>
Pancakes or waffles	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 pancakes or waffles	<input type="radio"/>	<input type="radio"/>



TYPE OF FOOD	HOW OFTEN										HOW MUCH			
	NEVER	SERVINGS									YOUR SERVING SIZE			
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY	SMALL	MEDIUM	LARGE	
<b>MEAT, POULTRY, FISH, EGGS, MIXED DISHES (continued)</b>														
Hot dogs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 hot dogs <input type="radio"/>	<input type="radio"/>
Lunch meats, such as bologna, salami, or processed ham	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 slices or 2 oz. <input type="radio"/>	<input type="radio"/>
Pork chops	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 chops or 4 oz. <input type="radio"/>	<input type="radio"/>
Pork roast	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4 ounces <input type="radio"/>	<input type="radio"/>
Baked or cured ham	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4 ounces <input type="radio"/>	<input type="radio"/>
Fried chicken	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 small or 1 large pc. <input type="radio"/>	<input type="radio"/>
Other chicken or turkey (roasted, stewed, or broiled, including on sandwiches)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 small or 1 large pc. <input type="radio"/>	<input type="radio"/>
Liver (all kinds)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4 ounces <input type="radio"/>	<input type="radio"/>
Fried fish, including on sandwiches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4 oz. or 1 sandwich <input type="radio"/>	<input type="radio"/>
Tuna, tuna salad, tuna casserole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1/2 cup <input type="radio"/>	<input type="radio"/>
Shellfish (shrimp, crab, lobster, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	5 pcs, 1/4 c, or 3 oz. <input type="radio"/>	<input type="radio"/>
Other fish (broiled or baked)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4 ounces <input type="radio"/>	<input type="radio"/>
Bacon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 slices <input type="radio"/>	<input type="radio"/>
Sausage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 patties or links <input type="radio"/>	<input type="radio"/>
Eggs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 eggs <input type="radio"/>	<input type="radio"/>
Pizza	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 slices <input type="radio"/>	<input type="radio"/>

TYPE OF FOOD	HOW OFTEN										HOW MUCH			
	NEVER	SERVINGS									YOUR SERVING SIZE			
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY	SMALL	MEDIUM	LARGE	
<b>DAIRY PRODUCTS</b>														
Cottage cheese	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1/2 cup <input type="radio"/>	<input type="radio"/>
Other cheeses and cheese spreads	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 slices or 2 ounces <input type="radio"/>	<input type="radio"/>
Yogurt	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 cup <input type="radio"/>	<input type="radio"/>
Sour cream	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	2 tablespoons <input type="radio"/>	<input type="radio"/>
Sweet cream, added to coffee, tea, fruit, or dessert	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 tablespoon <input type="radio"/>	<input type="radio"/>
Ice cream, regular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 scoop or 1/2 cup <input type="radio"/>	<input type="radio"/>
Frozen yogurt, ice milk, low-fat ice cream	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 scoop or 1/2 cup <input type="radio"/>	<input type="radio"/>

<b>OTHER</b>														
Margarine on bread, toast, or rolls	<input type="radio"/>	2 pats <input type="radio"/>	<input type="radio"/>											
Butter on bread, toast, or rolls	<input type="radio"/>	2 pats <input type="radio"/>	<input type="radio"/>											
Margarine, butter, or oil on vegetables or potatoes	<input type="radio"/>	2 pats <input type="radio"/>	<input type="radio"/>											
Gravies made with meat drippings	<input type="radio"/>	2 tablespoons <input type="radio"/>	<input type="radio"/>											
White sauce or cheese sauce	<input type="radio"/>	2 tablespoons <input type="radio"/>	<input type="radio"/>											
Salad dressing or mayonnaisse on salads or sandwiches	<input type="radio"/>	2 tablespoons <input type="radio"/>	<input type="radio"/>											
Peanuts, peanut butter	<input type="radio"/>	2 tablespoons <input type="radio"/>	<input type="radio"/>											
Salty snacks, such as potato chips, corn chips, popcorn	<input type="radio"/>	2 handfuls or 1 cup <input type="radio"/>	<input type="radio"/>											

TYPE OF FOOD	HOW OFTEN										HOW MUCH		
	NEVER	SERVINGS									YOUR SERVING SIZE		
		LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY	SMALL	MEDIUM	LARGE
<b>OTHER (continued)</b>													
Crackers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	4 crackers <input type="radio"/>	<input type="radio"/>
Pumpkin pie, sweet potato pie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium slice <input type="radio"/>	<input type="radio"/>
Other pies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 medium slice <input type="radio"/>	<input type="radio"/>
Cake	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 piece <input type="radio"/>	<input type="radio"/>
Doughnuts, sweet rolls, or coffee cake	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 piece <input type="radio"/>	<input type="radio"/>
Cookies or brownies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 pc or 3 cookies <input type="radio"/>	<input type="radio"/>
Chocolate bar or chocolate candy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 small bar or 1 oz. <input type="radio"/>	<input type="radio"/>
Other candy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	3 pieces or 1 lbs <input type="radio"/>	<input type="radio"/>
Jelly, jam, or honey	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 tablespoon <input type="radio"/>	<input type="radio"/>

TYPE OF FOOD	HOW OFTEN										HOW MUCH		
	NEVER	SERVINGS									YOUR SERVING SIZE		
		LESS THAN ONCE PER MONTH	1-3 TIMES PER MONTH	1 TIME PER WEEK	2-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2-3 TIMES PER DAY	4-5 TIMES PER DAY	6+ TIMES PER DAY	SMALL	MEDIUM	LARGE
<b>BEVERAGES</b>													
Orange juice or grapefruit juice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6-ounce glass <input type="radio"/>	<input type="radio"/>
Apple juice or apple cider	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6-ounce glass <input type="radio"/>	<input type="radio"/>
Other fruit juices	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	6-ounce glass <input type="radio"/>	<input type="radio"/>



102336

TYPE OF FOOD	HOW OFTEN										HOW MUCH		
	NEVER	SERVINGS									YOUR SERVING SIZE		
		LESS THAN ONCE PER MONTH	1-3 TIMES PER MONTH	1 TIME PER WEEK	2-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2-3 TIMES PER DAY	4-5 TIMES PER DAY	6+ TIMES PER DAY	SMALL	MEDIUM	LARGE
<b>BEVERAGES (continued)</b>													
Fruit drinks, such as Hi-C, Kool-Aid, or Hawaiian Punch	<input type="checkbox"/>	8-ounce glass	<input type="checkbox"/>										
Tomato juice or vegetable juice	<input type="checkbox"/>	8-ounce glass	<input type="checkbox"/>										
Whole milk and beverages with whole milk (not including on cereal)	<input type="checkbox"/>	8-ounce glass	<input type="checkbox"/>										
1% or 2% milk and beverages with 2% milk (not including on cereal)	<input type="checkbox"/>	8-ounce glass	<input type="checkbox"/>										
Skim milk, 1/2% milk, or buttermilk (not including on cereal)	<input type="checkbox"/>	8-ounce glass	<input type="checkbox"/>										
Regular soft drinks (not diet soda)	<input type="checkbox"/>	12-oz. can or bottle	<input type="checkbox"/>										
Beer	<input type="checkbox"/>	12-oz. can or bottle	<input type="checkbox"/>										
Wine or wine coolers	<input type="checkbox"/>	1 medium glass	<input type="checkbox"/>										
Liquor, such as whiskey, vodka, gin, or rum	<input type="checkbox"/>	1 shot	<input type="checkbox"/>										
Coffee, regular or decaf	<input type="checkbox"/>	1 medium cup	<input type="checkbox"/>										
Tea, hot or iced	<input type="checkbox"/>	1 medium cup	<input type="checkbox"/>										

5. Please indicate the usual method that you choose when eating or preparing the following foods. We realize many people cook by more than one method, but please choose only one response for each question.

When you eat steak, how is it usually cooked? (Mark only one response)	DON'T EAT STEAK	PAN FRIED	OVEN BROILED	GRILLED OR BARBECUED	DONT KNOW
	<input type="radio"/>				

When you eat steak how well done is it usually cooked? (Mark only one response)	DONT EAT STEAK	RARE	MEDIUM RARE	MEDIUM	MEDIUM WELL DONE	WELL DONE	VERY WELL DONE	DONT KNOW
	<input type="radio"/>							

When you eat hamburger, how is it usually cooked? (Mark only one response)	DONT EAT HAMBURGER	PAN FRIED	OVEN BROILED	GRILLED OR BARBECUED	DONT KNOW
	<input type="radio"/>				

When you eat hamburger how well done is it usually cooked? (Mark only one response)	DONT EAT HAMBURGER	RARE	MEDIUM RARE	MEDIUM	MEDIUM WELL DONE	WELL DONE	VERY WELL DONE	DONT KNOW
	<input type="radio"/>							

Not counting fried chicken, when you eat chicken, how is it usually cooked? (Mark only one response)	DONT EAT CHICKEN	EAT ONLY FRIED CHICKEN	ROASTED OR BAKED	GRILLED OR BARBECUED	BROILED	STEWED OR BOILED	DONT KNOW
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

When you eat pork chops, how are they usually cooked? (Mark only one response)	DONT EAT PORK CHOPS	BAKED	GRILLED OR BARBECUED	FRIED	BROILED	DONT KNOW
	<input type="radio"/>					

When you eat bacon or sausage, how well done is it usually cooked? (Mark only one response)	DONT EAT BACON OR SAUSAGE	JUST UNTIL DONE	WELL DONE OR CRISP	CHARRED	DONT KNOW
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



102336

During summer, how often do you eat meat, fish, or poultry that has been grilled or barbecued over coals, open fire, or ceramic briquets?	NEVER	LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

During the rest of the year, how often do you eat meat, fish, or poultry that has been grilled or barbecued over coals, open fire, or ceramic briquets?	NEVER	LESS THAN ONCE PER MONTH	1 TIME PER MONTH	2-3 TIMES PER MONTH	1 TIME PER WEEK	2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	2+ TIMES PER DAY
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

When you eat grilled or barbecued meat, fish, or poultry, how often is it charred on the surface?	NEVER GRILL OR BARBECUE MEAT	ALMOST NEVER OR NEVER	OCCASIONALLY	ABOUT HALF THE TIME	FREQUENTLY	ALMOST ALWAYS OR ALWAYS
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

When you eat pan-fried or oven-broiled meat, how often is it well-browned on the surface?	NEVER PAN-FRY OR OVEN-BROIL MEAT	ALMOST NEVER OR NEVER	OCCASIONALLY	ABOUT HALF THE TIME	FREQUENTLY	ALMOST ALWAYS OR ALWAYS
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## 6. Vitamins and Supplements

For each of the dietary supplements listed below that you have ever taken since age 25, please answer all questions on both pages for number of years, time periods, and amount you usually take. (If you have not taken a type of supplement since age 25, you do not need to answer for number of years, time periods, and amount you usually take for that supplement.)

Since you were 25, have you at any time taken multivitamins or other vitamin or mineral supplements?

Yes

No (If "No," SKIP TO QUESTION 8)

MULTIVITAMINS	TAKEN SINCE AGE 25?		HOW MANY YEARS HAVE YOU TAKEN IT?							ARE YOU TAKING IT NOW?		WERE YOU TAKING IT 2 YEARS AGO?		WERE YOU TAKING IT 5 YEARS AGO?			
	YES	NO	<1	1-2	3-4	5-9	10-14	15-19	20+	YES	NO	YES	NO	YES	NO		
One-a-Day type (100% RDA)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Therapeutic or high-dose type (> 100% RDA, like Theragran)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Stresstabs (B-Complex + Vitamin C)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
B-Complex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
OTHER SUPPLEMENTS	TAKEN SINCE AGE 25?		HOW MANY YEARS HAVE YOU TAKEN IT?							ARE YOU TAKING IT NOW?		WERE YOU TAKING IT 2 YEARS AGO?		WERE YOU TAKING IT 5 YEARS AGO?			
	YES	NO	<1	1-2	3-4	5-9	10-14	15-19	20+	YES	NO	YES	NO	YES	NO		
Vitamin A	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Beta-carotene	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Vitamin C	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Vitamin E	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Calcium, Dolomite, Tums, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→
Vitamin D (could be combined with calcium or vitamin A)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Cod liver oil or fish liver oil	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→



102336

HOW MANY PILLS DID/DO YOU USUALLY TAKE?					
	<2/week	2-4/week	5-6/week	1/day	2+/day
→	<input type="radio"/>				
→	<input type="radio"/>				
→	<input type="radio"/>				
→	<input type="radio"/>				
→	<input type="radio"/>				

WHAT DOSE PER DAY DID/DO YOU USUALLY TAKE? (SELECT THE CLOSEST AMOUNT)						
→	5000 I.U. <input type="radio"/>	10000 I.U. <input type="radio"/>	15000 I.U. <input type="radio"/>	20000 I.U. <input type="radio"/>	25000+ I.U. <input type="radio"/>	Don't Know <input type="radio"/>
→	5000 I.U. <input type="radio"/>	10000 I.U. <input type="radio"/>	15000 I.U. <input type="radio"/>	20000 I.U. <input type="radio"/>	25000+ I.U. <input type="radio"/>	Don't Know <input type="radio"/>
→	100 mg. <input type="radio"/>	250 mg. <input type="radio"/>	500 mg. <input type="radio"/>	1000 mg. <input type="radio"/>	1500+ mg. <input type="radio"/>	Don't Know <input type="radio"/>
→	100 I.U. <input type="radio"/>	200 I.U. <input type="radio"/>	400 I.U. <input type="radio"/>	800 I.U. <input type="radio"/>	1000+ I.U. <input type="radio"/>	Don't Know <input type="radio"/>
→	100 mg. <input type="radio"/>	250 mg. <input type="radio"/>	500 mg. <input type="radio"/>	800 mg. <input type="radio"/>	1200+ mg. <input type="radio"/>	Don't Know <input type="radio"/>

WHAT DOSE PER DAY DID/DO YOU USUALLY TAKE? (INDICATE TEASPOONS OR CAPSULES)					
→	<1 <input type="radio"/>	1 <input type="radio"/>	2 <input type="radio"/>	3+ <input type="radio"/>	<input type="radio"/> Teaspoons <input type="radio"/> Capsules

7. In addition to the vitamin supplements listed above, do you now take any of these specific supplements on a regular basis?
- No
- Brewer's yeast     Folic acid     Niacin     Vitamin B-6     Omega-fatty acids
- Iron     Zinc     Magnesium     Selenium     Copper

(If male, SKIP TO QUESTION 9)

8. During how many pregnancies did you take prenatal vitamins for at least 3 months?
- None, or never pregnant     1     2     3     4     5+

9. Summary Questions

AVERAGE USE LAST YEAR

During the past year, how often did you usually eat:	NEVER OR LESS THAN ONCE PER WEEK	1-2 TIMES PER WEEK	3-4 TIMES PER WEEK	5-6 TIMES PER WEEK	1 TIME PER DAY	BETWEEN 1 and 2 TIMES PER DAY	2 TIMES PER DAY	BETWEEN 2 and 3 TIMES PER DAY	3 TIMES PER DAY	4 TIMES PER DAY	5+ TIMES PER DAY
A serving of fresh fruit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of canned fruit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of fruit juice (do not count fruit drinks like Kool-Aid or Hi-C)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of baked, boiled, or mashed potatoes (do not count french fries or fried potatoes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of beans (do not count green beans)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of cooked vegetables (do not count potatoes, rice, or any beans other than green beans)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of lettuce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A serving of raw vegetables other than lettuce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Exercise	NONE	LESS THAN 1 HOUR PER WEEK	1 HOUR PER WEEK	2 HOURS PER WEEK	3 HOURS PER WEEK	4+ HOURS PER WEEK
About how many hours do you spend in vigorous activities, such as swimming, brisk walking, etc.?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When you were 40 years old, about how many hours did you spend in vigorous activities, such as swimming, brisk walking, etc.?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**THANK YOU VERY MUCH FOR TAKING THE TIME TO FILL OUT THIS QUESTIONNAIRE**

Please take a moment to fill in any questions you may have skipped.



102336

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE DIETARY QUESTIONNAIRE (DQX)**

This form is to be completed by all participants randomized to the intervention arm of the trial. The DQX should be presented to the participant upon completion of the initial screening visit. Because the DQX is a self-administered form, the participant can complete this form at home or at the screening center. Each center should provide their participants with a stamped envelope addressed to the screening center for return of the completed questionnaire. If the participant has difficulty in the completion of the form, this questionnaire, or selected items on this questionnaire, may also be administered as an interview (either in-person or by telephone) at the discretion of the screening center coordinator.

The specifications include guidelines for the completion of each type of question within the DQX, whether the questionnaire is completed by the participant, or the participant receives assistance from an SC staff member. It is strongly urged that this form be completed using a number two pencil. However, if a DQX is received that has been completed with either blue or black ink, there is no need to recode the questionnaire. Guidelines are also provided for SC staff on editing and data retrieval, as appropriate. Further information regarding the receipt, editing, completion, and shipping of the dietary questionnaires may be found in Chapter 6 of the Manual of Operations and Procedures.

Specifications for completing the form are given below:

**Cover Page:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form.

1. **Sex:** Participant should darken the oval for either male or female.
2. **What is your date of birth?:** Participant should enter the month, day and year of his/her birth. Single digit numbers should be zero-filled. For example, if the date of birth is June 6, 1925, 06-06-25 should be entered in the month, day and year boxes, and the appropriate numbered ovals darkened below each of the entered numbers.
3. **What is the date you are completing this questionnaire?:** Participant should enter the current month, day, and year when they complete this questionnaire. For example, if the participant is completing this questionnaire on January 15, 1994, 01-15-94 should be entered in the month, day, and year boxes, and the appropriate numbered ovals darkened below each of the entered numbers.
4. **Usual eating habits over the past year:** Participants should be encouraged to follow the instructions printed at the beginning of this section. Pages 3 through 5 cover only fruits and vegetables, and require the participant to indicate their average intake of these fruits and vegetables over the past year. Certain items appear twice, once for in season consumption, and once for consumption during the rest of the year. Participants should be encouraged to respond each time of these items, as seasonal variation in consumption patterns provide important dietary information. Spinach and carrots appear twice, once for cooked and once for raw consumption. Both of these items should also have responses.

On pages 6 through 11, there is an additional question for each item that addresses serving size. Participants should note the medium serving size for each item listed in the center column under "HOW MUCH." Participants should gauge their intake of the particular item based on the size of the medium serving size. The oval for small size should be darkened if they eat less than the medium serving size, and the oval for

large size should be darkened if they eat more than the medium serving size. If they eat the same size as the medium size, the oval under medium should be darkened.

SC Instructions: Participants should be encouraged to complete the frequency/number of servings, and serving sizes (when applicable) for each item in question 4. If they never eat the food, they should select "Never or less than once per month" rather than leave the response blank for that particular item. Data retrieval, i.e., re-interview by SC staff to ascertain responses to missing items, is only suggested if more than 10 items in a row are blank, or if an entire page has been overlooked.

5. **Food consumption and preparation habits:** This section includes ten questions (on pages 12 and 13) about food preparation and eating habits. Participants should choose only one response per question. Participants should choose the type of food preparation method that they usually use, regardless if more than one method applies for a particular question.

*SC Instructions: If a completed questionnaire is received by SC staff with more than one response darkened per item in this section, leave the item as is. No further editing of this section is required.*

6. **Since you were 25, have you at any time taken multivitamins or other vitamin or mineral supplements?:** This section includes questions about multivitamin and supplement use since the age of 25. If participants report no use of vitamins or supplements since the age of 25, they may simply darken the oval for "no" at the top of page 14 and proceed to question 7 at the bottom of page 15.

If the participant reports the use of vitamins and other supplements since the age of 25, the participant should darken the oval for "Yes" at the top of page 14 and proceed to respond to each item on page 14, carrying their responses over to page 15. The far right hand column on page 15 includes a space for hand-written response for the exact type and brand currently used (if known) for each multivitamin and supplement.

The other supplements listed (i.e., vitamin A; beta-carotene; vitamin C; vitamin E; calcium, dolomite, Tums, etc.; and vitamin D) ask the participant to recall the dose they usually take in international units (I.U.) or milligrams (mg), rather than number of pills usually taken. This information may be found on the bottle of the particular supplement they use. The item for cod liver oil or fish liver oil requires the participant to respond with the number of teaspoons or capsules they usually take.

*SC Instructions: Because items within this section of the questionnaire have responses on two consecutive pages, this should be emphasized to the participant before they leave the SC at the initial visit. Participants who have taken multivitamins and supplements should begin with the One-a-Day item at the beginning of this section answering "Yes" or "No" to "Have you ever taken it?", and then read across to "How many years have you taken it?" and respond with the number of years One-a-Day multivitamins have been taken since age 25. They should then proceed to the right still within the line for One-a-Day, responding to "Are you taking it now?", "Were you taking it 2 years ago?", and "Were you taking it 5 years ago?". The appropriate frequency for number of pills should then be answered (only one pill frequency per item is necessary). After completing all responses for One-a-Day, the participant can proceed to the next item at the left (i.e., therapeutic or high-dose type multivitamins). If a participant responds "No" to any multivitamin or supplement, they can proceed to the next item at the left.*

7. **In addition to the vitamin supplements listed above, do you now take any of these specific supplements on a regular basis?:** This question lists ten supplements. Participants can darken the ovals for any of the supplements that they take.

8. **During how many pregnancies did you take prenatal vitamins for at least 3 months?:** Males should skip this question, and proceed to question 9 on page 16. Females should darken the oval for the number of pregnancies they recall taking prenatal vitamins, or the oval for none or never pregnant.
9. **Summary questions:** The summary questions include eight items for which the participant should choose the number of times they consumed a serving (according to their own definition of "a serving") of the particular item during the past year. Only one frequency choice per item is appropriate.
10. **Exercise:** These last two items require the participant to recall the number of hours they spend doing vigorous activities on a weekly basis at the time of dietary questionnaire completion, and when they were 40 years old. Only one frequency choice per item is appropriate.

## **A-6-3**

A-6-3: Diet History Questionnaire (DHQ)

Specifications for the Diet History Questionnaire

# NATIONAL INSTITUTES OF HEALTH Diet History Questionnaire

## GENERAL INSTRUCTIONS

- Answer each question as best you can. Estimate if you are not sure. A guess is better than leaving a blank.
- Use only a No. 2 pencil.
- Be certain to completely blacken in each of the answers.
- Erase completely if you make any changes.
- Do not make any stray marks on this form.
- If you blacken NEVER or NO for a question, please follow any arrows or instructions that direct you to the next question.

### Statement of Confidentiality

Collection of this information is authorized by the Public Health Service Act, Section 412 (42 USC 285 a-1). Rights of study participants are protected by the Privacy Act of 1974. Participation is voluntary and there are no penalties for not participating or withdrawing from the study at any time. Participation will not influence a person's relationship with any provider of medical care or any federal program such as Social Security or Medicare. The information collected in this study will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. Names and other identifiers will be separated from information provided and will not appear in any report of the study. Information provided will be combined for all study participants and reported as statistical summaries. Study records will be kept for approximately 2 years past the end of the study, and then destroyed.

Public reporting burden for this collection of information is estimated to average 58 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974. ATTN: PRA (0925-0407). Do not return the completed form to this address.

**BEFORE TURNING THE PAGE, PLEASE COMPLETE THE FOLLOWING QUESTIONS.**

Today's date:

MONTH	DAY	YEAR
<input type="radio"/> JAN		<input type="radio"/> 1998
<input type="radio"/> FEB		<input type="radio"/> 1999
<input type="radio"/> MAR	<input type="radio"/> 0 <input type="radio"/> 0	<input type="radio"/> 2000
<input type="radio"/> APR	<input type="radio"/> 1 <input type="radio"/> 1	<input type="radio"/> 2001
<input type="radio"/> MAY	<input type="radio"/> 2 <input type="radio"/> 2	<input type="radio"/> 2002
<input type="radio"/> JUN	<input type="radio"/> 3 <input type="radio"/> 3	<input type="radio"/> 2003
<input type="radio"/> JUL	<input type="radio"/> 4	<input type="radio"/> 2004
<input type="radio"/> AUG	<input type="radio"/> 5	<input type="radio"/> 2005
<input type="radio"/> SEP	<input type="radio"/> 6	<input type="radio"/> 2006
<input type="radio"/> OCT	<input type="radio"/> 7	
<input type="radio"/> NOV	<input type="radio"/> 8	
<input type="radio"/> DEC	<input type="radio"/> 9	

In what month were you born?

JAN  
 FEB  
 MAR  
 APR  
 MAY  
 JUN  
 JUL  
 AUG  
 SEP  
 OCT  
 NOV  
 DEC

In what year were you born?

1 9

Are you male or female?

Male  
 Female

PASTE  
 PID  
 LABEL  
 HERE

PLEASE DO NOT WRITE IN THIS AREA



174642

1. Over the past 12 months, how often did you drink **tomato juice or vegetable juice**?

- NEVER (GO TO QUESTION 2)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

1a. Each time you drank **tomato juice or vegetable juice**, how much did you usually drink?

- Less than  $\frac{3}{4}$  cup (6 ounces)  
  $\frac{3}{4}$  to  $1\frac{1}{4}$  cups (6 to 10 ounces)  
 More than  $1\frac{1}{4}$  cups (10 ounces)

2. Over the past 12 months, how often did you drink **orange juice or grapefruit juice**?

- NEVER (GO TO QUESTION 3)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

2a. Each time you drank **orange juice or grapefruit juice**, how much did you usually drink?

- Less than  $\frac{3}{4}$  cup (6 ounces)  
  $\frac{3}{4}$  to  $1\frac{1}{4}$  cups (6 to 10 ounces)  
 More than  $1\frac{1}{4}$  cups (10 ounces)

3. Over the past 12 months, how often did you drink **other 100% fruit juice or 100% fruit juice mixtures** (such as apple, grape, pineapple, or others)?

- NEVER (GO TO QUESTION 4)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

3a. Each time you drank **other fruit juice or fruit juice mixtures**, how much did you usually drink?

- Less than  $\frac{3}{4}$  cup (6 ounces)  
  $\frac{3}{4}$  to  $1\frac{1}{2}$  cups (6 to 12 ounces)  
 More than  $1\frac{1}{2}$  cups (12 ounces)

Question 4 appears in the next column.

Over the past 12 months...

4. How often did you drink other **fruit drinks** (such as cranberry cocktail, Hi-C, lemonade, or Kool-Aid, diet or regular)?

- NEVER (GO TO QUESTION 5)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

4a. Each time you drank **fruit drinks**, how much did you usually drink?

- Less than 1 cup (8 ounces)  
 1 to 2 cups (8 to 16 ounces)  
 More than 2 cups (16 ounces)

4b. How often were your fruit drinks **diet or sugar-free drinks**?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

5. How often did you drink **milk as a beverage** (NOT in coffee, NOT in cereal)? (Please include chocolate milk and hot chocolate.)

- NEVER (GO TO QUESTION 6)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

5a. Each time you drank **milk as a beverage**, how much did you usually drink?

- Less than 1 cup (8 ounces)  
 1 to  $1\frac{1}{2}$  cups (8 to 12 ounces)  
 More than  $1\frac{1}{2}$  cups (12 ounces)

5b. What kind of **milk** did you usually drink?

- Whole milk  
 2% fat milk  
 1% fat milk  
 Skim, nonfat, or  $\frac{1}{2}$ % fat milk  
 Soy milk  
 Rice milk  
 Other

Question 6 appears on the next page.

Over the past 12 months...

6. How often did you drink **meal replacement, energy, or high-protein beverages** such as Instant Breakfast, Ensure, Slimfast, Sustacal or others?

NEVER (GO TO QUESTION 7)

- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

6a. Each time you drank **meal replacement beverages**, how much did you usually drink?

- Less than 1 cup (8 ounces)  
 1 to 1½ cups (8 to 12 ounces)  
 More than 1½ cups (12 ounces)

7. Over the past 12 months, did you drink **soft drinks, soda, or pop**?

NO (GO TO QUESTION 8)

YES

7a. How often did you drink **soft drinks, soda, or pop IN THE SUMMER**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

7b. How often did you drink **soft drinks, soda, or pop DURING THE REST OF THE YEAR**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

7c. Each time you drank **soft drinks, soda, or pop**, how much did you usually drink?

- Less than 12 ounces or less than 1 can or bottle  
 12 to 16 ounces or 1 can or bottle  
 More than 16 ounces or more than 1 can or bottle

Question 8 appears in the next column.

7d. How often were these soft drinks, soda, or pop **diet or sugar-free**?

- Almost never or never  
 About ¼ of the time  
 About ½ of the time  
 About ¾ of the time  
 Almost always or always

7e. How often were these soft drinks, soda, or pop **caffeine-free**?

- Almost never or never  
 About ¼ of the time  
 About ½ of the time  
 About ¾ of the time  
 Almost always or always

8. Over the past 12 months, did you drink **beer**?

NO (GO TO QUESTION 9)

YES

8a. How often did you drink **beer IN THE SUMMER**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

8b. How often did you drink **beer DURING THE REST OF THE YEAR**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

8c. Each time you drank **beer**, how much did you usually drink?

- Less than a 12-ounce can or bottle  
 1 to 3 12-ounce cans or bottles  
 More than 3 12-ounce cans or bottles



Question 9 appears on the next page.

Over the past 12 months...

9. How often did you drink wine or wine coolers?

- NEVER (GO TO QUESTION 10)
- 1 time per month or less
- 2-3 times per month
- 1-2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

9a. Each time you drank wine or wine coolers, how much did you usually drink?

- Less than 5 ounces or less than 1 glass
- 5 to 12 ounces or 1 to 2 glasses
- More than 12 ounces or more than 2 glasses

10. How often did you drink liquor or mixed drinks?

- NEVER (GO TO QUESTION 11)
- 1 time per month or less
- 2-3 times per month
- 1-2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

10a. Each time you drank liquor or mixed drinks, how much did you usually drink?

- Less than 1 shot of liquor
- 1 to 3 shots of liquor
- More than 3 shots of liquor

11. Over the past 12 months, did you eat oatmeal, grits, or other cooked cereal?

NO (GO TO QUESTION 12)

YES

11a. How often did you eat oatmeal, grits, or other cooked cereal IN THE WINTER?

- NEVER
- 1-6 times per winter
- 7-11 times per winter
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 12 appears in the next column.

11b. How often did you eat oatmeal, grits, or other cooked cereal DURING THE REST OF THE YEAR?

- NEVER
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

11c. Each time you ate oatmeal, grits, or other cooked cereal, how much did you usually eat?

- Less than 3/4 cup
- 3/4 to 1 1/4 cups
- More than 1 1/4 cups

12. How often did you eat cold cereal?

NEVER (GO TO QUESTION 13)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

12a. Each time you ate cold cereal, how much did you usually eat?

- Less than 1 cup
- 1 to 2 1/2 cups
- More than 2 1/2 cups

12b. How often was the cold cereal you ate Total, Product 19, or Right Start?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

12c. How often was the cold cereal you ate All Bran, Fiber One, 100% Bran, or Bran Buds?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 13 appears on the next page.

Over the past 12 months...

12d. How often was the cold cereal you ate **some other bran or fiber cereal** (such as Cheerios, Shredded Wheat, Raisin Bran, Bran Flakes, Grape-Nuts, Granola, Wheaties, or Healthy Choice)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

12e. How often was the cold cereal you ate any **other type of cold cereal** (such as Corn Flakes, Rice Krispies, Frosted Flakes, Special K, Froot Loops, Cap'n Crunch, or others)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

12f. Was **milk** added to your cold cereal?

NO (GO TO QUESTION 13)

YES

12g. What kind of **milk** was usually added?

- Whole milk
- 2% fat milk
- 1% fat milk
- Skim, nonfat, or 1/2% fat milk
- Soy milk
- Rice milk
- Other

12h. Each time **milk was added to your cold cereal**, how much was usually added?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

13. How often did you eat **applesauce**?

NEVER (GO TO QUESTION 14)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

*Question 14 appears in the next column.*

13a. Each time you ate **applesauce**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

14. How often did you eat **apples**?

NEVER (GO TO QUESTION 15)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

14a. Each time you ate **apples**, how many did you usually eat?

- Less than 1 apple
- 1 apple
- More than 1 apple

15. How often did you eat **pears** (fresh, canned, or frozen)?

NEVER (GO TO QUESTION 16)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

15a. Each time you ate **pears**, how much did you usually eat?

- Less than 1 pear
- 1 pear
- More than 1 pear

16. How often did you eat **bananas**?

NEVER (GO TO QUESTION 17)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

*Question 17 appears on the next page.*

Over the past 12 months...

16a. Each time you ate **bananas**, how many did you usually eat?

- Less than 1 banana
- 1 banana
- More than 1 banana

17. How often did you eat **dried fruit**, such as prunes or raisins (not including dried apricots)?

- NEVER (GO TO QUESTION 18)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

17a. Each time you ate **dried fruit**, how much did you usually eat (not including dried apricots)?

- Less than 2 tablespoons
- 2 to 5 tablespoons
- More than 5 tablespoons

18. Over the past 12 months, did you eat **peaches, nectarines, or plums**?

- NO (GO TO QUESTION 19)
- YES

18a. How often did you eat **fresh peaches, nectarines, or plums** WHEN IN SEASON?

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

18b. How often did you eat **peaches, nectarines, or plums** (fresh, canned, or frozen) **DURING THE REST OF THE YEAR**?

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

Question 19 appears in the next column.

18c. Each time you ate **peaches, nectarines, or plums**, how much did you usually eat?

- Less than 1 fruit or less than  $\frac{1}{2}$  cup
- 1 to 2 fruits or  $\frac{1}{2}$  to  $\frac{3}{4}$  cup
- More than 2 fruits or more than  $\frac{3}{4}$  cup

19. How often did you eat **grapes**?

- NEVER (GO TO QUESTION 20)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

19a. Each time you ate **grapes**, how much did you usually eat?

- Less than  $\frac{1}{2}$  cup or less than 10 grapes
- $\frac{1}{2}$  to 1 cup or 10 to 30 grapes
- More than 1 cup or more than 30 grapes

20. Over the past 12 months, did you eat **cantaloupe**?

- NO (GO TO QUESTION 21)
- YES

20a. How often did you eat **fresh cantaloupe** **WHEN IN SEASON**?

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

20b. How often did you eat **fresh or frozen cantaloupe** **DURING THE REST OF THE YEAR**?

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

Question 21 appears on the next page.

Over the past 12 months...

20c. Each time you ate **cantaloupe**, how much did you usually eat?

- Less than  $\frac{1}{4}$  melon or less than  $\frac{1}{2}$  cup
- $\frac{1}{4}$  melon or  $\frac{1}{2}$  to 1 cup
- More than  $\frac{1}{4}$  melon or more than 1 cup

21. Over the past 12 months, did you eat **melon, other than cantaloupe** (such as watermelon or honeydew)?

NO (GO TO QUESTION 22)

YES

21a. How often did you eat **fresh melon, other than cantaloupe**, (such as watermelon or honeydew) **WHEN IN SEASON?**

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

21b. How often did you eat **fresh or frozen melon, other than cantaloupe** (such as watermelon or honeydew) **DURING THE REST OF THE YEAR?**

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

21c. Each time you ate **melon other than cantaloupe**, how much did you usually eat?

- Less than  $\frac{1}{2}$  cup or 1 small wedge
- $\frac{1}{2}$  to 2 cups or 1 medium wedge
- More than 2 cups or 1 large wedge



Question 22 appears in the next column.

22. Over the past 12 months, did you eat **strawberries**?

NO (GO TO QUESTION 23)

YES

22a. How often did you eat **fresh strawberries** **WHEN IN SEASON?**

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

22b. How often did you eat **fresh or frozen strawberries** **DURING THE REST OF THE YEAR?**

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

22c. Each time you ate **strawberries**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup or less than 3 berries
- $\frac{1}{4}$  to  $\frac{3}{4}$  cup or 3 to 8 berries
- More than  $\frac{3}{4}$  cup or more than 8 berries

23. Over the past 12 months, did you eat **oranges, tangerines, or tangelos**?

NO (GO TO QUESTION 24)

YES

23a. How often did you eat **fresh oranges, tangerines, or tangelos** **WHEN IN SEASON?**

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

Question 24 appears on the next page.

Over the past 12 months...

23b. How often did you eat **oranges, tangerines, or tangelos** (fresh or canned) **DURING THE REST OF THE YEAR?**

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

23c. Each time you ate **oranges, tangerines, or tangelos**, how many did you usually eat?

- Less than 1 fruit
- 1 fruit
- More than 1 fruit

24. Over the past 12 months, did you eat **grapefruit**?

NO (GO TO QUESTION 25)

YES

24a. How often did you eat **fresh grapefruit** **WHEN IN SEASON?**

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

24b. How often did you eat **grapefruit** (fresh or canned) **DURING THE REST OF THE YEAR?**

- Never
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

24c. Each time you ate **grapefruit**, how much did you usually eat?

- Less than 1/2 grapefruit
- 1/2 grapefruit
- More than 1/2 grapefruit

Question 25 appears in the next column.

25. How often did you eat **other kinds of fruit**?

- NEVER (GO TO QUESTION 26)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

25a. Each time you ate **other kinds of fruit**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 3/4 cup
- More than 3/4 cup

26. How often did you eat **COOKED greens** (such as spinach, turnip, collard, mustard, chard, or kale)?

- NEVER (GO TO QUESTION 27)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

26a. Each time you ate **COOKED greens**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

27. How often did you eat **RAW greens** (such as spinach, turnip, collard, mustard, chard, or kale)? (*We will ask about lettuce later.*)

- NEVER (GO TO QUESTION 28)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

27a. Each time you ate **RAW greens**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

Question 28 appears on the next page.

Over the past 12 months...

28. How often did you eat **coleslaw**?

- NEVER (GO TO QUESTION 29)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

28a. Each time you ate **coleslaw**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup  
  $\frac{1}{4}$  to  $\frac{3}{4}$  cup  
 More than  $\frac{3}{4}$  cup

29. How often did you eat **sauerkraut** or **cabbage** (other than coleslaw)?

- NEVER (GO TO QUESTION 30)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

29a. Each time you ate **cabbage** or **sauerkraut**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup  
  $\frac{1}{4}$  to 1 cup  
 More than 1 cup

30. How often did you eat **carrots** (fresh, canned, or frozen)?

- NEVER (GO TO QUESTION 31)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

30a. Each time you ate **carrots**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup or less than 2 baby carrots  
  $\frac{1}{4}$  to  $\frac{1}{2}$  cup or 2 to 5 baby carrots  
 More than  $\frac{1}{2}$  cup or more than 5 baby carrots

31. How often did you eat **string beans** or **green beans** (fresh, canned, or frozen)?

- NEVER (GO TO QUESTION 32)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

31a. Each time you ate **string beans** or **green beans**, how much did you usually eat?

- Less than  $\frac{1}{2}$  cup  
  $\frac{1}{2}$  to 1 cup  
 More than 1 cup

32. How often did you eat **peas** (fresh, canned, or frozen)?

- NEVER (GO TO QUESTION 33)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

32a. Each time you ate **peas**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup  
  $\frac{1}{4}$  to  $\frac{3}{4}$  cup  
 More than  $\frac{3}{4}$  cup

33. Over the past 12 months, did you eat **corn**?

- NO (GO TO QUESTION 34)  
 YES

33a. How often did you eat **fresh corn** WHEN IN SEASON?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per season  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per season | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

Question 31 appears in the next column.

Question 34 appears on the next page.

Over the past 12 months...

33b. How often did you eat **corn** (fresh, canned, or frozen) **DURING THE REST OF THE YEAR**?

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

33c. Each time you ate **corn**, how much did you usually eat?

- Less than 1 ear or less than 1/2 cup
- 1 ear or 1/2 to 1 cup
- More than 1 ear or more than 1 cup

34. Over the past 12 months, how often did you eat **broccoli** (fresh or frozen)?

- NEVER (GO TO QUESTION 35)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

34a. Each time you ate **broccoli**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1 cup
- More than 1 cup

35. How often did you eat **cauliflower** or **Brussels sprouts** (fresh or frozen)?

- NEVER (GO TO QUESTION 36)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

35a. Each time you ate **cauliflower** or **Brussels sprouts**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1/2 cup
- More than 1/2 cup

Question 36 appears in the next column.

36. How often did you eat **mixed vegetables**?

- NEVER (GO TO QUESTION 37)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

36a. Each time you ate **mixed vegetables**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

37. How often did you eat **onions**?

- NEVER (GO TO QUESTION 38)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

37a. Each time you ate **onions**, how much did you usually eat?

- Less than 1 slice or less than 1 tablespoon
- 1 slice or 1 to 4 tablespoons
- More than 1 slice or more than 4 tablespoons

38. Now think about all the **cooked vegetables** you ate in the past 12 months and how they were prepared. How often were your vegetables **COOKED WITH** some sort of **fat**, including oil spray? (*Please do not include potatoes.*)

- NEVER (GO TO QUESTION 39)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day



Question 39 appears on the next page.

Over the past 12 months...

38a. Which fats were usually added to your vegetables **DURING COOKING**? (Please do not include potatoes. **Mark as many as apply.**)

- Margarine (including low-fat)
- Butter (including low-fat)
- Lard, fatback, or bacon fat
- Olive oil
- Corn oil
- Canola or rapeseed oil
- Oil spray, such as Pam or others
- Other kinds of oils
- None of the above

39. Now, thinking again about all the **cooked vegetables** you ate in the past 12 months, how often was some sort of fat, sauce, or dressing added **AFTER COOKING OR AT THE TABLE**? (Please do not include potatoes.)

- NEVER (GO TO QUESTION 40)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1–2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 times per day
- 3 or more times per day

39a. Which fats, sauces, or dressings were usually added **AFTER COOKING OR AT THE TABLE**? (Please do not include potatoes. **Mark as many as apply.**)

- Margarine (including low-fat)
- Butter (including low-fat)
- Lard, fatback, or bacon fat
- Salad dressing
- Cheese sauce
- White sauce
- Other

39b. If margarine, butter, lard, fatback, or bacon fat was added to your cooked vegetables **AFTER COOKING OR AT THE TABLE**, how much did you usually add?

- Did not usually add these
- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

39c. If salad dressing, cheese sauce, or white sauce was added to your cooked vegetables **AFTER COOKING OR AT THE TABLE**, how much did you usually add?

- Did not usually add these
- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

Question 40 appears in the next column.

40. Over the past 12 months, how often did you eat **sweet peppers** (green, red, or yellow)?

- NEVER (GO TO QUESTION 41)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

40a. Each time you ate **sweet peppers**, how much did you usually eat?

- Less than 1/8 pepper
- 1/8 to 1/4 pepper
- More than 1/4 pepper

41. Over the past 12 months, did you eat **fresh tomatoes** (including those in salads)?

- NO (GO TO QUESTION 42)
- YES

41a. How often did you eat **fresh tomatoes** (including those in salads) **WHEN IN SEASON**?

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

41b. How often did you eat **fresh tomatoes** (including those in salads) **DURING THE REST OF THE YEAR**?

- NEVER
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

41c. Each time you ate **fresh tomatoes**, how much did you usually eat?

- Less than 1/4 tomato
- 1/4 to 1/2 tomato
- More than 1/2 tomato

Question 42 appears on the next page.

Over the past 12 months...

42. How often did you eat **lettuce salads** (with or without other vegetables)?

- NEVER (GO TO QUESTION 43)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

42a. Each time you ate **lettuce salads**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup  
  $\frac{1}{4}$  to  $1\frac{1}{4}$  cups  
 More than  $1\frac{1}{4}$  cups

43. How often did you eat **salad dressing** (including low-fat) on salads?

- NEVER (GO TO QUESTION 44)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

43a. Each time you ate **salad dressing** on salads, how much did you usually eat?

- Less than 2 tablespoons  
 2 to 4 tablespoons  
 More than 4 tablespoons

44. How often did you eat **sweet potatoes** or **yams**?

- NEVER (GO TO QUESTION 45)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

44a. Each time you ate **sweet potatoes** or **yams**, how much did you usually eat?

- 1 small potato or less than  $\frac{1}{4}$  cup  
 1 medium potato or  $\frac{1}{4}$  to  $\frac{3}{4}$  cup  
 1 large potato or more than  $\frac{3}{4}$  cup

Question 45 appears in the next column.

45. How often did you eat **French fries, home fries, hash browned potatoes, or tater tots**?

- NEVER (GO TO QUESTION 46)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

45a. Each time you ate **French fries, home fries, hash browned potatoes, or tater tots** how much did you usually eat?

- Less than 10 fries or less than  $\frac{1}{2}$  cup  
 10 to 25 fries or  $\frac{1}{2}$  to 1 cup  
 More than 25 fries or more than 1 cup

46. How often did you eat **potato salad**?

- NEVER (GO TO QUESTION 47)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

46a. Each time you ate **potato salad**, how much did you usually eat?

- Less than  $\frac{1}{2}$  cup  
  $\frac{1}{2}$  to 1 cup  
 More than 1 cup

47. How often did you eat **baked, boiled, or mashed potatoes**?

- NEVER (GO TO QUESTION 48)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

47a. Each time you ate **baked, boiled, or mashed potatoes**, how much did you usually eat?

- 1 small potato or less than  $\frac{1}{2}$  cup  
 1 medium potato or  $\frac{1}{2}$  to 1 cup  
 1 large potato or more than 1 cup

Question 48 appears on the next page.

Over the past 12 months...

47b. How often was **sour cream** (including low-fat) added to your potatoes, **EITHER IN COOKING OR AT THE TABLE?**

- Almost never or never (GO TO QUESTION 47d)
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

47c. Each time **sour cream** was added to your potatoes, how much was usually added?

- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

47d. How often was **margarine** (including low-fat) added to your potatoes, **EITHER IN COOKING OR AT THE TABLE?**

- Almost never or never
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

47e. How often was **butter** (including low-fat) added to your potatoes, **EITHER IN COOKING OR AT THE TABLE?**

- Almost never or never
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

47f. Each time **margarine** or **butter** was added to your potatoes, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

47g. How often was **cheese** or **cheese sauce** added to your potatoes, **EITHER IN COOKING OR AT THE TABLE?**

- Almost never or never (GO TO QUESTION 48)
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

47h. Each time **cheese** or **cheese sauce** was added to your potatoes, how much was usually added?

- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

48. How often did you eat **salsa**?

- NEVER (GO TO QUESTION 49)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

48a. Each time you ate **salsa**, how much did you usually eat?

- Less than 1 tablespoon
- 1 to 5 tablespoons
- More than 5 tablespoons

49. How often did you eat **catsup**?

- NEVER (GO TO QUESTION 50)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

49a. Each time you ate **catsup**, how much did you usually eat?

- Less than 1 teaspoon
- 1 to 6 teaspoons
- More than 6 teaspoons

50. How often did you eat **stuffing, dressing, or dumplings**?

- NEVER (GO TO QUESTION 51)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

50a. Each time you ate **stuffing, dressing, or dumplings**, how much did you usually eat?

- Less than  $\frac{1}{2}$  cup
- $\frac{1}{2}$  to 1 cup
- More than 1 cup

Question 48 appears in the next column.

Question 51 appears on the next page.

Over the past 12 months...

51. How often did you eat **chili**?

- NEVER (GO TO QUESTION 52)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

51a. Each time you ate **chili**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 3/4 cups
- More than 1 3/4 cups

52. How often did you eat **Mexican foods** (such as tacos, tostados, burritos, tamales, fajitas, enchiladas, quesadillas, and chimichangas)?

- NEVER (GO TO QUESTION 53)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

52a. Each time you ate **Mexican foods**, how much did you usually eat?

- Less than 1 taco, burrito, etc.
- 1 to 2 tacos, burritos, etc.
- More than 2 tacos, burritos, etc.

53. How often did you eat **cooked dried beans** (such as baked beans, pintos, kidney, blackeyed peas, lima, lentils, soybeans, or refried beans)? *(Please don't include bean soups or chili.)*

- NEVER (GO TO QUESTION 54)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

53a. Each time you ate **beans**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

Question 54 appears in the next column.

53b. How often were the beans you ate **refried beans, beans prepared with any type of fat, or with meat added**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

54. How often did you eat **other kinds of vegetables**?

- NEVER (GO TO QUESTION 55)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

54a. Each time you ate **other kinds of vegetables**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1/2 cup
- More than 1/2 cup

55. How often did you eat **rice or other cooked grains** (such as bulgur, cracked wheat, or millet)?

- NEVER (GO TO QUESTION 56)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

55a. Each time you ate **rice or other cooked grains**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 1/2 cups
- More than 1 1/2 cups

55b. How often was **butter, margarine, or oil** added to your rice **IN COOKING OR AT THE TABLE**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 56 appears on the next page.

Over the past 12 months...

56. How often did you eat **pancakes, waffles, or French toast**?

- NEVER (GO TO QUESTION 57)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

56a. Each time you ate **pancakes, waffles, or French toast**, how much did you usually eat?

- Less than 1 medium piece
- 1 to 3 medium pieces
- More than 3 medium pieces

56b. How often was **margarine** (including low-fat) added to your pancakes, waffles, or French toast **AFTER COOKING OR AT THE TABLE**?

- Almost never or never
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

56c. How often was **butter** (including low-fat) added to your pancakes, waffles, or French toast **AFTER COOKING OR AT THE TABLE**?

- Almost never or never
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

56d. Each time **margarine** or **butter** was added to your pancakes, waffles, or French toast, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

56e. How often was **syrup** added to your pancakes, waffles, or French toast?

- Almost never or never (GO TO QUESTION 57)
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

Question 57 appears in the next column.

56f. Each time **syrup** was added to your pancakes, waffles, or French toast, how much was usually added?

- Less than 1 tablespoon
- 1 to 4 tablespoons
- More than 4 tablespoons

57. How often did you eat **lasagna, stuffed shells, stuffed manicotti, ravioli, or tortellini**? (Please do not include spaghetti or other pasta.)

- NEVER (GO TO QUESTION 58)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

57a. Each time you ate **lasagna, stuffed shells, stuffed manicotti, ravioli, or tortellini**, how much did you usually eat?

- Less than 1 cup
- 1 to 2 cups
- More than 2 cups

58. How often did you eat **macaroni and cheese**?

- NEVER (GO TO QUESTION 59)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

58a. Each time you ate **macaroni and cheese**, how much did you usually eat?

- Less than 1 cup
- 1 to  $1\frac{1}{2}$  cups
- More than  $1\frac{1}{2}$  cups

59. How often did you eat **pasta salad or macaroni salad**?

- NEVER (GO TO QUESTION 60)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

Question 60 appears on the next page.

Over the past 12 months...

59a. Each time you ate **pasta salad** or **macaroni salad**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

60. Other than the pastas listed in Questions 57, 58, and 59, how often did you eat **pasta, spaghetti, or other noodles**?

NEVER (GO TO QUESTION 61)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

60a. Each time you ate **pasta, spaghetti, or other noodles**, how much did you usually eat?

- Less than 1 cup
- 1 to 3 cups
- More than 3 cups

60b. How often did you eat your pasta, spaghetti, or other noodles with **tomato sauce** or **spaghetti sauce made WITH meat**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

60c. How often did you eat your pasta, spaghetti, or other noodles with **tomato sauce** or **spaghetti sauce made WITHOUT meat**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

60d. How often did you eat your pasta, spaghetti, or other noodles with **margarine, butter, oil, or cream sauce**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 61 appears in the next column.

61. How often did you eat **bagels** or **English muffins**?

NEVER (GO TO INTRODUCTION TO QUESTION 62)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

61a. Each time you ate **bagels** or **English muffins**, how many did you usually eat?

- Less than 1 bagel or English muffin
- 1 bagel or English muffin
- More than 1 bagel or English muffin

61b. How often was **margarine** (including low-fat) added to your bagels or English muffins?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

61c. How often was **butter** (including low-fat) added to your bagels or English muffins?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

61d. Each time **margarine** or **butter** was added to your bagels or English muffins, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 2 teaspoons
- More than 2 teaspoons

61e. How often was **cream cheese** (including low-fat) spread on your bagels or English muffins?

- Almost never or never (GO TO INTRODUCTION TO QUESTION 62)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Introduction to Question 62 appears on the next page.

Over the past 12 months...

61f. Each time **cream cheese** was added to your bagels or English muffins, how much was usually added?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons

The next questions ask about your intake of breads other than bagels or English muffins. First, we will ask about bread you ate as part of sandwiches only. Then we will ask about all other bread you ate.

62. How often did you eat **breads or rolls AS PART OF SANDWICHES** (including burger and hot dog rolls)?

- NEVER (GO TO QUESTION 63)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

62a. Each time you ate **breads or rolls AS PART OF SANDWICHES**, how many did you usually eat?

- 1 slice or 1/2 roll
- 2 slices or 1 roll
- More than 2 slices or more than 1 roll

62b. How often were the breads or rolls that you used for your sandwiches **white bread** (including burger and hot dog rolls)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62c. How often was **mayonnaise or mayonnaise-type dressing** (including low-fat) added to your sandwich bread or rolls?

- Almost never or never (GO TO QUESTION 62e)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 62e appears in the next column.

Question 63 appears in the next column.

62d. Each time **mayonnaise or mayonnaise-type dressing** was added to your sandwich breads or rolls, how much was usually added?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

62e. How often was **margarine** (including low-fat) added to your sandwich bread or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62f. How often was **butter** (including low-fat) added to your sandwich bread or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62g. Each time **margarine or butter** was added to your sandwich breads or rolls, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 2 teaspoons
- More than 2 teaspoons

63. How often did you eat **breads or dinner rolls, NOT AS PART OF SANDWICHES**?

- NEVER (GO TO QUESTION 64)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

63a. Each time you ate **breads or dinner rolls, NOT AS PART OF SANDWICHES**, how much did you usually eat?

- 1 slice or 1 dinner roll
- 2 slices or 2 dinner rolls
- More than 2 slices or 2 dinner rolls



Question 64 appears on the next page.

Over the past 12 months...

63b. How often were the breads or rolls you ate **white bread**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63c. How often was **margarine** (including low-fat) added to your breads or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63d. How often was **butter** (including low-fat) added to your breads or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63e. Each time **margarine** or **butter** was added to your breads or rolls, how much was usually added?

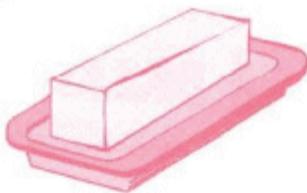
- Never added
- Less than 1 teaspoon
- 1 to 2 teaspoons
- More than 2 teaspoons

63f. How often was **cream cheese** (including low-fat) added to your breads or rolls?

- Almost never or never (GO TO QUESTION 64)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63g. Each time **cream cheese** was added to your breads or rolls, how much was usually added?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons



Question 64 appears in the next column.

64. How often did you eat **jam, jelly, or honey** on bagels, muffins, bread, rolls, or crackers?

- NEVER (GO TO QUESTION 65)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

64a. Each time you ate **jam, jelly, or honey**, how much did you usually eat?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

65. How often did you eat **peanut butter** or **other nut butter**?

- NEVER (GO TO QUESTION 66)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

65a. Each time you ate **peanut butter** or **other nut butter**, how much did you usually eat?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons

66. How often did you eat **roast beef** or **steak IN SANDWICHES**?

- NEVER (GO TO QUESTION 67)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

66a. Each time you ate **roast beef** or **steak IN SANDWICHES**, how much did you usually eat?

- Less than 1 slice or less than 2 ounces
- 1 to 2 slices or 2 to 4 ounces
- More than 2 slices or more than 4 ounces

Question 67 appears on the next page.

Over the past 12 months...

67. How often did you eat **turkey or chicken cold CUTS** (such as loaf, luncheon meat, turkey ham, turkey salami, or turkey pastrami)? (We will ask about other turkey or chicken later.)

- NEVER (GO TO QUESTION 68)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

67a. Each time you ate **turkey or chicken COLD CUTS**, how much did you usually eat?

- Less than 1 slice  
 1 to 3 slices  
 More than 3 slices

68. How often did you eat **luncheon or deli-style ham**? (We will ask about other ham later.)

- NEVER (GO TO QUESTION 69)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

68a. Each time you ate **luncheon or deli-style ham**, how much did you usually eat?

- Less than 1 slice  
 1 to 3 slices  
 More than 3 slices

68b. How often was the luncheon or deli-style ham you ate **light, low-fat, or fat-free**?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always



Question 69 appears in the next column.

69. How often did you eat **other cold cuts or luncheon meats** (such as bologna, salami, corned beef, pastrami, or others, including low-fat)? (Please do not include ham, turkey, or chicken cold cuts.)

- NEVER (GO TO QUESTION 70)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

69a. Each time you ate **other cold cuts or luncheon meats**, how much did you usually eat?

- Less than 1 slice  
 1 to 3 slices  
 More than 3 slices

69b. How often were the other cold cuts or luncheon meats you ate **light, low-fat, or fat-free cold cuts or luncheon meats**? (Please do not include ham, turkey, or chicken cold cuts.)

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

70. How often did you eat **canned tuna** (including in salads, sandwiches, or casseroles)?

- NEVER (GO TO QUESTION 71)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

70a. Each time you ate **canned tuna**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup or less than 2 ounces  
  $\frac{1}{4}$  to  $\frac{1}{2}$  cup or 2 to 3 ounces  
 More than  $\frac{1}{2}$  cup or more than 3 ounces

70b. How often was the canned tuna you ate **water-packed tuna**?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

Question 71 appears on the next page.

Over the past 12 months...

70c. How often was the canned tuna you ate prepared with **mayonnaise** or **other dressing** (including low-fat)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

71. How often did you eat **GROUND chicken** or **turkey**?  
(We will ask about other chicken and turkey later.)

- NEVER (GO TO QUESTION 72)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

71a. Each time you ate **GROUND chicken** or **turkey**, how much did you usually eat?

- Less than 2 ounces or less than 1/2 cup
- 2 to 4 ounces or 1/2 to 1 cup
- More than 4 ounces or more than 1 cup

72. How often did you eat **beef hamburgers** or **cheeseburgers**?

- NEVER (GO TO QUESTION 73)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

72a. Each time you ate **beef hamburgers** or **cheeseburgers**, how much did you usually eat?

- Less than 1 patty or less than 2 ounces
- 1 patty or 2 to 4 ounces
- More than 1 patty or more than 4 ounces

72b. How often were the beef hamburgers or cheeseburgers you ate made with **lean ground beef**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 73 appears in the next column.

73. How often did you eat **ground beef in mixtures** (such as meatballs, casseroles, chili, or meatloaf)?

- NEVER (GO TO QUESTION 74)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

73a. Each time you ate **ground beef in mixtures**, how much did you usually eat?

- Less than 3 ounces or less than 1/2 cup
- 3 to 8 ounces or 1/2 to 1 cup
- More than 8 ounces or more than 1 cup

74. How often did you eat **hot dogs** or **frankfurters**?  
(Please do not include sausages or vegetarian hot dogs.)

- NEVER (GO TO QUESTION 75)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

74a. Each time you ate **hot dogs** or **frankfurters**, how many did you usually eat?

- Less than 1 hot dog
- 1 to 2 hot dogs
- More than 2 hot dogs

74b. How often were the hot dogs or frankfurters you ate **light** or **low-fat hot dogs**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Question 75 appears on the next page.

Over the past 12 months...

75. How often did you eat beef mixtures such as **beef stew, beef pot pie, beef and noodles, or beef and vegetables**?

- NEVER (GO TO QUESTION 76)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

75a. Each time you ate **beef stew, beef pot pie, beef and noodles, or beef and vegetables**, how much did you usually eat?

- Less than 1 cup
- 1 to 2 cups
- More than 2 cups

76. How often did you eat **roast beef or pot roast**? (Please do not include roast beef or pot roast in sandwiches.)

- NEVER (GO TO QUESTION 77)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

76a. Each time you ate **roast beef or pot roast** (including in mixtures), how much did you usually eat?

- Less than 2 ounces
- 2 to 5 ounces
- More than 5 ounces

77. How often did you eat **steak** (beef)? (Do not include steak in sandwiches)

- NEVER (GO TO QUESTION 78)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

77a. Each time you ate **steak** (beef), how much did you usually eat?

- Less than 3 ounces
- 3 to 7 ounces
- More than 7 ounces

Question 78 appears in the next column.

77b. How often was the steak you ate **lean steak**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

78. How often did you eat **pork or beef spareribs**?

- NEVER (GO TO QUESTION 79)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

78a. Each time you ate **pork or beef spareribs**, how much did you usually eat?

- Less than 4 ribs
- 4 to 12 ribs
- More than 12 ribs

79. How often did you eat **roast turkey, turkey cutlets, or turkey nuggets** (including in sandwiches)?

- NEVER (GO TO QUESTION 80)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

79a. Each time you ate **roast turkey, turkey cutlets, or turkey nuggets**, how much did you usually eat? (Please note: 4–8 turkey nuggets = 3 ounces.)

- Less than 2 ounces
- 2 to 4 ounces
- More than 4 ounces

80. How often did you eat **chicken** as part of **salads, sandwiches, casseroles, stews, or other mixtures**?

- NEVER (GO TO QUESTION 81)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

Question 81 appears on the next page.

Over the past 12 months...

80a. Each time you ate **chicken** as part of **salads, sandwiches, casseroles, stews, or other mixtures**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 1/2 cups
- More than 1 1/2 cups

81. How often did you eat **baked, broiled, roasted, stewed, or fried chicken** (including nuggets)? *(Please do not include chicken in mixtures.)*

- NEVER (GO TO QUESTION 82)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

81a. Each time you ate **baked, broiled, roasted, stewed, or fried chicken** (including nuggets), how much did you usually eat?

- Less than 2 drumsticks or wings, 1 breast or thigh, or less than 4 nuggets
- 2 drumsticks or wings, 1 breast or thigh, or 4 to 8 nuggets
- More than 2 drumsticks or wings, 1 breast or thigh, or more than 8 nuggets

81b. How often was the chicken you ate **fried chicken** (including deep fried) or **chicken nuggets**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

81c. How often was the chicken you ate **WHITE meat**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

81d. How often did you eat chicken **WITH skin**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 82 appears in the next column.

82. How often did you eat **baked ham or ham steak**?

- NEVER (GO TO QUESTION 83)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

82a. Each time you ate **baked ham or ham steak**, how much did you usually eat?

- Less than 1 ounce
- 1 to 3 ounces
- More than 3 ounces

83. How often did you eat **pork** (including chops, roasts, and in mixed dishes)? *(Please do not include ham, ham steak, or sausage.)*

- NEVER (GO TO QUESTION 84)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

83a. Each time you ate **pork**, how much did you usually eat?

- Less than 2 ounces or less than 1 chop
- 2 to 5 ounces or 1 chop
- More than 5 ounces or more than 1 chop

84. How often did you eat **gravy** on meat, chicken, potatoes, rice, etc.?

- NEVER (GO TO QUESTION 85)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

84a. Each time you ate **gravy** on meat, chicken, potatoes, or rice, etc., how much did you usually eat?

- Less than 1/8 cup
- 1/8 to 1/2 cup
- More than 1/2 cup

Question 85 appears on the next page.

Over the **past 12 months...**

85. How often did you eat **liver** (all kinds) or **liverwurst**?

- NEVER (GO TO QUESTION 86)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

85a. Each time you ate **liver** or **liverwurst**, how much did you usually eat?

- Less than 1 ounce
- 1 to 4 ounces
- More than 4 ounces

86. How often did you eat **bacon** (including low-fat)?

- NEVER (GO TO QUESTION 87)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

86a. Each time you ate **bacon**, how much did you usually eat?

- Fewer than 2 slices
- 2 to 3 slices
- More than 3 slices

86b. How often was the bacon you ate **light, low-fat, or lean bacon**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

87. How often did you eat **sausage** (including low-fat)?

- NEVER (GO TO QUESTION 88)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

87a. Each time you ate **sausage**, how much did you usually eat?

- Less than 1 patty or 2 links
- 1 to 3 patties or 2 to 5 links
- More than 3 patties or 5 links

87b. How often was the sausage you ate **light, low-fat, or lean sausage**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

88. How often did you eat **fish sticks** or **fried fish** (including fried seafood or shellfish)?

- NEVER (GO TO QUESTION 89)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

88a. Each time you ate **fish sticks** or **fried fish**, how much did you usually eat?

- Less than 2 ounces or less than 1 fillet
- 2 to 7 ounces or 1 fillet
- More than 7 ounces or more than 1 fillet

89. How often did you eat **fish or seafood that was NOT FRIED** (including shellfish)?

- NEVER (GO TO THE INTRODUCTION TO QUESTION 90)
- 1–6 times per year       2 times per week
- 7–11 times per year     3–4 times per week
- 1 time per month         5–6 times per week
- 2–3 times per month     1 time per day
- 1 time per week          2 or more times per day

89a. Each time you ate **fish or seafood that was not fried**, how much did you usually eat?

- Less than 2 ounces or less than 1 fillet
- 2 to 5 ounces or 1 fillet
- More than 5 ounces or more than 1 fillet



Question 88 appears in the next column.

Introduction to Question 90 appears on the next page.

Over the past 12 months...

Now think about all the meat, poultry, and fish you ate in the past 12 months and how they were prepared.

90. How often was oil, butter, margarine, or other fat used to **FRY, SAUTE, BASTE, OR MARINATE** any meat, poultry, or fish you ate? (Please do not include deep frying.)

- NEVER (GO TO QUESTION 91)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

90a. Which of the following fats were regularly used to prepare your meat, poultry, or fish? (Mark all that apply.)

- |   |  |
|---|--|
| <input type="radio"/> Margarine (including low-fat) | <input type="radio"/> Corn oil                         |
| <input type="radio"/> Butter (including low-fat)    | <input type="radio"/> Canola or rapeseed oil           |
| <input type="radio"/> Lard, fatback, or bacon fat   | <input type="radio"/> Oil spray, such as Pam or others |
| <input type="radio"/> Olive oil                     | <input type="radio"/> Other kinds of oils              |
|   | <input type="radio"/> None of the above                |

91. How often did you eat **tofu, soy burgers, or soy meat-substitutes**?

- NEVER (GO TO QUESTION 92)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

91a. Each time you ate **tofu, soy burgers, or soy meat-substitutes**, how much did you usually eat?

- Less than  $\frac{1}{4}$  cup or less than 2 ounces
- $\frac{1}{4}$  to  $\frac{1}{2}$  cup or 2 to 4 ounces
- More than  $\frac{1}{2}$  cup or more than 4 ounces



Question 92 appears in the next column.

92. Over the past 12 months, did you eat soups?

- NO (GO TO QUESTION 93)
- YES

92a. How often did you eat **soup DURING THE WINTER**?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per winter  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per winter | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

92b. How often did you eat **soup DURING THE REST OF THE YEAR**?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

92c. Each time you ate **soup**, how much did you usually eat?

- Less than 1 cup
- 1 to 2 cups
- More than 2 cups

92d. How often were the soups you ate **bean soups**?

- Almost never or never
- Almost  $\frac{1}{4}$  of the time
- Almost  $\frac{1}{2}$  of the time
- Almost  $\frac{3}{4}$  of the time
- Almost always or always

92e. How often were the soups you ate **cream soups** (including chowders)?

- Almost never or never
- Almost  $\frac{1}{4}$  of the time
- Almost  $\frac{1}{2}$  of the time
- Almost  $\frac{3}{4}$  of the time
- Almost always or always

Question 93 appears on the next page.

Over the past 12 months...

92f. How often were the soups you ate **tomato** or **vegetable soups**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

92g. How often were the soups you ate **broth soups** (including chicken) **with** or **without noodles** or **rice**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

93. How often did you eat **pizza**?

NEVER (GO TO QUESTION 94)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

93a. Each time you ate **pizza**, how much did you usually eat?

- Less than 1 slice or less than 1 mini pizza
- 1 to 3 slices or 1 mini pizza
- More than 3 slices or more than 1 mini pizza

93b. How often did you eat pizza with **pepperoni**, **sausage**, or **other meat**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

94. How often did you eat **crackers**?

NEVER (GO TO QUESTION 95)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

Question 95 appears in the next column.

94a. Each time you ate **crackers**, how many did you usually eat?

- Fewer than 4 crackers
- 4 to 10 crackers
- More than 10 crackers

95. How often did you eat **corn bread** or **corn muffins**?

NEVER (GO TO QUESTION 96)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

95a. Each time you ate **corn bread** or **corn muffins**, how much did you usually eat?

- Less than 1 piece or muffin
- 1 to 2 pieces or muffins
- More than 2 pieces or muffins

96. How often did you eat **biscuits**?

NEVER (GO TO QUESTION 97)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

96a. Each time you ate **biscuits**, how many did you usually eat?

- Fewer than 1 biscuit
- 1 to 2 biscuits
- More than 2 biscuits

97. How often did you eat **potato chips**, **tortilla chips**, or **corn chips** (including low-fat, fat-free, or low-salt)?

NEVER (GO TO QUESTION 98)

- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

Question 98 appears on the next page.

Over the past 12 months...

97a. Each time you ate **potato chips, tortilla chips, or corn chips**, how much did you usually eat?

- Fewer than 10 chips or less than 1 cup
- 10 to 25 chips or 1 to 2 cups
- More than 25 chips or more than 2 cups

97b. How often were the chips you ate **Wow chips** or other **chips** made with fat substitute (Olean or Olestra)?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

97c. How often were the chips you ate other **low-fat or fat-free chips**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

98. How often did you eat **popcorn** (including low-fat)?

- NEVER (GO TO QUESTION 99)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

98a. Each time you ate **popcorn**, how much did you usually eat?

- Less than 2 cups, popped
- 2 to 5 cups, popped
- More than 5 cups, popped

99. How often did you eat **pretzels**?

- NEVER (GO TO QUESTION 100)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 100 appears in the next column.

99a. Each time you ate **pretzels**, how many did you usually eat?

- Fewer than 5 average twists
- 5 to 20 average twists
- More than 20 average twists

100. How often did you eat **peanuts, walnuts, seeds, or other nuts**?

- NEVER (GO TO QUESTION 101)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

100a. Each time you ate **peanuts, walnuts, seeds, or other nuts**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1/2 cup
- More than 1/2 cup

101. How often did you eat **energy, high-protein, or breakfast bars** such as **Power Bars, Balance, Clif, or others**?

- NEVER (GO TO QUESTION 102)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

101a. Each time you ate **energy, high-protein, or breakfast bars**, how much did you usually eat?

- Less than 1 bar
- 1 bar
- More than 1 bar

102. How often did you eat **yogurt** (NOT including frozen yogurt)?

- NEVER (GO TO QUESTION 103)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 103 appears on the next page.

Over the past 12 months...

102a. Each time you ate **yogurt**, how much did you usually eat?

- Less than 1/2 cup or less than 1 container
- 1/2 to 1 cup or 1 container
- More than 1 cup or more than 1 container

103. How often did you eat **cottage cheese** (including low-fat)?

- NEVER (GO TO QUESTION 104)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

103a. Each time you ate **cottage cheese**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1 cup
- More than 1 cup

104. How often did you eat **cheese** (including low-fat; including on cheeseburgers or in sandwiches or subs)?

- NEVER (GO TO QUESTION 105)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

104a. Each time you ate **cheese**, how much did you usually eat?

- Less than 1/2 ounce or less than 1 slice
- 1/2 to 1 1/2 ounces or 1 slice
- More than 1 1/2 ounces or more than 1 slice

104b. How often was the cheese you ate **light** or **low-fat cheese**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

104c. How often was the **cheese** you ate **fat-free cheese**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

105. How often did you eat **frozen yogurt, sorbet, or ices** (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 106)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

105a. Each time you ate **frozen yogurt, sorbet, or ices**, how much did you usually eat?

- Less than 1/2 cup or less than 1 scoop
- 1/2 to 1 cup or 1 to 2 scoops
- More than 1 cup or more than 2 scoops

106. How often did you eat **ice cream, ice cream bars, or sherbet** (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 107)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

106a. Each time you ate **ice cream, ice cream bars, or sherbet**, how much did you usually eat?

- Less than 1/2 cup or less than 1 scoop
- 1/2 to 1 1/2 cups or 1 to 2 scoops
- More than 1 1/2 cups or more than 2 scoops

106b. How often was the ice cream you ate **light, low-fat, or fat-free ice cream or sherbet**?

- Almost never or never
- Almost 1/4 of the time
- Almost 1/2 of the time
- Almost 3/4 of the time
- Almost always or always

Question 105 appears in the next column.

Question 107 appears on the next page.

Over the past 12 months...

107. How often did you eat **cake** (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 108)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

107a. Each time you ate **cake**, how much did you usually eat?

- Less than 1 medium piece  
 1 medium piece  
 More than 1 medium piece

107b. How often was the cake you ate **light, low-fat, or fat-free cake**?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

108. How often did you eat **cookies or brownies** (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 109)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

108a. Each time you ate **cookies or brownies**, how much did you usually eat?

- Less than 2 cookies or 1 small brownie  
 2 to 4 cookies or 1 medium brownie  
 More than 4 cookies or 1 large brownie

108b. How often were the cookies or brownies you ate **light, low-fat, or fat-free cookies or brownies**?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

Question 109 appears in the next column.

109. How often did you eat **doughnuts, sweet rolls, Danish, or pop-tarts**?

- NEVER (GO TO QUESTION 110)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

109a. Each time you ate **doughnuts, sweet rolls, Danish, or pop-tarts**, how much did you usually eat?

- Less than 1 piece  
 1 to 2 pieces  
 More than 2 pieces

110. How often did you eat **sweet muffins or dessert breads** (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 111)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

110a. Each time you ate **sweet muffins or dessert breads**, how much did you usually eat?

- Less than 1 medium piece  
 1 medium piece  
 More than 1 medium piece

110b. How often were the sweet muffins or dessert breads you ate **light, low-fat, or fat-free sweet muffins or dessert breads**?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

111. How often did you eat **fruit crisp, cobbler, or strudel**?

- NEVER (GO TO QUESTION 112)
- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

Question 112 appears on the next page.

Over the past 12 months...

111a. Each time you ate **fruit crisp, cobbler, or strudel** how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

112. How often did you eat **pie**?

- NEVER (GO TO QUESTION 113)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

112a. Each time you ate **pie**, how much did you usually eat?

- Less than 1/8 of a pie
- About 1/8 of a pie
- More than 1/8 of a pie

The next four questions ask about the kinds of pie you ate. Please read all four questions before answering.

112b. How often were the pies you ate **fruit pie** (such as apple, blueberry, others)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

112c. How often were the pies you ate **cream, pudding, custard, or meringue pie**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

112d. How often were the pies you ate **pumpkin or sweet potato pie**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

112e. How often were the pies you ate **pecan pie**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

113. How often did you eat **chocolate candy**?

- NEVER (GO TO QUESTION 114)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

113a. Each time you ate **chocolate candy**, how much did you usually eat?

- Less than 1 average bar or less than 1 ounce
- 1 average bar or 1 to 2 ounces
- More than 1 average bar or more than 2 ounces

114. How often did you eat **other candy**?

- NEVER (GO TO QUESTION 115)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

114a. Each time you ate **other candy**, how much did you usually eat?

- Fewer than 2 pieces
- 2 to 9 pieces
- More than 9 pieces

115. How often did you eat **eggs, egg whites, or egg substitutes** (NOT counting eggs in baked goods and desserts)? (Please include eggs in salads, quiche, and souffles.)

- NEVER (GO TO QUESTION 116)
- 1–6 times per year
- 7–11 times per year
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

Question 113 appears in the next column.

Question 116 appears on the next page.

Over the past 12 months...

115a. Each time you ate **eggs**, how many did you usually eat?

- 1 egg
- 2 eggs
- 3 or more eggs

115b. How often were the eggs you ate **egg substitutes**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115c. How often were the eggs you ate **egg whites only**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115d. How often were the eggs you ate **regular whole eggs**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115e. How often were the eggs you ate **cooked in oil, butter, or margarine**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115f. How often were the eggs you ate part of **egg salad**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Question 116 appears in the next column.

116. How many cups of **coffee**, caffeinated or decaffeinated, did you drink?

- NONE (GO TO QUESTION 117)
- Less than 1 cup per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6 or more cups per day

116a. How often was the coffee you drank **decaffeinated**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

117. How many glasses of **ICED tea**, caffeinated or decaffeinated, did you drink?

- NONE (GO TO QUESTION 118)
- Less than 1 cup per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6 or more cups per day

117a. How often was the iced tea you drank **decaffeinated or herbal tea**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

118. How many cups of **HOT tea**, caffeinated or decaffeinated, did you drink?

- NONE (GO TO QUESTION 119)
- Less than 1 cup per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6 or more cups per day

118a. How often was the hot tea you drank **decaffeinated or herbal tea**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 119 appears on the next page.

Over the past 12 months...

119. How often did you add **sugar** or **honey** to your coffee or tea?

- NEVER (GO TO QUESTION 120)
- Less than 1 time per month
- 1–3 times per month
- 1 time per week
- 2–4 times per week
- 5–6 times per week
- 1 time per day
- 2–3 times per day
- 4–5 times per day
- 6 or more times per day

119a. Each time **sugar** or **honey** was added to your coffee or tea, how much was usually added?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

120. How often did you add **artificial sweetener** to your coffee or tea?

- NEVER (GO TO QUESTION 121)
- Less than 1 time per month
- 1–3 times per month
- 1 time per week
- 2–4 times per week
- 5–6 times per week
- 1 time per day
- 2–3 times per day
- 4–5 times per day
- 6 or more times per day

120a. What kind of **artificial sweetener** do you usually use?

- Equal or aspartame
- Sweet N Low or saccharin

121. How often was **non-dairy creamer** added to your coffee or tea?

- NEVER (GO TO QUESTION 122)
- Less than 1 time per month
- 1–3 times per month
- 1 time per week
- 2–4 times per week
- 5–6 times per week
- 1 time per day
- 2–3 times per day
- 4–5 times per day
- 6 or more times per day

121a. Each time **non-dairy creamer** was added to your coffee or tea, how much was usually used?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

Question 122 appears in the next column.

121b. What kind of **non-dairy creamer** did you usually use?

- Regular powdered
- Low-fat or fat-free powdered
- Regular liquid
- Low-fat or fat-free liquid

122. How often was **cream** or **half and half** added to your coffee or tea?

- NEVER (GO TO QUESTION 123)
- Less than 1 time per month
- 1–3 times per month
- 1 time per week
- 2–4 times per week
- 5–6 times per week
- 1 time per day
- 2–3 times per day
- 4–5 times per day
- 6 or more times per day

122a. Each time **cream** or **half and half** was added to your coffee or tea, how much was usually added?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons

123. How often was **milk** added to your coffee or tea?

- NEVER (GO TO QUESTION 124)
- Less than 1 time per month
- 1–3 times per month
- 1 time per week
- 2–4 times per week
- 5–6 times per week
- 1 time per day
- 2–3 times per day
- 4–5 times per day
- 6 or more times per day

123a. Each time **milk** was added to your coffee or tea, how much was usually added?

- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

123b. What kind of **milk** was usually added to your coffee or tea?

- Whole milk
- 2% milk
- 1% milk
- Skim, nonfat, or 1/2% milk
- Evaporated or condensed (canned) milk
- Soy milk
- Rice milk
- Other

Question 124 appears on the next page.

Over the past 12 months...

124. How often was **sugar** or **honey** added to foods you ate? (Please do not include sugar in coffee, tea, other beverages, or baked goods.)

NEVER (GO TO INTRODUCTION TO QUESTION 125)

- |   |   |
|---|---|
| <input type="radio"/> 1–6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7–11 times per year | <input type="radio"/> 3–4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5–6 times per week      |
| <input type="radio"/> 2–3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

124a. Each time **sugar** or **honey** was added to foods you ate, how much was usually added?

- Less than 1 teaspoon  
 1 to 3 teaspoons  
 More than 3 teaspoons

The following questions are about the kinds of margarine, mayonnaise, sour cream, cream cheese, and salad dressing that you eat. If possible, please check the labels of these foods to help you answer.

125. Over the past 12 months, did you eat **margarine**?

NO (GO TO QUESTION 126)

YES

125a. How often was the margarine you ate **regular-fat margarine** (stick or tub)?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

125b. How often was the margarine you ate **light or low-fat margarine** (stick or tub)?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always



Question 126 appears in the next column.

125c. How often was the margarine you ate **fat-free margarine**?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

126. Over the past 12 months, did you eat **butter**?

NO (GO TO QUESTION 127)

YES

126a. How often was the butter you ate **light or low-fat butter**?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

127. Over the past 12 months, did you eat **mayonnaise** or **mayonnaise-type dressing**?

NO (GO TO QUESTION 128)

YES

127a. How often was the mayonnaise you ate **regular-fat mayonnaise**?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

127b. How often was the mayonnaise you ate **light or low-fat mayonnaise**?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always



Question 128 appears on the next page.

Over the past 12 months...

127c. How often was the mayonnaise you ate **fat-free mayonnaise**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

128. Over the past 12 months, did you eat **sour cream**?

NO (GO TO QUESTION 129)

YES

128a. How often was the sour cream you ate **regular-fat sour cream**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

128b. How often was the sour cream you ate **light, low-fat, or fat-free sour cream**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

129. Over the past 12 months, did you eat **cream cheese**?

NO (GO TO QUESTION 130)

YES

129a. How often was the cream cheese you ate **regular-fat cream cheese**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

129b. How often was the cream cheese you ate **light, low-fat, or fat-free cream cheese**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

130. Over the past 12 months, did you eat **salad dressing**?

NO (GO TO INTRODUCTION TO QUESTION 131)

YES

130a. How often was the salad dressing you ate **regular-fat salad dressing** (including oil and vinegar dressing)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

130b. How often was the salad dressing you ate **light or low-fat salad dressing**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

130c. How often was the salad dressing you ate **fat-free salad dressing**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

The following two questions ask you to summarize your usual intake of vegetables and fruits. Please do not include salads, potatoes, or juices.

131. Over the past 12 months, how many servings of **vegetables** (not including salad or potatoes) did you eat per week or per day?

- |  |   |
|--|---|
| <input type="radio"/> Less than 1 per week | <input type="radio"/> 2 per day         |
| <input type="radio"/> 1-2 per week         | <input type="radio"/> 3 per day         |
| <input type="radio"/> 3-4 per week         | <input type="radio"/> 4 per day         |
| <input type="radio"/> 5-6 per week         | <input type="radio"/> 5 or more per day |
| <input type="radio"/> 1 per day            |   |

Question 130 appears in the next column.

Over the past 12 months...

132. Over the past 12 months, how many servings of **fruit** (not including juices) did you eat per week or per day?

- Less than 1 per week
- 1–2 per week
- 3–4 per week
- 5–6 per week
- 1 per day
- 2 per day
- 3 per day
- 4 per day
- 5 or more per day

133. Over the past month, which of the following foods did you eat **AT LEAST THREE TIMES**? (*Mark as many as apply.*)

- Avocado, guacamole
- Cheesecake
- Chocolate, fudge, or butterscotch toppings or syrups
- Chow mein noodles
- Croissants
- Dried apricots
- Egg rolls
- Granola bars
- Hot peppers
- Jello, gelatin
- Milkshakes or ice-cream sodas
- Olives
- Oysters
- Pickles or pickled vegetables or fruit
- Plantains
- Pork neckbones, hock, head, feet
- Pudding or custard
- Veal, venison, lamb
- Whipped cream, regular
- Whipped cream, substitute
- NONE

134. For **ALL** of the past 12 months, have you followed any type of **vegetarian diet**?

- NO (GO TO INTRODUCTION TO QUESTION 135)
- YES

134a. Which of the following foods did you **TOTALLY EXCLUDE** from your diet? (*Mark all that apply.*)

- Meat (beef, pork, lamb, etc.)
- Poultry (chicken, turkey, duck)
- Fish and seafood
- Eggs
- Dairy products (milk, cheese, etc.)



Introduction to Question 135 appears in the next column.

The next questions are about your use of fiber supplements or vitamin pills.

135. Over the past 12 months, did you take any of the following types of **fiber or fiber supplements** on a regular basis (more than once per week for at least 6 of the last 12 months)? (*Mark all that apply.*)

- NO, didn't take any fiber supplements on a regular basis (GO TO QUESTION 136)
- YES, psyllium products (such as Metamucil, Fiberall, Serutan, Perdiem, Correctol)
- YES, methylcellulose/cellulose products (such as Citrucel, Unifiber)
- YES, Fibercon
- YES, Bran (such as wheat bran, oat bran, or bran wafers)

136. Over the past 12 months, did you take any **multivitamins**, such as One-a-Day-, Theragran-, or Centrum-type multivitamins (as pills, liquids, or packets)?

- NO (GO TO INTRODUCTION TO QUESTION 138)
- YES

137. How often did you take **One-a-day-, Theragran-, or Centrum-type** multivitamins?

- Less than 1 day per month
- 1–3 days per month
- 1–3 days per week
- 4–6 days per week
- Every day

137a. Does your **multivitamin** usually contain **minerals** (such as iron, zinc, etc.)?

- NO
- YES
- Don't know

137b. For how many years have you taken **multivitamins**?

- Less than 1 year
- 1–4 years
- 5–9 years
- 10 or more years



Introduction to Question 138 appears on the next page.

Over the past 12 months...

137c. Over the past 12 months, did you take any vitamins, minerals, or other herbal supplements other than your multivitamin?

- NO (GO TO QUESTION 143.)
- YES (GO TO INTRODUCTION TO QUESTION 138.)

These last questions are about the vitamins, minerals, or herbal supplements you took that are **NOT** part of a One-a-day-, Theragran-, or Centrum-type of multivitamin.

Please include vitamins taken as part of an antioxidant supplement.

138. How often did you take **Beta-carotene** (NOT as part of a multivitamin in Question 137)?

- NEVER (GO TO QUESTION 139)
- Less than 1 day per month
- 1–3 days per month
- 1–3 days per week
- 4–6 days per week
- Every day

138a. When you took Beta-carotene, about how much did you take in one day?

- Less than 10,000 IU
- 10,000–14,999 IU
- 15,000–19,999 IU
- 20,000–24,999 IU
- 25,000 IU or more
- Don't know

138b. For how many years have you taken **Beta-carotene**?

- Less than 1 year
- 1–4 years
- 5–9 years
- 10 or more years

Question 139 appears in the next column.

139. How often did you take **Vitamin A** (NOT as part of a multivitamin in Question 137)?

- NEVER (GO TO QUESTION 140)
- Less than 1 day per month
- 1–3 days per month
- 1–3 days per week
- 4–6 days per week
- Every day

139a. When you took **Vitamin A**, about how much did you take in one day?

- Less than 8,000 IU
- 8,000–9,999 IU
- 10,000–14,999 IU
- 15,000–24,999 IU
- 25,000 IU or more
- Don't know

139b. For how many years have you taken **Vitamin A**?

- Less than 1 year
- 1–4 years
- 5–9 years
- 10 or more years

140. How often did you take **Vitamin C** (NOT as part of a multivitamin in Question 137)?

- NEVER (GO TO QUESTION 141)
- Less than 1 day per month
- 1–3 days per month
- 1–3 days per week
- 4–6 days per week
- Every day

140a. When you took **Vitamin C**, about how much did you take in one day?

- Less than 500 mg
- 500–999 mg
- 1,000–1,499 mg
- 1,500–1,999 mg
- 2,000 mg or more
- Don't know

140b. For how many years have you taken **Vitamin C**?

- Less than 1 year
- 1–4 years
- 5–9 years
- 10 or more years

Question 141 appears on the next page.

Over the past 12 months...

141. How often did you take **Vitamin E** (NOT as part of a multivitamin in Question 137)?

- NEVER (GO TO QUESTION 142)
- Less than 1 day per month
- 1–3 days per month
- 1–3 days per week
- 4–6 days per week
- Every day

141a. When you took **Vitamin E**, about how much did you take in one day?

- Less than 400 IU
- 400–799 IU
- 800–999 IU
- 1,000 IU or more
- Don't know

141b. For how many years have you taken **Vitamin E**?

- Less than 1 year
- 1–4 years
- 5–9 years
- 10 or more years

Question 142 appears in the next column.

142. How often did you take **Calcium** or **Calcium-containing antacids** (NOT as part of a multivitamin in Question 137)?

- NEVER (GO TO QUESTION 143)
- Less than 1 day per month
- 1–3 days per month
- 1–3 days per week
- 4–6 days per week
- Every day

142a. When you took **Calcium** or **Calcium-containing antacids**, about how much elemental calcium did you take in one day? (If possible, please check the label for elemental calcium.)

- Less than 500 mg
- 500–599 mg
- 600–999 mg
- 1,000 mg or more
- Don't know

142b. For how many years have you taken **Calcium** or **Calcium-containing antacids**?

- Less than 1 year
- 1–4 years
- 5–9 years
- 10 or more years

Question 143 appears below.

143. In the grid below, **FIRST**, mark the number of years you have taken each of the following botanical or herbal supplements **AT LEAST 25 TIMES**. Mark **NEVER** for each botanical or herbal supplement that you did not take at least 25 times in a single year, and then go on to the next supplement. **SECOND**, to the right, mark the approximate number of months during each year that you took the supplement.

	NUMBER OF YEARS SUPPLEMENT TAKEN AT LEAST 25 TIMES				NUMBER OF MONTHS DURING EACH YEAR YOU TOOK THE SUPPLEMENT		
	NEVER	1–2 YEARS	3–4 YEARS	5+ YEARS	1–3	4–6	7–12
					MONTHS/YEAR	MONTHS/YEAR	MONTHS/YEAR
Aloe (tablets/pills)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Echinacea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Garlic (tablets/pills)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ginko	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ginseng (American or Asian)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Goldenseal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Saw palmetto	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
St. John's wort	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The next two questions ask you about other supplements you took more than once per week.

Over the past 12 months...

144. Please mark any of the following **single supplements** you took more than once per week (NOT as part of a multivitamin in Question 137):

- |                                      |   |
|--------------------------------------|---|
| <input type="radio"/> B-6            | <input type="radio"/> Folic acid/folate       |
| <input type="radio"/> B-complex      | <input type="radio"/> Glucosamine             |
| <input type="radio"/> Brewer's yeast | <input type="radio"/> Hydroxytryptophan (HTP) |
| <input type="radio"/> Cod liver oil  | <input type="radio"/> Iron                    |
| <input type="radio"/> Coenzyme Q     | <input type="radio"/> Niacin                  |
| <input type="radio"/> Fish oil       | <input type="radio"/> Selenium                |
| (Omega-3 fatty acids)                | <input type="radio"/> Zinc                    |

145. Please mark any of the following **herbal or botanical supplements** you took more than once per week.

- |  |   |
|--|---|
| <input type="radio"/> Astragalus           | <input type="radio"/> Feverfew          |
| <input type="radio"/> Bilberry             | <input type="radio"/> Ginger            |
| <input type="radio"/> Cascara sagrada      | <input type="radio"/> Grapeseed extract |
| <input type="radio"/> Cat's claw           | <input type="radio"/> Kava, kava        |
| <input type="radio"/> Cayenne              | <input type="radio"/> Milk thistle      |
| <input type="radio"/> Cranberry            | <input type="radio"/> Siberian ginseng  |
| <input type="radio"/> Dong Kuai (Tangkwei) | <input type="radio"/> Valerian          |
| <input type="radio"/> Evening primrose oil | <input type="radio"/> Other             |

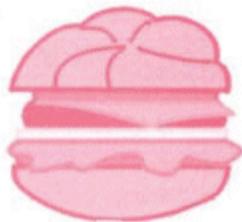
The next questions ask about how you cook your meat, fish, or poultry. Over the past 12 months...

146. When you ate **steak**, what was the most common way it was cooked?

- NEVER ATE STEAK (GO TO QUESTION 147)
- Pan-fried  
 Oven-broiled  
 Grilled or barbecued  
 Don't know

146a. What was the second most common way it was cooked?

- Pan-fried  
 Oven-broiled  
 Grilled or barbecued  
 Don't know



Question 147 appears in the next column.

146b. Which of the following best describes how you like your steak cooked?

- Rare  
 Medium rare  
 Medium  
 Medium well done  
 Well done  
 Very well done  
 Don't know

147. When you ate **hamburger or cheeseburger patties**, how often did you get them from fast food restaurants?

- NEVER ATE HAMBURGER OR CHEESEBURGER PATTIES (GO TO QUESTION 148)
- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Always or almost always

147a. Not including from fast food restaurants, when you ate **hamburger or cheeseburger patties**, what was the most common way they were cooked?

- Pan-fried  
 Oven-broiled  
 Grilled or barbecued  
 Don't know

147b. What was the second most common way they were cooked?

- Pan-fried  
 Oven-broiled  
 Grilled or barbecued  
 Don't know

147c. Which of the following best describes how you like your **hamburger or cheeseburger patties** cooked?

- Rare  
 Medium rare  
 Medium  
 Medium well done  
 Well done  
 Very well done  
 Don't know

Question 148 appears in the next column.

Over the past 12 months...

148. When you ate **chicken**, what was the most common way it was cooked?

NEVER ATE CHICKEN (GO TO QUESTION 149)

- Breaded and fried
- Pan-fried
- Roasted or baked
- Grilled or barbecued
- Oven-broiled
- Stewed or boiled
- Don't know

148a. When you ate **chicken**, what was the second most common way it was cooked?

- Breaded and fried
- Pan-fried
- Roasted or baked
- Grilled or barbecued
- Oven-broiled
- Stewed or boiled
- Don't know

148b. Which of the following best describes how you like your **chicken** cooked?

- Well done
- Very well done

149. When you ate **pork roast** or **chops**, what was the most common way it was cooked?

NEVER ATE PORK ROAST OR CHOPS

- Baked
- Grilled or barbecued
- Breaded and fried
- Pan-fried (unbreaded)
- Oven-broiled
- Don't know

150. Which of the following best describes how you like your **bacon** cooked?

NEVER EAT BACON

- Just until done
- Well done or crisp
- Well done or charred
- Don't know

151. Which of the following best describes how you like your **sausage** cooked?

- NEVER EAT SAUSAGE
- Just until done
- Well done or crisp
- Very well done or charred
- Don't know

152. During the summer, how often did you eat meat, fish, or poultry that was **grilled** or **barbecued** over coals, an open fire, or ceramic briquettes?

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

153. During the rest of the year, how often did you eat meat, fish, or poultry that was **grilled** or **barbecued** over coals, an open fire, or ceramic briquettes?

- NEVER
- 1–6 times per season
- 7–11 times per season
- 1 time per month
- 2–3 times per month
- 1 time per week
- 2 times per week
- 3–4 times per week
- 5–6 times per week
- 1 time per day
- 2 or more times per day

154. When you ate grilled or barbecued meat, fish, or poultry, how often was it **charred** on the surface?

- NEVER ATE MEAT, FISH, OR POULTRY
- Almost never or never
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

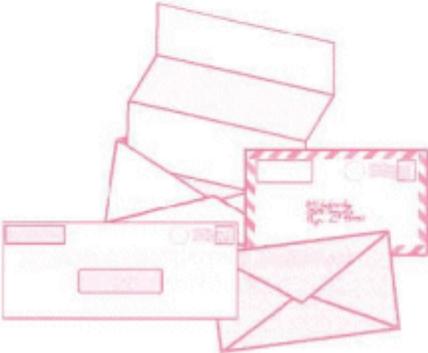
155. When you ate pan-fried or oven-broiled meat, how often was it **well-browned** on the surface?

- NEVER ATE MEAT
- Almost never or never
- About  $\frac{1}{4}$  of the time
- About  $\frac{1}{2}$  of the time
- About  $\frac{3}{4}$  of the time
- Almost always or always

156. When you were the ages described below, how many drinks per day, week, or month did you have? First, we ask about beer, then wine, then liquor, including liquor in mixed drinks. (Count sherry and wine coolers as wine; count brandy as liquor.) For those ages when you did not consume beer or wine or liquor, please mark NEVER for the specific beverage. When you are finished with this section, there should be one response in each line.

	NEVER	1 drink per month or fewer	2-3 drinks per month	1-2 drinks per week	3-4 drinks per week	5-6 drinks per week	1 drink per day	2-3 drinks per day	4-5 drinks per day	6 or more drinks per day
<b>18-24 years of age</b>										
12 ounce bottle or can of <b>beer</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5 ounce glass of <b>wine</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1.5 ounce shot of <b>liquor</b> (including mixed drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>25-39 years of age</b>										
12 ounce bottle or can of <b>beer</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5 ounce glass of <b>wine</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1.5 ounce shot of <b>liquor</b> (including mixed drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>40-54 years of age</b>										
12 ounce bottle or can of <b>beer</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5 ounce glass of <b>wine</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1.5 ounce shot of <b>liquor</b> (including mixed drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>55 years of age or older</b>										
12 ounce bottle or can of <b>beer</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5 ounce glass of <b>wine</b>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1.5 ounce shot of <b>liquor</b> (including mixed drinks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Thank you very much for completing this questionnaire.  
Please return it in the self-addressed postage-paid envelope.**



NATIONAL INSTITUTES OF HEALTH  
Washington, DC



## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE DIET HISTORY QUESTIONNAIRE (DHQ)

The DHQ should be given to control participants during their Baseline (T0) activity window and to intervention participants during their T3 activity window. Because the DHQ is a self-administered form, the participant can complete this form at home or at the screening center. Each center should provide their participants with a stamped envelope addressed to the screening center for return of the completed questionnaire. If the participant has difficulty in the completion of the form, this questionnaire, or selected items on this questionnaire, may also be administered as an interview (either in-person or by telephone) at the discretion of the screening center coordinator.

The specifications include guidelines for the completion of each type of question within the DHQ. It is strongly urged that this form be completed using a number two pencil. However, if a DHQ is received that has been completed with either blue or black ink, there is no need to recode the questionnaire. Guidelines are also provided for SC staff on editing and data retrieval, as appropriate. A manual review of each form to identify missing critical data items (identified below) should be performed before shipping forms to NCS for scanning. Further information regarding the receipt, editing, completion, and shipping of the DHQ may be found in MOOP chapter 6.

Note: Since the DHQ does not have a forms processing box, attempted data retrieval should be noted either in the pink box on the cover of the form or next to the actual data item. All notes should be made in red pen or pencil and initialed and dated. Notes should not be made near the skunk marks or data bubbles.

Specifications for completing the form are given below:

#### Cover Page:

- **Participant ID:** Affix a Participant ID label to the space provided in the lower right corner of the form. The bar code portion of the label should be closest to the spine of the form. This is a critical item. A form should not be sent for processing without a PID label.
- **Today's date:** Participant should enter the month, day, and year that they complete this questionnaire. For example, if the participant is completing this questionnaire on January 15, 1999, the bubble for "JAN" should be darkened; "01" should be written in the boxes and the bubbles darkened; and the bubble for "1999" should also be darkened. If the participant returns the form without a completion date, it can be estimated as the date the form was received at the SC. When this date is entered into SMS, a flag should be entered to identify forms with an estimated completion date. This is a critical item. A form should not be sent for processing without a completion date.
- **In what month were you born?:** Participant should darken the bubble for their month of birth. This is a critical item—data retrieval is required. A form should not be sent for processing without a month of birth.
- **In what year were you born?:** Participant should write the last two digits of their birth year into the boxes and darken the appropriate bubbles. This is a critical item—date retrieval is required. A form should not be sent for processing without a year of birth.

- **Are you male or female?:** Participant should darken the circle next to their gender. This is a critical item—data retrieval is required. A form should not be sent for processing without gender.

**Questions 1-134, Usual eating habits over the past year:** Questions 1-134 ask the participant to recall their eating patterns over the past 12 months. The majority of the questions ask an introductory question for a type of food. If the participant answers NEVER, they should skip to the next item. If they do eat the food in question, they should answer the frequency and portion size questions that follow. For a few items the participants are asked to estimate their consumption by season, i.e. "In the summer how often did you..."

*Data retrieval, i.e., re-interview by SC staff to ascertain responses to missing items, is only suggested if more than 10 items in a row (that require completion) are blank, or if an entire page has been overlooked.*

**Questions 135-145, Vitamins and Other Supplements:** Questions 135-145 ask the participant to recall the types of vitamins or other supplements they have taken over the past 12 months. The majority of the questions ask an introductory question for a specific supplement. If the participant answers NEVER, they should skip to the next item. If they do use the supplement in question, they should answer the frequency and dosage questions that follow. If the participant answers question 137c ("Over the past 12 months, did you take any vitamins, minerals, or other herbal supplements other than your multivitamin?") as NO, they should skip to question 143.

*Question 143, Botanical and Herbal Supplements Table:* This table should be completed regardless of whether or not the participant marked NO for question 137c. For each row the participant should select the number of years they have taken that supplement AT LEAST 25 TIMES within a given year. If they select NEVER they should skip to the next row. If they did take the supplement, they should move to the right hand column and complete the number of months during each year that they took that supplement. Each row should have at least one and no more than 2 responses.

*Data retrieval, i.e., re-interview by SC staff to ascertain responses to missing items, is only suggested if more than 10 items in a row (that require completion) are blank, or if an entire page has been overlooked.*

**Questions 146-155, Food Preparation:** These questions ask the participant about how they cook their meat, fish, or poultry. For the majority of the questions, the preparation methods are listed and the participant is asked which was the most common method they used for the food in question. Next, they are asked what was the second most common method.

*Data retrieval, i.e., re-interview by SC staff to ascertain responses to missing items, is only suggested if more than 10 items in a row (that require completion) are blank, or if an entire page has been overlooked.*

**Question 156, Alcohol Consumption:** This chart asks the participant to answer questions about their alcohol consumption during four stages of their life: 18-24 years of age, 25-39 year of age, 40-54 years of age, and 55 years of age or older. Within each of these age ranges they are asked how many drinks of beer, wine, or hard liquor they had. One drink is defined as a 12-ounce bottle of beer, a 5-ounce glass of wine, and a 1.5-ounce shot of liquor (including mixed drinks). They are asked to include sherry and wine coolers in the wine category and to count brandy as hard liquor. If they answer NEVER, they should move on to the next row. When

the participant is finished, each row should have one (and not more than one) response.

*Data retrieval, i.e., re-interview by SC staff to ascertain responses to missing items, is only suggested if more than 10 items in a row (that require completion) are blank, or if an entire page has been overlooked.*

**A-6-4**

A-6-4: DHQ/DQX

Shipment Notification Fax, Combined

# PLCO DHQ Shipment Notification FAX

## For NCS AND WESTAT

Please send this fax to both NCS and Westat

NCS: Data Prep.: Fax: 651-683-6221

Sherry Hayes: Phone: 651-683-6294

Date: \_\_\_\_\_

WESTAT: Beth Bridgeman: 301-294-2085

From: \_\_\_\_\_

Screening Center: \_\_\_\_\_

Telephone: \_\_\_\_\_

### Shipment Information:

Form Type	Shipment this month?	Ship Date	Number of Batches	Number of Forms	Shipment Method (UPS, FedEx, etc.)
<input type="checkbox"/> DHQ	<input type="checkbox"/> No <input type="checkbox"/> Yes <span style="font-size: 2em;">→</span>	____/____/____			

### List Batch Numbers:


TOTAL NUMBER OF BOXES SENT \_\_\_\_\_

### FOR NCS/WESTAT USE ONLY:

Date Shipment Received from SC/NCS: \_\_\_\_\_

Number of Boxes Received: \_\_\_\_\_

Number of Batches Received: \_\_\_\_\_ (To indicate which batches were received, place a check mark next to the batch number above.)

**A-6-6**

A-6-6: NCS Discrepancy Notification Fax

# NCS Discrepancy Notification

To: \_\_\_\_\_ (Screening Center Coordinator)

FAX: \_\_\_\_\_ Date: \_\_\_\_\_

From: Ardell Anderson, Pearson NCS

Phone: 320-289-2142

This FAX is to notify you of a discrepancy found in your dietary questionnaire shipment. The following discrepancy needs your investigation:

**No Shipment Was Received:** Your Shipment Notification Fax noted that your shipment was sent on \_\_\_\_\_ but NCS has not received any boxes.

**Missing Box(es):** Your Shipment Notification Fax noted \_\_\_\_\_ boxes, but NCS only received \_\_\_\_\_ boxes. The missing box(es) appears to be number \_\_\_\_\_ of \_\_\_\_\_.

**Missing Batch(es):** Your Shipment Notification Fax noted batches that were not received at NCS. The missing batch number(s) are listed below:

---

---

---

**Shipment Received Late:** Your shipment was received on \_\_\_\_\_. This falls outside of the specified first 10 working days of the month. This FAX is to notify you that this batch will be held for processing until next month.

Please investigate the above mentioned discrepancy and call NCS with your findings. (If the discrepancy is a late shipment, there is no need for follow-up with NCS.)

cc: Beth Bridgeman, Westat, FAX: 301-610-5516

## **A-7-1**

A-7-1: Annual Study Update (ASU)

Specifications for the Annual Study Update

## Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

### ANNUAL STUDY UPDATE (ASU)

Participant ID: FIELD(9)

\*FIELD(11)\*

November 23, 1998

\*FIELD(12)\*

Participant Name: FIELD(10)

Study Year: FIELD(13)

**If Your Name (Printed Above) Is Incorrect, Please Record Your Corrected Name Below.**

Corrected Name: \_\_\_\_\_

1. In the period from FIELD(14) to the present, have you been diagnosed with cancer by a health care provider? (Do not include basal-cell or squamous-cell skin cancers.)
- Yes [ ]  
No [ ]
- (If no, men go to item 3; women go to item 4)

2. What type of cancer was diagnosed? (Please record all cancers diagnosed during this period except basal-cell and squamous-cell skin cancers.)

Type/Site of Cancer (breast, lung, etc)	Date of Diagnosis	Hospital or clinic where the cancer was diagnosed
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____

**What is the name, phone number and address of the physician who diagnosed the most recent cancer?**

Name: \_\_\_\_\_ Phone: (\_\_\_\_) \_\_\_\_\_

Address: \_\_\_\_\_

3. FOR MEN ONLY: In the period from FIELD(15) to the present, have you taken the medication Proscar or Propecia (Finasteride)?
- Yes [ ] No [ ]

4. Today's Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
- Month    Day    Year

5. Who completed this questionnaire? (Please check one)

[ ] Study Participant    [ ] Spouse    [ ] Someone else (SPECIFY) \_\_\_\_\_

Relationship

6. Comments:
- \_\_\_\_\_
- \_\_\_\_\_

**Thank you for completing this questionnaire. Please return this form in the enclosed envelope**

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Branch Office, 6705 Rockledge Drive, MSC 7974 Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE ANNUAL STUDY UPDATE (ASU)**

The ASU is to be completed annually by all participants, both intervention and control, for each year of follow-up starting with T1. This form was previously called the Periodic Survey of Health (PSH). In situations where the participant is unable to complete the form, the form may be completed for the participant by someone else such as a spouse, other family member, or friend. The form may be self-administered or administered by an SC staff member.

The ASU may be generated in two ways: (1) through the SMS, using Paradox; or (2) through Word using a merge file produced by the SMS. Please refer to the documentation accompanying SMS upgrades 5.2 for information regarding generation of the ASU through Word. Refer to the documentation accompanying SMS upgrade 2.04 for information regarding generation of the ASU through Paradox.

The reporting window for completion of this form is from 1 month prior to 1 month past the participant's randomization anniversary date. The delinquency period is from 1 month past to 3 months past the randomization anniversary date (see Chapter 7 in the PLCO Manual of Operations and Procedures).

An asterisk (\*) in these specifications indicates a critical data item that NCI has determined is critical for analysis. The SC should perform data retrieval on all critical data items.

The following items are pre-printed at the top of the form:

<b>Participant ID:</b>	This is the participant's ID number in eye-readable format.
<b>Participant ID - Barcode:</b>	This is the participant's ID number in barcode format.
<b>Participant Name:</b>	This is the participant's full name as recorded in the SMS.
<b>Report Date:</b>	This is the date the ASU was generated.
<b>Study Year:</b>	This is the study year (T1, T2, T3, etc.) for which the ASU was generated and the randomization group of the participant ("I" for intervention and "C" for control).

Specifications for completion of the form are given below.

**Corrected name:** If the participant name printed at the top of the form is incorrect, instruct the participant to record the corrected name in the space provided.

*SC Instructions: If the corrected name is significantly different from the pre-printed participant name (i.e., more than a simple typographical error), the SC should verify that the correct participant completed the questionnaire.*

1. **\*In the period from (date) to the present, have you been diagnosed with cancer by a healthcare provider?** (Do not include basal-cell or squamous-cell skin cancers.)

Instruct the participant to check "Yes" or "No" depending on whether or not s/he was diagnosed with cancer during this time period. This does not include self-diagnosed cancer. The participant must have been told by a healthcare provider (physician, nurse, etc.) that s/he has cancer.

*SC Instructions: On an actual ASU, the (date) will be the date the participant last completed a PSH/ASU for the PLCO study. The system will search for last year's PSH/ASU. If an MDF is found for that form, it will continue to search for the previ-*

ous year's PSH/ASU. If the previous PSH/ASU form is found in the system but the date of completion was not filled in, the current ASU will not be generated and the SC will receive a report indicating which ASUs could not be generated. The SC should enter a date of completion (either actual or estimated) for the previous PSH/ASU, and rerun the directive to generate the current ASU. For study year T1 and in cases where the participant has not completed any questionnaire for the study (i.e., Missing Data Forms are receipted for all prior questionnaires), the system will replace (date) with the participant's randomization date.

This question is a critical data item. If it is incomplete or not answered, data retrieval must be attempted. If data retrieval is successful, make any changes in a different color ink, and record your initials and the date of data retrieval in the white space next to the question. If data retrieval is unsuccessful, write "D.R. attempted," your initials, and the date of the data retrieval attempt in the white space next to the question.

2. **What type of cancer was diagnosed?** (Please record all cancers diagnosed during this period except basal-cell and squamous-cell skin cancers):

Instruct the participant to list each cancer that was diagnosed *during the period of time outlined in Question 1* (i.e., "from (date) to the present"). As noted in the question, basal-cell and squamous-cell skin cancers should not be recorded on the form since NCI is not interested in non-melanoma skin cancers. Also instruct the participant to complete the month, day, and year of the diagnosis and the hospital or clinic where the cancer was diagnosed.

*SC Instructions: A qualified abstractor should code the cancers using the Cancer Codes List in Appendix I. Enter the code(s) into the SMS during the receipt of the ASU.*

*The following guidelines also apply to the coding of cancers and data retrieval for the ASU:*

*If Q.1 = Yes and a cancer is listed in Q.2, code the cancer as it is specified.*

*Perform data retrieval in the following situations:*

*Q.1 = Yes and Q.2 is blank;*

*Q.1 = No and a cancer is listed in Q.2;*

*Q.1 is blank.*

*In cases where Q.1 = Yes, if the participant does not know the type of cancer, code Q.2 as "Don't Know" (998). If the participant cannot be contacted for data retrieval or cannot give a response for some other reason, code Q.2 as "Not Ascertained" (999).*

*If Q.1 = No and Q.2 is blank, this is an appropriate response. No data retrieval is necessary.*

*If Q.1 = Yes and the cancer listed in Q.2 is basal-cell or squamous-cell skin cancer, change the response to Q.1 to "No." Any response to Q.2 of basal-cell or squamous-cell skin cancer should not be entered into the SMS.*

3. **FOR MEN ONLY: In the period from (date) to the present, have you taken the medication Proscar or Propecia (also known as Finasteride)?** This question is to be completed by male participants only. Instruct the participant to check "Yes" or "No."

*SC Instructions: See instructions regarding the (date) in Item 1 (above).*

#### 4. Today's Date:

The participant should write in the month, day and year he/she completed this questionnaire in the space provided.

*SC Instructions: If this item is incomplete or not answered, use the date of receipt of the form as the date of completion according to the following guidelines:*

- 1. If the participant left all parts of the date blank (month, day, and year), replace the blanks with the full receipt date (month, day, and year). Record this date in another color ink in the space provided.*
- 2. If the participant wrote a partial date (e.g., month, day only) or a partially incorrect date (e.g., month and day fall prior to date questionnaire was sent to him/her), replace what the participant wrote with the full receipt date (month, day, and year). Record this date in another color ink in the space provided. Do not replace part(s) of the completion date with part(s) of the receipt date.*
- 3. In the white space next to the question, record the fact that the date is the receipt date and your initials.*
- 4. Place an "X" in the estimated date field on the ASU receipt screen in the SMS.*

#### 5. Who completed this questionnaire:

- If the participant completed the form himself/herself, he/she should place a check (÷) next to "Study Participant."
- If the participant's spouse completed the form for the participant, he/she should place a check (÷) next to "Spouse."
- If the person who completed this form is not the participant or his/her spouse (e.g., brother, friend, neighbor, SC staff member), the respondent should place a check (÷) next to "Someone else" and specify the relationship to the participant on the line provided.

#### 6. Comments:

The participant may use this space to record any other information or comments which he/she would like to communicate to the screening center staff. It is not necessary to key these comments into the SMS, however the SC should enter an "X" in the first position of the comments field on the ASU receipt screen to indicate that a comment was recorded on the hardcopy form.

##### **After completing the form:**

- If this form was administered by SC staff, thank the participant for completing the form.
- If completed by the participant at the SC, s/he should return it to the designated SC staff member or location.
- If completed by the participant at home, s/he should mail the form to the SC address at the bottom of the form. The SC may provide a self-addressed envelope for this purpose.

##### **Upon receiving the form at the SC:**

- Manually edit the form for completeness and legibility. If a cancer is recorded in Question 2, write the corresponding cancer code on the form in another color ink, or choose the correct code from the on-line lookup table during data entry. The cancer codes for use on the ASU are provided in Appendix I of the Manual of Operations and Procedures.

- Receipt the form into the SMS, including data entry. Question 1 is a critical data item and will require double data entry. If the participant records "Don't Know" next to a question, this item should be left blank during data entry. Refer to the documentation accompanying SMS Upgrades 2.03 and 2.04 for information regarding data entry of the ASU.
- If the date of diagnosis is partially completed, it may be keyed into the SMS as it appears on the hardcopy form. If the date of diagnosis is blank on the hardcopy form, it may be left blank in the SMS.
- File the form in the participant's folder.

## **A-7-2**

A-7-2: Follow-up Locator Form (FLF)

Specifications for the Follow-up Locator Form

**Prostate, Lung, Colorectal  
and Ovarian Cancer  
Screening Trial**

Participant ID Label

Form Approved OMB #: 0925-0407

Exp. Date: 07/05

Version Date: 10/96



FLF

**FOLLOW-UP LOCATOR FORM**

Today's Date: | | / | | / | | | |  
MONTH DAY YEAR

**1. What is your full name?**

TITLE	FIRST	MIDDLE	LAST	SUFFIX
-------	-------	--------	------	--------

**2. Are you known by any other last name (please include your maiden name and any previous married names)?**

MAIDEN NAME	OTHER LAST NAME
-------------	-----------------

**3. What is your date of birth?**

| | / | | / | | | |  
MONTH DAY YEAR

**4. What is your Social Security Number?**

| | | - | | | - | | | | |

The National Institutes of Health is requesting your Social Security Number under Public Health Service Act 42 USC 285a. The primary use of this information is for researchers to locate you in the future if they are unable to locate you at your home address, and to search vital records in a followup study conducted in the future. Additional disclosures of information may be: to HHS contractors, grantees, and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected; to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual; and as otherwise required by Law. **Furnishing your Social Security Number is voluntary, and you will not be denied any federal right, benefit, or privilege by your refusal to disclose it.**

**5. What is your current primary home address and telephone number?**

STREET ADDRESS		APT. NO.
CITY	STATE	ZIP
TELEPHONE NUMBER: ( )		

**6. What is your work telephone number? (IF NOT APPLICABLE, CHECK HERE  AND GO TO QUESTION 7)**

TELEPHONE NUMBER:  
( )

(OVER)

<b>7.</b> If you have a vacation home or other residence, what is that address, telephone number and time of year of residence? (IF NOT APPLICABLE, CHECK HERE <input type="checkbox"/> AND GO TO QUESTION 8)	
STREET ADDRESS <span style="float: right;">APT. NO.</span>	
CITY	STATE <span style="float: right;">ZIP</span>
TELEPHONE NUMBER:  (        )	MONTHS OF YEAR SPENT AT OTHER RESIDENCE (RECORD EXACT DATES IF POSSIBLE)  FROM: <span style="float: right;">TO:</span>

<b>8.</b> Please list the names of two adults who live in your household and their relationship to you. (Include your spouse, partner, children, relatives, and/or roommates.) (IF NOT APPLICABLE, CHECK HERE <input type="checkbox"/> AND GO TO QUESTION 9)	
FULL NAME OF HOUSEHOLD MEMBER	RELATIONSHIP TO PARTICIPANT
1.	
2.	

<b>9.</b> What is the name, address, and telephone number of your current primary care physician or clinic? (IF NOT APPLICABLE, CHECK HERE <input type="checkbox"/> AND GO TO QUESTION 10)	
FULL NAME OF PHYSICIAN OR CLINIC	
STREET ADDRESS:	SUITE OR OFFICE NO.
CITY	STATE <span style="float: right;">ZIP</span>
TELEPHONE NUMBER:  (        )	

<b>10.</b> It would be of great help to us if you could provide us with the names and addresses of <b>two</b> people who could give us your new address should you move. We would only contact these people if we were unable to reach you at your home address. It would be helpful to get the names of people who <u>do not</u> live with you.	
FULL NAME	RELATIONSHIP TO YOU
1.	
STREET ADDRESS	TELEPHONE NUMBER
CITY	STATE <span style="float: right;">ZIP</span>
	(        )
FULL NAME	RELATIONSHIP TO YOU
2.	
STREET ADDRESS	TELEPHONE NUMBER
CITY	STATE <span style="float: right;">ZIP</span>
	(        )

## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE FOLLOW-UP LOCATOR FORM (FLF)

This form is self-administered. It is to be completed annually by all participants, both intervention and control, for each year of follow-up, starting with T1. The reporting window for completion of this form is from one month prior to one month past the participant's randomization anniversary date. The delinquency period for this form is from one month past the participant's randomization anniversary date to three months past the randomization anniversary date (see Chapter 7 of the Manual of Operations and Procedures).

Two different versions of this form may be administered, depending on SC preference. One version is generated from the SMS and is "intelligent," that is, it presents the specific participant's locator information that is on file in the SMS for the participant to confirm. The other version is a generic form that is similar in format to the Baseline Locator Form, and requires the participant to provide complete locator information.

#### THE FOLLOWING ARE THE SPECIFICATIONS FOR THE SMS-GENERATED FLF:

##### Generated by SMS (in advance of administration/mailing):

**Participant ID:** This information will be pre-printed in both numeric format and in barcode format. The barcode may be read by a barcode reader (wand) during receipt of the form into the SMS.

**Study Year:** This information will be pre-printed: T1, T2, T3 etc., for the follow-up study years, followed by an indicator for randomization group ("I" for intervention or "C" for control).

**Report Date:** This information will be pre-printed: the month day and year the form is generated.

##### Completed by Participant:

Instruct the participant to review the information printed in the left column of the form. If it is not correct, the participant should record the "new" information, that is, additions or corrections, on the line provided in the right column. Instruct the participant to write or print clearly. If there are no changes to an item, the participant should place a check (÷) in the box to the right of "OK."

**Today's Date:** This is the day the form is completed. Instruct the participant to enter the month, day, and year.

**Full Name:** Instruct the participant to review the information printed in the left column of the form.

- If the participant has had a change in either the first, middle or last name or any corrections to the spelling are needed, he/she should enter the new full name/corrections in the right column on the line provided.
- If there is no change to this item, instruct the participant to place a check (÷) to the right of "OK."

**Other Names:** Instruct the participant to review the information printed in the left column of the form. Other names include any names other than those previously listed as part of the full name, by which the participant is commonly known, or which the participant may have used in seeking medical care; such as a maiden name, a previous or present spouse's last name, a new first name, nickname, or professional name.

- If the participant has a new other name, he/she should enter the new other name in the right column on the line provided.
- If there is no change to this item, instruct the participant to place a check (✓) in the box to the right of "OK."

**Social Security Number:** Instruct the participant to review the information printed in the left column of the form.

- If the participant has corrections to his/her social security number, or for some reason a new number has been issued, he/she should enter the new social security number in the right column on the line provided.
- If there is no change to this item, instruct the participant to place a check (✓) in the box to the right of "OK."

**Box explaining request for Social Security Number:** If the form is administered by SC staff, this statement should be read to the participant.

**Home Address/Phone(s):** The participant should record any change to his/her home address (place of usual residence) and/or telephone number. Instruct the participant to review the information printed in the left column of the form.

- -If there have been any changes to the participant's street address, home or work telephones, he/she should enter the change(s) in the right column on the lines provided.
- -If there are no change(s) to this item, instruct the participant to place a check (✓) in the box to the right of "OK."

**Vacation/Other Address/Phone:** Instruct the participant to record any change in the address or telephone number of their vacation home or any other home where they reside for a part of the year, aside from their usual residence. Instruct the participant to review the information printed in the left column of the form.

- If there have been any changes in street address, or telephone(s), or time of year, he/she should enter the change(s) in the right column on the lines provided.
- If the participant has a new vacation home or other residence in addition to his/her usual residence, he/she should enter this information in the right column on the lines provided.
- If the participant reported a vacation home on the BLF or the previous FLF and no longer has a vacation home, he/she should cross out the information in the left column and write "None" in the right column.
- If there are no changes to this item, instruct the participant to place a check (✓) in the box to the right of "OK."

**Household Members:** Instruct the participant to review the list of household members (adults living in the same home as the respondent) in the left column, and to cross out the name of anyone no longer living in his/her household.

- If any part of the household member's name, or their relationship to the participant has changed, instruct the participant to write these changes in the right column.
- Instruct the participant to write the name of the new household members, and their relationship to the participant in the right column.
- If there are no change(s) to this item, instruct the participant to place a check (✓) in the box to the right of "OK."

**Primary Care Physician/Clinic:** Instruct the participant that if the source of his/her health care is a clinic, we are interested in the name of the doctor at the clinic. Instruct the participant to review the name, address, and phone number of the primary care physician or clinic in left column.

- If the participant has a new primary care physician or clinic, or if any part of the current physician's/clinic address or phone number has changed, instruct the participant to write these changes in the right column.
- If there are no changes to this item, instruct the participant to place a check (✓) in the box to the right of "OK."

**Contacts:** If the form is administered by SC staff, this statement should be read to the participant. Here, the participant should provide the names of two people who do not live with the participant, and who could give us the new address if the participant were to move.

- Instruct the participant to review the name, address and phone number of the two contacts in the left column. If any part of the contact's name, address, or phone number has changed, instruct the participant to write these changes in the right column.
- If the participant wishes to list a new contact, s/he should cross out the name in the left column, and list the name of the new contact person, address, phone number, and relationship to the participant, in the right column.
- If there are no change(s) to the contact or to the information about the contact, instruct the participant to place a check (✓) in the box to the right of "OK."

#### THE FOLLOWING ARE THE SPECIFICATIONS FOR THE GENERIC FLF:

##### **Completed by Screening Center (in advance of administration/ mailing):**

**Participant ID:** Affix a Participant ID label to the space provided at the top of the form.

##### **Completed by Participant:**

**Today's Date:** This is the date the form is completed. Instruct the participant to enter the month, day, and year. Month and day should be zero filled, if applicable, and the year should be four digits.

1. **What is your full name?** Instruct the participant to record his/her title (Dr., Mr., Ms., Mrs., Miss) first, middle, last name and suffix (Jr., Sr., III, Esq.).
2. **Are you known by any other last name (please include your maiden name and any previous married names)?** Instruct the participant to record any other last names such as a maiden name or any previous married names.
3. **What is your date of birth?** Instruct the participant to enter the month, day and year of his/her birth. Month and day should be zero filled, if applicable, and the year should be four digits.
4. **What is your Social Security Number?** Instruct the participant to record his/her social security number in the boxes provided.

**Box explaining request for Social Security Number:** If the form is administered by SC staff, this statement should be read to the participant.

5. **What is your current primary home address and telephone number?** The current primary home address is the participant's usual residence. Instruct the participant to record his/her full address, including street, apartment number (if applicable), city, state, and zip code. Instruct the participant to record the telephone number, including area code at his/her primary home.
6. **What is your work telephone number?** If the participant is employed outside the home or has a business at home, instruct him/her to record a telephone number, including area code, which could be used to contact him/her at work. Assure the participant that we will not contact him/her at work unless we are unable to contact him/her at the home telephone number or by mail after repeated attempts. If the participant does not have a work telephone number, instruct him/her to place a check (✓) in the box and go to Question 7.
7. **If you have a vacation home or other residence, what is that address, telephone number and time of year of residence?** The participant may spend part of the year at another residence, or have a vacation home in another area where he/she spends a certain time of year. Instruct the participant to record the full address, including street, apartment number, city, state and zip code of the vacation home or other residence. Instruct the participant to record the telephone number, including area code, of this residence. Instruct the participant to indicate the months of the year that s/he is at this residence. If possible, the participant should record the exact dates that he/she is at this residence (e.g., From: March 1 To: October 1).

If the participant does not have a vacation home/other residence, instruct him/her to place a check (✓) in the box and go to Question 8.

8. **Please list the names of two adults who live in your household and their relationship to you.** (Include your spouse, partner, children, relatives, and/or roommates.) Instruct the participant to record the names of two adults living in the same home as the participant, and their relationship to the participant. If only one other adult is living with the participant, he/she should record that person's name and their relationship to the respondent. If no adults aside from the participant, live in the participant's household, instruct the participant to place a check (÷) in the box and go to Question 9.
9. **What is the name, address and telephone number of your current primary care physician or clinic?** Instruct the participant that if the source of his/her health care is a clinic, we are interested in the name of the doctor at the clinic. Instruct the participant to record the full name of the physician (and clinic, if applicable), the full street address, including suite or office number, the city, state, and zip code, and full telephone number, including area code, in the space provided.

If the participant does not have a current source of primary care, such as a physician or clinic, instruct him/her to place a check (÷) in the box and go to Question 10.

10. **It would be of great help to us if you could provide us with the names and addresses of two people who could give us your new address should you move. We would only contact these people if we were unable to reach you at your home address. It would be helpful to get the names of people who do not live with you.** This information will be used by the Screening Centers to trace a participant if he/she cannot be contacted at his/her residential address(es). Instruct the participant to provide the names of two people who do not live with the participant, and who could give us the new address if the participant were to move.

Instruct the participant to record the full name, street address including apartment number, city, state, zip code, and telephone number including area code, of each con-

tact in the space provided. Instruct the participant to record the relationship of each contact to him/her in the space provided.

**After completing the form:**

- If this form is administered by SC staff, thank the participant for completing the form.
- If completed by the participant at the SC, he/she should return it to the designated SC staff member or location.
- If completed at home, the participant should mail this form to the SC in the envelope provided.

**Upon receiving the form at the SC:**

- Review the form for completeness and legibility.
- The state information in Questions 5, 7, 9, and 10 must be entered into the SMS as two character state abbreviations such as "MO," "MN," "HI," etc. For ease of receipt into the SMS, you may wish to write these codes in another color ink directly on the Follow-up Locator Form, next to the state name provided by the participant. The valid state codes are given in Appendix I of the Manual of Operations and Procedures. These abbreviations may also be selected from the on-line lookup table during the SMS receipt process.
- The relationship information in Questions 8 and 10 must be entered into the SMS as 2-digit codes such as "01" for mother, "02" for father, etc. For ease of receipt into the SMS, you may wish to write these codes in another color ink directly on the Follow-up Locator Form, next to the relationship recorded by the participant. The valid relationship codes are given in Appendix I of the Manual of Operations and Procedures. These codes may also be selected from the on-line lookup table during the SMS receipt process. For relationships that do not appear in the list of codes in Appendix I (e.g., step-son, step-daughter, step-brother, brother-in-law, mother-in-law, etc.) use the code for "Other" (88).
- Receipt the form into the SMS.
- File the form in the participant's folder.

## **A-8-1**

**A-8-1: Prostate Cancer Medical Record Abstract  
Forms (DEP3, TIP2)  
[Diagnostic Evaluation and Treatment Information]**

**Specifications for the Prostate Cancer Medical  
Record Abstract Forms**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM DIAGNOSTIC EVALUATION - PROSTATE (DEP3/DPQ3)

<b>1.</b>	Date Abstracted: <small>MO. DAY YEAR</small>	<b>2.</b>	Abstractor ID #:	<b>3.</b>	Nosologist ID #:	<b>4.</b>	CTR ID#:	<b>5.</b>	Study Year T <sub>0</sub> -T <sub>13</sub> :	<b>6.</b>	Purpose of Abstract:																																																																																																																																																																																											
	MO. DAY YEAR 20							T			<input type="radio"/> Initial abstract <input type="radio"/> Re-abstract for QA																																																																																																																																																																																											
	<table border="1" style="font-size: 8px; width: 100%;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="font-size: 8px; width: 100%;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="font-size: 8px; width: 100%;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="font-size: 8px; width: 100%;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="font-size: 8px; width: 100%;"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<table border="1" style="font-size: 8px; width: 100%;"> <tr> <td style="text-align: center;"><b>7.</b></td> <td style="text-align: center;">Multiple Primary Cancer #:</td> </tr> <tr> <td style="text-align: center;"> <table style="width: 100%;"> <tr><td>2</td><td>3</td><td>4</td><td>5</td></tr> <tr><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table> </td> <td style="text-align: center;">(GO TO A.9)</td> </tr> </table>	<b>7.</b>	Multiple Primary Cancer #:	<table style="width: 100%;"> <tr><td>2</td><td>3</td><td>4</td><td>5</td></tr> <tr><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	2	3	4	5	6	7	8	9	(GO TO A.9)
0	0	0	0																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																			
0	0	0	0																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																			
0	0	0	0																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																			
0	0	0	0																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																			
0	0																																																																																																																																																																																																					
1	1																																																																																																																																																																																																					
2	2																																																																																																																																																																																																					
3	3																																																																																																																																																																																																					
4	4																																																																																																																																																																																																					
5	5																																																																																																																																																																																																					
6	6																																																																																																																																																																																																					
7	7																																																																																																																																																																																																					
8	8																																																																																																																																																																																																					
9	9																																																																																																																																																																																																					
<b>7.</b>	Multiple Primary Cancer #:																																																																																																																																																																																																					
<table style="width: 100%;"> <tr><td>2</td><td>3</td><td>4</td><td>5</td></tr> <tr><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	2	3	4	5	6	7	8	9	(GO TO A.9)																																																																																																																																																																																													
2	3	4	5																																																																																																																																																																																																			
6	7	8	9																																																																																																																																																																																																			

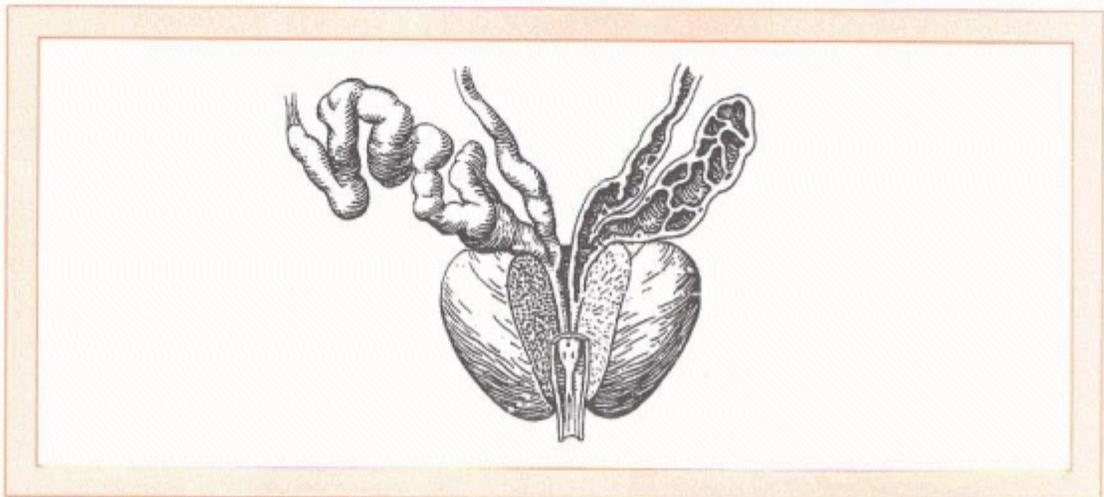
### FOR OFFICE USE ONLY

**8. Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)**

Form Received into SMS <input type="radio"/>	<b>Data Entry of Non-Scannable Items:</b> Completed <input type="radio"/> None Required <input type="radio"/>	<b>Data Retrieval:</b> Attempted <input type="radio"/> None Required <input type="radio"/>
Manual Review Completed <input type="radio"/>	<b>Disposition:</b> Interim Complete (ICM) <input type="radio"/> Final Complete (FCM) <input type="radio"/> Final Incomplete (FIC) <input type="radio"/>	

### PART A: DIAGNOSTIC EVALUATION AND STAGING

<b>1. Diagnostic Procedures Performed:</b>  <input type="radio"/> Yes <input type="radio"/> No, Physician report <input type="radio"/> No, Participant self-report } (GO TO A.9)	<b>2. Reason for Initial Visit for Clinical Assessment:</b> (MARK ALL THAT APPLY) <input type="radio"/> Symptomatic <input type="radio"/> Follow-up of positive PLCO screen <input type="radio"/> Other (SPECIFY) _____
--	---



DesignExpert™ by NCS Printed in U.S.A. Mark Reflex® EW-215676-4-654321 HC05

PLEASE DO NOT WRITE IN THIS AREA

044880

- 1 -



**PART A CONTINUED . . .**

**4. Digital Rectal Examination (DRE): (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**

No       Yes (COMPLETE TABLE BELOW)       Unknown

RECTAL EXAMINATION	1	2	3																																																																																																			
DATE OF PROCEDURE (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**5. Transrectal Ultrasonography (TRUS):**

No       Yes (COMPLETE TABLE BELOW)       Unknown

TRUS	1	2	3																																																																																																			
PROSTATE DIMENSIONS (cm)  99 = Not available	<table border="1"> <thead> <tr> <th>1</th> <th>2</th> <th>3</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	1	2	3	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>1</th> <th>2</th> <th>3</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	1	2	3	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>1</th> <th>2</th> <th>3</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	1	2	3	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
1	2	3																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
1	2	3																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
1	2	3																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
DATE OF PROCEDURE (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

PLEASE DO NOT WRITE IN THIS AREA



044880

**PART A CONTINUED . . .**

**6. Pathologic Examination (Prostate Biopsy):**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

PROSTATE BIOPSY #	1	2	3																																																																																																																																																																																																						
<b>TYPE OF BIOPSY</b> 1 = Cytological 2 = Histological 9 = Not available	(1) (2) (9)	(1) (2) (9)	(1) (2) (9)																																																																																																																																																																																																						
<b>LOCATION OF BIOPSY</b> (MARK ALL THAT APPLY) 1 = Right prostate 2 = Left prostate 9 = Not available	(1) (2) (9)	(1) (2) (9)	(1) (2) (9)																																																																																																																																																																																																						
<b>RESULT</b> (SEE RESULT CODES BELOW)	(01) (02) (04) (05) (08) (09) (99)	(01) (02) (04) (05) (08) (09) (99)	(01) (02) (04) (05) (08) (09) (99)																																																																																																																																																																																																						
<b>DATE OF BIOPSY</b> (MO. - DAY - YEAR)	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td></td><td></td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td></td><td></td><td>3</td><td>3</td><td></td><td></td></tr> <tr><td></td><td></td><td>4</td><td>4</td><td></td><td></td></tr> <tr><td></td><td></td><td>5</td><td>5</td><td></td><td></td></tr> <tr><td></td><td></td><td>6</td><td>6</td><td></td><td></td></tr> <tr><td></td><td></td><td>7</td><td>7</td><td></td><td></td></tr> <tr><td></td><td></td><td>8</td><td>8</td><td></td><td></td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR		0	1	0	0	0	0	1	1	1	1	1	1			2	2	2	2			3	3					4	4					5	5					6	6					7	7					8	8			9	9	9	9	9	9	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td></td><td></td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td></td><td></td><td>3</td><td>3</td><td></td><td></td></tr> <tr><td></td><td></td><td>4</td><td>4</td><td></td><td></td></tr> <tr><td></td><td></td><td>5</td><td>5</td><td></td><td></td></tr> <tr><td></td><td></td><td>6</td><td>6</td><td></td><td></td></tr> <tr><td></td><td></td><td>7</td><td>7</td><td></td><td></td></tr> <tr><td></td><td></td><td>8</td><td>8</td><td></td><td></td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR		0	0	0	0	0	0	1	1	1	1	1	1			2	2	2	2			3	3					4	4					5	5					6	6					7	7					8	8			9	9	9	9	9	9	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td></td><td></td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td></td><td></td><td>3</td><td>3</td><td></td><td></td></tr> <tr><td></td><td></td><td>4</td><td>4</td><td></td><td></td></tr> <tr><td></td><td></td><td>5</td><td>5</td><td></td><td></td></tr> <tr><td></td><td></td><td>6</td><td>6</td><td></td><td></td></tr> <tr><td></td><td></td><td>7</td><td>7</td><td></td><td></td></tr> <tr><td></td><td></td><td>8</td><td>8</td><td></td><td></td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR		0	0	0	0	0	0	1	1	1	1	1	1			2	2	2	2			3	3					4	4					5	5					6	6					7	7					8	8			9	9	9	9	9	9
MO.		DAY		YEAR																																																																																																																																																																																																					
0	1	0	0	0	0																																																																																																																																																																																																				
1	1	1	1	1	1																																																																																																																																																																																																				
		2	2	2	2																																																																																																																																																																																																				
		3	3																																																																																																																																																																																																						
		4	4																																																																																																																																																																																																						
		5	5																																																																																																																																																																																																						
		6	6																																																																																																																																																																																																						
		7	7																																																																																																																																																																																																						
		8	8																																																																																																																																																																																																						
9	9	9	9	9	9																																																																																																																																																																																																				
MO.		DAY		YEAR																																																																																																																																																																																																					
0	0	0	0	0	0																																																																																																																																																																																																				
1	1	1	1	1	1																																																																																																																																																																																																				
		2	2	2	2																																																																																																																																																																																																				
		3	3																																																																																																																																																																																																						
		4	4																																																																																																																																																																																																						
		5	5																																																																																																																																																																																																						
		6	6																																																																																																																																																																																																						
		7	7																																																																																																																																																																																																						
		8	8																																																																																																																																																																																																						
9	9	9	9	9	9																																																																																																																																																																																																				
MO.		DAY		YEAR																																																																																																																																																																																																					
0	0	0	0	0	0																																																																																																																																																																																																				
1	1	1	1	1	1																																																																																																																																																																																																				
		2	2	2	2																																																																																																																																																																																																				
		3	3																																																																																																																																																																																																						
		4	4																																																																																																																																																																																																						
		5	5																																																																																																																																																																																																						
		6	6																																																																																																																																																																																																						
		7	7																																																																																																																																																																																																						
		8	8																																																																																																																																																																																																						
9	9	9	9	9	9																																																																																																																																																																																																				

**RESULT CODES**

- |  |  |
|--|--|
| 01 = Negative (normal)<br>02 = Abnormal, not suspicious for prostate cancer<br>04 = Abnormal, suspicious for prostate cancer<br>05 = Abnormal, diagnostic of prostate cancer | 08 = Unsatisfactory<br>09 = Inconclusive<br>99 = Not available |
|--|--|

**PART A CONTINUED . . .**

**7. Other Diagnostic/Staging Procedures: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**

No       Yes (COMPLETE TABLE BELOW)       Unknown

PROCEDURE #	1	2	3																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF PAP, RECORD VALUE; IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88 _____ SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
PROCEDURE #	4	5	6																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF PAP, RECORD VALUE; IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88 _____ SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**PROCEDURE CODES**

- |  |   |  |
|--|---|--|
| 01 = CT scan - abdominal                               | 11 = Preoperative prostatic acid phosphatase (PAP) (RECORD VALUE) | 20 = Prostatectomy                         |
| 02 = CT scan - other (SPECIFY)                         | 12 = Bone radiograph  | 21 = Clinical evaluation                   |
| 03 = CT scan - pelvic                                  | 13 = Chest radiograph   | 22 = CT scan - abdomen and pelvis combined |
| 04 = Intravenous pyelography (IVP)/excretory urography | 14 = Radioisotope bone scan                                       | 23 = Cystogram                             |
| 05 = Laparoscopic lymph node biopsy                    | 15 = TURP   | 24 = Cystourethroscopy/Cystopanendoscopy   |
| 06 = Lymphangiogram                                    | 16 = Lymphadenectomy/Lymph node sampling                          | 25 = Other radiograph (SPECIFY)            |
| 07 = MRI scan - abdominal                              | 17 = Cystoscopy   | 26 = Record review                         |
| 08 = MRI scan - other (SPECIFY)                        | 18 = Proctosigmoidoscopy  | 27 = Ultrasound (SPECIFY)                  |
| 09 = MRI scan - pelvic                                 | 19 = Other endoscopy (SPECIFY)                                    | 28 = Ureterogram                           |
| 10 = Other biopsy (SPECIFY)                            |   | 88 = Other (SPECIFY)                       |

**PART A CONTINUED . . .**

PROCEDURE #	7	8	9																																																																																																												
<b>TYPE OF PROCEDURE</b>  (SEE PROCEDURE CODES BELOW. IF PAP, RECORD VALUE; IF OTHER, SPECIFY.)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88																																																																																																												
	SPECIFY	SPECIFY	SPECIFY																																																																																																												
<b>DATE OF PROCEDURE</b>  (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
	MO.	DAY	YEAR																																																																																																												
0	0	0																																																																																																													
1	1	1																																																																																																													
2	2	2																																																																																																													
3	3	3																																																																																																													
4	4	4																																																																																																													
5	5	5																																																																																																													
6	6	6																																																																																																													
7	7	7																																																																																																													
8	8	8																																																																																																													
9	9	9																																																																																																													
MO.	DAY	YEAR																																																																																																													
0	0	0																																																																																																													
1	1	1																																																																																																													
2	2	2																																																																																																													
3	3	3																																																																																																													
4	4	4																																																																																																													
5	5	5																																																																																																													
6	6	6																																																																																																													
7	7	7																																																																																																													
8	8	8																																																																																																													
9	9	9																																																																																																													
MO.	DAY	YEAR																																																																																																													
0	0	0																																																																																																													
1	1	1																																																																																																													
2	2	2																																																																																																													
3	3	3																																																																																																													
4	4	4																																																																																																													
5	5	5																																																																																																													
6	6	6																																																																																																													
7	7	7																																																																																																													
8	8	8																																																																																																													
9	9	9																																																																																																													

PROCEDURE #	10	11	12																																																																																																												
<b>TYPE OF PROCEDURE</b>  (SEE PROCEDURE CODES BELOW. IF PAP, RECORD VALUE; IF OTHER, SPECIFY.)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 88																																																																																																												
	SPECIFY	SPECIFY	SPECIFY																																																																																																												
<b>DATE OF PROCEDURE</b>  (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
	MO.	DAY	YEAR																																																																																																												
0	0	0																																																																																																													
1	1	1																																																																																																													
2	2	2																																																																																																													
3	3	3																																																																																																													
4	4	4																																																																																																													
5	5	5																																																																																																													
6	6	6																																																																																																													
7	7	7																																																																																																													
8	8	8																																																																																																													
9	9	9																																																																																																													
MO.	DAY	YEAR																																																																																																													
0	0	0																																																																																																													
1	1	1																																																																																																													
2	2	2																																																																																																													
3	3	3																																																																																																													
4	4	4																																																																																																													
5	5	5																																																																																																													
6	6	6																																																																																																													
7	7	7																																																																																																													
8	8	8																																																																																																													
9	9	9																																																																																																													
MO.	DAY	YEAR																																																																																																													
0	0	0																																																																																																													
1	1	1																																																																																																													
2	2	2																																																																																																													
3	3	3																																																																																																													
4	4	4																																																																																																													
5	5	5																																																																																																													
6	6	6																																																																																																													
7	7	7																																																																																																													
8	8	8																																																																																																													
9	9	9																																																																																																													

**7b.** DIAGNOSTIC/STAGING PROCEDURES SUPPLEMENT FORM COMPLETED

**PROCEDURE CODES**

- |  |   |  |
|--|---|--|
| 01 = CT scan - abdominal                               | 11 = Preoperative prostatic acid phosphatase (PAP) (RECORD VALUE) | 20 = Prostatectomy                         |
| 02 = CT scan - other (SPECIFY)                         | 12 = Bone radiograph  | 21 = Clinical evaluation                   |
| 03 = CT scan - pelvic                                  | 13 = Chest radiograph   | 22 = CT scan - abdomen and pelvis combined |
| 04 = Intravenous pyelography (IVP)/excretory urography | 14 = Radioisotope bone scan                                       | 23 = Cystogram                             |
| 05 = Laparoscopic lymph node biopsy                    | 15 = TURP   | 24 = Cystourethroscopy/Cystopanendoscopy   |
| 06 = Lymphangiogram                                    | 16 = Lymphadenectomy/Lymph node sampling                          | 25 = Other radiograph (SPECIFY)            |
| 07 = MRI scan - abdominal                              | 17 = Cystoscopy   | 26 = Record review                         |
| 08 = MRI scan - other (SPECIFY)                        | 18 = Proctosigmoidoscopy  | 27 = Ultrasound (SPECIFY)                  |
| 09 = MRI scan - pelvic                                 | 19 = Other endoscopy (SPECIFY)                                    | 28 = Ureterogram                           |
| 10 = Other biopsy (SPECIFY)                            |   | 88 = Other (SPECIFY)                       |

PLEASE DO NOT WRITE IN THIS AREA



044880

**PART A CONTINUED . . .**

**8. Medical Complications of Diagnostic Evaluation and Staging:**

No       Yes (COMPLETE TABLE BELOW)       Unknown

COMPLICATION #	1	2	3																																																																																																			
<b>TYPE OF COMPLICATION</b>  (SEE COMPLICATION CODES BELOW)	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 100 101 104 105 106 107 108 109 110 111  _____ SPECIFY	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 100 101 104 105 106 107 108 109 110 111  _____ SPECIFY	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 100 101 104 105 106 107 108 109 110 111  _____ SPECIFY																																																																																																			
<b>DATE OF COMPLICATION</b>  (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
COMPLICATION #	4	5	6																																																																																																			
<b>TYPE OF COMPLICATION</b>  (SEE COMPLICATION CODES BELOW)	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 100 101 104 105 106 107 108 109 110 111  _____ SPECIFY	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 100 101 104 105 106 107 108 109 110 111  _____ SPECIFY	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 100 101 104 105 106 107 108 109 110 111  _____ SPECIFY																																																																																																			
<b>DATE OF COMPLICATION</b>  (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**MEDICAL COMPLICATION CODES**

- |  |  |   |
|--|--|---|
| 1 = Infection (SPECIFY)<br>2 = Fever requiring antibiotics<br>20 = Cardiac arrest<br>21 = Respiratory arrest<br>22 = Hospitalization<br>23 = Pulmonary embolus/emboli<br>24 = Myocardial infarction<br>25 = Cardiac arrhythmia<br>26 = Cerebral vascular accident (CVA)/Stroke | 27 = Blood loss requiring transfusion<br>28 = Deep venous thrombosis (DVT)<br>29 = Acute/chronic respiratory failure<br>30 = Hypotension<br>31 = Congestive heart failure (CHF)<br>32 = Wound dehiscence<br>33 = Hypokalemia<br>100 = Bladder neck contracture<br>101 = Extraperitoneal leakage from bladder | 104 = Impotence<br>105 = Diminished potency<br>106 = Incontinence - partial stress<br>107 = Incontinence - total<br>108 = Rectal damage<br>109 = Urethral stricture<br>110 = Diarrhea<br>111 = Blood in stool |
|--|--|---|

PLEASE DO NOT WRITE IN THIS AREA



044880

**PART A CONTINUED . . .**

**9. Result of Diagnostic Evaluation for Prostate Cancer:**

- No malignancy (GO TO PART B)
- No malignancy and no diagnostic/staging procedures performed (GO TO PART D)
- Prostate malignancy confirmed histologically (exclude carcinoma in situ) (GO TO PART C)
- Prostate malignancy confirmed cytologically (GO TO PART C)
- Prostate malignancy diagnosed by clinical examination only (GO TO PART C)
- Other malignancy confirmed histologically or cytologically (GO TO PART B)
- No information available (GO TO PART D)

**PART B: DIAGNOSIS INFORMATION FOR SPECIFIC CONDITIONS OTHER THAN PROSTATE CANCER**

**10. Specific Prostate Diagnosis:**

- No       Yes (COMPLETE TABLE BELOW)

DIAGNOSIS #	1	2	3																																																																																																			
<b>DIAGNOSIS</b> 1 = Prostatitis 2 = Benign prostatic hypertrophy (BPH) 3 = Prostatic intraepithelial neoplasia (PIN) (Carcinoma in situ)	① ② ③	① ② ③	① ② ③																																																																																																			
<b>DATE OF DIAGNOSIS</b> (MO. - DAY - YEAR)	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3">MO. DAY YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO. DAY YEAR			0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3">MO. DAY YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO. DAY YEAR			0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3">MO. DAY YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO. DAY YEAR			0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO. DAY YEAR																																																																																																						
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO. DAY YEAR																																																																																																						
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO. DAY YEAR																																																																																																						
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**11. Other Cancer Diagnosis:**

- No       Yes (COMPLETE TABLE BELOW)

OTHER CANCER DIAGNOSIS 1				OTHER CANCER DIAGNOSIS 2																																																																																																																																																			
ICD-9-CM CLASSIFICATION		DATE OF OTHER CANCER DIAGNOSIS		ICD-9-CM CLASSIFICATION		DATE OF OTHER CANCER DIAGNOSIS																																																																																																																																																	
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td>X</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	X	X	X		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td>X</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	X	X	X		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td>X</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	X	X	X		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td>X</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	X	X	X	
MO.	DAY	YEAR																																																																																																																																																					
0	0	0																																																																																																																																																					
1	1	1																																																																																																																																																					
2	2	2																																																																																																																																																					
3	3	3																																																																																																																																																					
4	4	4																																																																																																																																																					
5	5	5																																																																																																																																																					
6	6	6																																																																																																																																																					
7	7	7																																																																																																																																																					
8	8	8																																																																																																																																																					
9	9	9																																																																																																																																																					
X	X	X																																																																																																																																																					
MO.	DAY	YEAR																																																																																																																																																					
0	0	0																																																																																																																																																					
1	1	1																																																																																																																																																					
2	2	2																																																																																																																																																					
3	3	3																																																																																																																																																					
4	4	4																																																																																																																																																					
5	5	5																																																																																																																																																					
6	6	6																																																																																																																																																					
7	7	7																																																																																																																																																					
8	8	8																																																																																																																																																					
9	9	9																																																																																																																																																					
X	X	X																																																																																																																																																					
MO.	DAY	YEAR																																																																																																																																																					
0	0	0																																																																																																																																																					
1	1	1																																																																																																																																																					
2	2	2																																																																																																																																																					
3	3	3																																																																																																																																																					
4	4	4																																																																																																																																																					
5	5	5																																																																																																																																																					
6	6	6																																																																																																																																																					
7	7	7																																																																																																																																																					
8	8	8																																																																																																																																																					
9	9	9																																																																																																																																																					
X	X	X																																																																																																																																																					
MO.	DAY	YEAR																																																																																																																																																					
0	0	0																																																																																																																																																					
1	1	1																																																																																																																																																					
2	2	2																																																																																																																																																					
3	3	3																																																																																																																																																					
4	4	4																																																																																																																																																					
5	5	5																																																																																																																																																					
6	6	6																																																																																																																																																					
7	7	7																																																																																																																																																					
8	8	8																																																																																																																																																					
9	9	9																																																																																																																																																					
X	X	X																																																																																																																																																					

**GO TO PART D**

**PART C: PRIMARY PROSTATE CANCER DIAGNOSIS INFORMATION**

**12. Date of Primary Prostate Cancer Diagnosis:**

MO.		DAY		YEAR		
0	1	0	0	0	0	0
1	1	1	1	1	1	1
2	2	2	2	2	2	2
3	3	3		3	3	3
4		4		4	4	4
5		5		5	5	5
6		6		6	6	6
7		7		7	7	7
8		8		8	8	8
9	9	9		9	9	9

**13. Verbatim Description of Primary Prostate Cancer Diagnosis:**

---



---



---



---



---



---



---



---

**14. ICD-O-2 Cancer Classification:**

Topography	Morphology	Behavior	Grade
C 0 0 0 0	0 0 0 0		
1 1 1	1 1 1 1	1	1
2 2 2	2 2 2 2		2
3 3 3	3 3 3 3	3	3
4 4 4	4 4 4 4		4
5 5 5	5 5 5 5		5
6 6 6	6 6 6 6		6
7 7 7	7 7 7 7		7
8 8 8	8 8 8 8		8
9 9 9	9 9 9 9	9	9

**15. Photocopy of Report Confirming Primary Prostate Cancer: (MARK ONE)**

- Pathology/Histopathology (ATTACH COPY)
- Cytology/Cytopathology (ATTACH COPY)
- Not available

**16. Histopathologic Type for Primary Prostate Cancer:**

- Adenocarcinoma, NOS
- Adenocarcinoma, acinar
- Adenocarcinoma, mucinous
- Adenocarcinoma, ductal
- Transitional cell carcinoma
- Squamous cell carcinoma
- Neuroendocrine tumor
- Small cell (anaplastic) carcinoma
- Undifferentiated carcinoma
- Other (SPECIFY) \_\_\_\_\_
- Unknown

**17. Histopathologic Grade for Primary Prostate Cancer:**

- Grade cannot be assessed (GX)
- Well differentiated slight anaplasia (G1)
- Moderately differentiated, moderate anaplasia (G2)
- Poorly differentiated or undifferentiated, marked anaplasia (G3-4)
- Unknown

**18. Gleason Score (MARK ONE):**

- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 99 Not available

**PART C CONTINUED . . .**

**19. TNM Staging for Primary Prostate Cancer:**  
 If TNM Staging performed, what AJCC Cancer Staging Manual did you use?  4th Edition  5th Edition

**a. TNM Clinical Staging:**  
 Yes (COMPLETE 19.a.1, 19.a.2, 19.a.3)  No (GO TO C.19.b)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
(T) Codes	(N) Codes	(M) Codes
<input type="radio"/> Tx <input type="radio"/> T2c <input type="radio"/> T0 <input type="radio"/> T3 <input type="radio"/> T1 <input type="radio"/> T3a <input type="radio"/> T1a <input type="radio"/> T3b <input type="radio"/> T1b <input type="radio"/> T3c <input type="radio"/> T1c <input type="radio"/> T4 <input type="radio"/> T2 <input type="radio"/> T4a <input type="radio"/> T2a <input type="radio"/> T4b <input type="radio"/> T2b <input type="radio"/> Not available	<input type="radio"/> Nx <input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2 <input type="radio"/> N3  <input type="radio"/> Not available	<input type="radio"/> Mx <input type="radio"/> M0 <input type="radio"/> M1A <input type="radio"/> M1B <input type="radio"/> M1C  <input type="radio"/> Not available

**b. TNM Pathologic Staging:**  
 Yes (COMPLETE 19.b.1, 19.b.2, 19.b.3)  No (GO TO C.20)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
(T) Codes	(N) Codes	(M) Codes
<input type="radio"/> Tx <input type="radio"/> T2c <input type="radio"/> T0 <input type="radio"/> T3 <input type="radio"/> T1 <input type="radio"/> T3a <input type="radio"/> T1a <input type="radio"/> T3b <input type="radio"/> T1b <input type="radio"/> T3c <input type="radio"/> T1c <input type="radio"/> T4 <input type="radio"/> T2 <input type="radio"/> T4a <input type="radio"/> T2a <input type="radio"/> T4b <input type="radio"/> T2b <input type="radio"/> Not available	<input type="radio"/> Nx <input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2 <input type="radio"/> N3  <input type="radio"/> Not available	<input type="radio"/> Mx <input type="radio"/> M0 <input type="radio"/> M1A <input type="radio"/> M1B <input type="radio"/> M1C  <input type="radio"/> Not available

**20. Record Stage: (COMPLETE IF 19.b.1, 19.b.2, OR 19.b.3 IS NOT AVAILABLE, OTHERWISE SKIP)**  
 Yes (COMPLETE 20.1, 20.2, 20.3)  No (GO TO PART E)

1. STAGE ONLY	2. AUA (WHITMORE) STAGING	3. SUMMARY STAGING
<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV  <input type="radio"/> Not available	<input type="radio"/> A <input type="radio"/> B2 <input type="radio"/> A1 <input type="radio"/> C1 <input type="radio"/> A2 <input type="radio"/> C2 <input type="radio"/> B <input type="radio"/> D1 <input type="radio"/> B1 <input type="radio"/> D2  <input type="radio"/> Not available	<input type="radio"/> Localized <input type="radio"/> Regional <input type="radio"/> Distant  <input type="radio"/> Not available

**GO TO PART E**

PLEASE DO NOT WRITE IN THIS AREA



044880

**PART D: DATE OF DIAGNOSTIC EVALUATION DETERMINATION**

**21.**

Complete this item if:

- Item A.9 = No malignancy and Item B.10 and Item B.11 = No **OR**
- Item A.9 = No malignancy and no diagnostic procedures performed **OR**
- Item A.9 = No information available

MO.		DAY		YEAR	
0	0	0	0	0	0
1	1	1	1	1	1
2	2	2	2	2	2
3	3	3	3	3	3
4	4	4	4	4	4
5	5	5	5	5	5
6	6	6	6	6	6
7	7	7	7	7	7
8	8	8	8	8	8
9	9	9	9	9	9

**PART E: PHYSICIAN/HOSPITAL LOCATION INFORMATION**

**22.**

**Physician for Diagnostic Evaluation:**

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

**23.**

**Hospital or Clinic for Diagnostic Evaluation:**

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

**24.**

**Comments:**

- No     Yes (SPECIFY)

Item #	Comments



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**DIAGNOSTIC EVALUATION - PROSTATE VERSION 3 (DEP3/DPQ3)**

This form is to be completed by the Medical Record Abstractor, a nosologist (trained medical coder), and a Tumor (or Cancer) Registrar who is also a Certified Tumor Registrar (CTR) or CTR - eligible. Items, which are to be completed by a nosologist or a CTR, are specified. The abstractor should complete all other items. Specifically, the nosologist will be required to complete Item B.11 (Other Cancer Diagnosis). The CTR will be required to complete Part C: Items C.12 (Date of Primary Prostate Cancer Diagnosis), C.13 (Verbatim Description of Primary Prostate Cancer Diagnosis), C.14 (ICD-O-2 Cancer Classification), C.15 (Photocopy of Report Confirming Primary Prostate Cancer), C.16 (Histopathologic Type for Primary Prostate Cancer), C.17 (Histopathologic Grade for Primary Prostate Cancer), C.18 (Gleason Score), C.19 (TNM Staging for Prostate Cancer) and C.20 (Record Stage).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry; it should not be obtained from the participant except in the case when the physician recommends against follow-up for an AS screening exam, and the decision cannot be verified by physician report or from the medical records. This applies only to A.1, and the report from the participant is acceptable documentation and the recommendation by the physician against follow up.. Written documentation from the physician or the medical record, for example, is preferable to obtaining information verbally.
- Information about diagnostic procedures could possibly be collected up to 12 months after the date of a positive screen (if a conclusive diagnosis or the next screening exam does not come first). In addition, information about complications of diagnostic procedures should be collected up to 12 months from the time diagnostic procedures began. In the event of a cancer diagnosis, medical complications should be collected for an additional 6 months after the diagnosis.
- Before beginning abstraction, the medical record documents should be placed in chronological order and the diagnostic/staging procedures should be abstracted chronologically. If, however, a diagnostic or staging procedure is identified and added after the form has been completed, it is not necessary to shift all of the data to maintain the chronological order; the new procedure may be added at the end of the appropriate item.
- This form includes items, which require that data be entered verbatim, such as recording diagnoses, recording "Other (specify)," and recording comments. Verbatim comments should be accurate and succinct. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If the medical record contains unclear, discrepant, or conflicting information for any item, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should first be consulted for a resolution and for making an appropriate coding decision, prior to contacting the CC MRA Coordinator.

- When recording information in the Comments section, be sure to identify the item to which the comment refers. Appropriate identification will aid in the analysis of Comments data. Throughout the specifications, examples have been given for recording information in Comments.

Below are some guidelines for the collection of diagnostic evaluation information:

- Information regarding diagnostic procedures that occurred prior to the participant's randomization date should not be recorded.
- Procedures that occurred prior to the date of the initial visit for clinical assessment (i.e., the first visit to a doctor for clinical assessment) should not be recorded, with the exception of procedures that are part of the diagnostic evaluation for a suspected cancer. In a control participant who is asymptomatic and undergoes a screening exam which prompts further evaluation, that screening exam should be recorded on the DE form in A.2, Reason for Initial Visit for Clinical Assessment under Other (Specify). The clinical exam that follows would be recorded in A.6, as well as any procedure done to evaluate for possible cancer. The screening PSA or DRE would not be recorded in A.3 or A.4, respectively, as these sections are reserved for diagnostic tests once there is a suspicion of cancer. If a screening test is positive or a participant experiences symptoms and a diagnostic procedure is performed before the participant actually visits the doctor, this diagnostic procedure should be recorded on the DE form (even though it took place prior to the initial visit for clinical assessment).

For example, in the case of a positive PLCO screen with a biopsy performed, the screen is the event that led to the initiation of diagnostic follow-up and should not be recorded, but the biopsy is the first procedure in the diagnostic follow-up process, and should be recorded.

- Following a positive screening exam, the SC should collect diagnostic evaluation information until:
  - a conclusive diagnosis (either malignant or non-malignant) is made, OR
  - 12 months after the date of the positive screen, OR
  - the next screening exam,

*whichever comes first.*

At the end of the 12 months or on the date of the next screen, if the diagnostic evaluation is not conclusively malignant, record the result of the diagnostic evaluation in Item A.9 as "No malignancy."

- An exception to the above is when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a prostate or other malignancy. In this situation it is not appropriate to record a conclusive diagnosis, but rather to record "No information available." *If a Lead Abstractor cannot conclusively determine the result of a diagnostic evaluation from the medical record, contact the CC MRA Coordinator.*

It is the SC's responsibility to encourage timely follow-up of positive screens. If, despite SC efforts, the participant does not initiate follow-up of a positive screen until late in the year, 10 months after the positive screen for example, the SC should still collect only the diagnostic evaluation data until 12 months after the positive screen or the next screen, whichever comes first. In the example given, this would mean two months of diagnostic evaluation data.

- All staging information related to the initial diagnosis of primary prostate cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEP form). Staging information on prostate cancer recurrence should not be collected.
- If multiple primary prostate cancers are diagnosed at the same time (i.e., as part of the same diagnostic evaluation process and prior to the first definitive treatment), it is necessary to complete portions of a separate DEP for each multiple primary. Item 7 (Multiple Primary Cancer #) allows the abstractor to indicate whether the DEP is being used for abstracting information about a multiple primary prostate cancer. If there are multiple primary cancers, each cancer should be recorded on a separate DEP3 form.
- A procedure should be abstracted onto both the Diagnostic Evaluation Form and the Treatment Information Forms if the procedure would be considered part of diagnosis and staging and initial treatment. Examples of this are prostatectomy and lymphaderectomy..

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy black marks that fill the circle completely.**



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled in. Darken the circle corresponding to each remaining number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized ("Final Complete" or "Final Incomplete"), erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the DE. If more than one abstractor completes the DE, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form -- this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.
3. **Nosologist ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item B.11 (ICD-9-CM Classification of Other Cancer Diagnoses). Darken the circles corresponding to the four digits.
4. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting specific items related to ICD-O-2 Classification and cancer diagnosis/staging in Part C. Darken the circles corresponding to the four digits.
5. **Study Year:** Record the study year, T0 to T13. This is the study year in which the SC was notified of a suspicion of prostate cancer. For example, if the cancer was reported on a T1 ASU, the study year for the DEP is T1. Darken the corresponding circles. Remember to right justify and zero-fill the number for study years T0 - T9 (e.g., T00, T01, T02, etc.).
6. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the "first" time to confirm a suspicion of prostate cancer. This includes an initial abstract for a multiple primary cancer (see Item 7).
  - **Re-abstract for QA:** Medical record information that has already been abstracted to confirm a suspicion of prostate cancer is being re-abstracted for the purpose of quality assurance. This includes a re-abstract for a multiple primary cancer (see Item 7). Not yet implemented.
7. **Multiple Primary Cancer #:** The purpose of this item is to indicate whether this form is being used to abstract information about an *additional* primary prostate cancer that was diagnosed at the same time as the first primary prostate cancer (i.e., as part of the same diagnostic evaluation and staging process, and before the first definitive treatment). Indicate the sequence number for the primary cancer. If this primary cancer is the second primary diagnosed (in chronological date order), darken the circle for "2." If it is the third, darken the circle for "3," etc. *If only one primary cancer was diagnosed, this item should be skipped.*

If the participant was diagnosed with more than one primary prostate cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For the first primary, the DEP must be completed in full (all parts). For all subsequent primaries, use another DEP form and complete the administrative section, Item A.9 (Result of Diagnostic Evaluation for Prostate Cancer), and Part C only. If more than one primary was diagnosed on the first date of diagnosis, designate the most advanced cancer diagnosed on that day as the "first primary" and complete the entire DEP form. Use additional DEP forms for any other cancers diagnosed on that day.

8. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except "Disposition" are optional. "Disposition" is required and may be marked on the form and/or entered directly into

DEES. Dispositions of "Final Complete" (FCM) may also be set automatically in DEES when the form is edited (See DEES User's Guide).

- **Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)
- **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)
- **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 of the MOOP for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
- **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
- **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
  - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data are abstracted, remove the ICM so that the appropriate disposition is assigned.
  - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report, or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
  - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **Part A: Diagnostic Evaluation and Staging:**

This section refers to the diagnostic evaluation and staging for prostate cancer. Abstracting this data will require careful review of the participant's medical records from one or more hospitals, clinics, or physicians' offices.

When abstracting information onto this form, do not include information from any physician/hospital visits or procedures that took place prior to the participant's date of randomization, even if these visits or procedures are related to a diagnosis which was made after the participant was enrolled in the trial.

1. **Diagnostic Procedures Performed:** The purpose of this item is to document whether or not a physician recommended and performed diagnostic procedures as part of the follow-up to a positive PLCO screening examination (DRE and PSA). If the DEP is being completed in response to prostate cancer being reported via an ASU, for example, if the participant was in fact diagnosed with cancer, it is assumed that diagnostic procedures were performed and this item should be coded "Yes." Darken the circle corresponding to the most appropriate response as follows:

**Yes:** The record indicates that diagnostic procedures were recommended by a physician and were performed. This includes situations when diagnostic procedures were performed to follow-up a positive PLCO screening exam or when prostate cancer was reported to the SC via an ASU.

**No, Physician Report:** The record indicated or the physician reported to the SC that based on review of the PLCO screening exam results, and possibly any medical history prior to the screening exam, no additional follow-up was deemed necessary. Complete Item A.9 (Result of Diagnostic Evaluation for Prostate Cancer) and Parts B, D and E of the form.

**No, Participant Self-Report:** The participant reported that his physician reviewed the PLCO screening exam results, and possibly other medical history prior to the screening exam, and deemed no additional follow-up was necessary. Complete Item A.9 (Result of Diagnostic Evaluation for Prostate Cancer) and Parts D and E of the form.

- *Before accepting a participant self-report the SC should first attempt to obtain written documentation from the participant's physician. If written documentation cannot be obtained from the physician, the SC should then attempt to obtain verbal confirmation from the physician's office that the physician did not recommend additional follow-up of the positive PLCO screening exam. In cases where only the participant's report of the physician's recommendation can be obtained, this circle should be darkened.*

2. **Reason for Initial Visit for Clinical Assessment:** The purpose of this item is to identify the participant's motivation for seeking clinical evaluation. Because motivation is sometimes not clearly stated in the record, NCI assumes that if a participant seeks medical care within 12 months of a positive screen, it is for the purpose of follow-up of that positive screen. If medical care is sought more than 12 months after a positive screen, NCI assumes that it is not for follow-up to a positive screen. Darken the circles corresponding to all the reasons that apply as follows:
  - **Symptomatic:** The record indicates that symptoms prompted the participant to seek a clinical evaluation.
  - **Follow-up of positive PLCO screen:** The record indicates that the participant went for an initial clinical evaluation to follow-up a positive PLCO screen, within 12 months of the positive screen.

- **Other (SPECIFY):** If the record indicates that the participant went for a clinical evaluation for a reason other than those listed, and specify the reason in the space provided. For example, if the participant is in the control arm, and undergoes a health surveillance screen which is positive and prompts further evaluation, indicate "other" and specify "Abnormal Non-PLCO PSA (or DRE)", whichever applies. Please indicate the result.
3. **Prostate Specific Antigen (PSA) Blood Test:** This item refers to whether the participant had at least one *diagnostic* PSA blood test performed for prostate cancer. Record the results and approximate date of the test.
- Do not record any PSA blood tests performed during the PLCO screening examinations.
  - Do not record any *screening* PSA blood tests in this section.
  - Do not record any PSA blood test unless it is part of the diagnostic evaluation for a suspected prostate cancer.
  - If a participant has several PSA blood tests within the 12 month period following a positive screen, NCI assumes that a conclusive diagnosis is not made until the results of the last PSA test are reported, regardless of whether the participant saw a physician during the time that the follow-up lab tests were performed.
  - Do not record any PSA tests completed after a diagnosis of prostate cancer is confirmed.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any PSA blood tests. Darken the circle for "No" and go to Item A.4.

**Yes:** The record indicates that the participant had one or more PSA blood tests performed. Darken the circle for "Yes" and complete the table for Item A.3. If space is needed to record additional PSA result data, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional PSA in Comments would be the fourth PSA blood test recorded:

Item E.24, Comments:

Item #	Comments
A.3	4; Level = __; Assay brand = __; Lab range = __ to __; Date = __

**Unknown:** If there is no indication in the record whether PSA blood tests were or were not performed, darken the circle for "Unknown" and go to Item A.4.

For each PSA blood test performed, complete the following items:

- **PSA Level:** Record the PSA level (ng/ml) for each blood test obtained as part of the diagnostic evaluation and staging and then darken the circle corresponding to each number.
- **PSA Assay Brand:** Darken the circle corresponding to the name of the PSA assay brand used by the lab. This information can be found on the lab report for the test.

- **Hybritech, Abbott, Yang, Bayer, and Diagnostic Products:** These are the most common PSA assay brands. Note that "IMx" is an assay produced by Abbott, and should be coded as "Abbott."
  - **Other (SPECIFY):** If the PSA assay brand is other than those listed, darken the circle for "Other (SPECIFY)" and record the assay brand name on the line provided.
  - **Not available:** The PSA assay brand name is not available in the record. It is not necessary to attempt to obtain this information if it is not available in the record.
- **Lab Range:** Record the reference range (ng/ml) used by the lab for the particular test. This information can be found on the lab report for the test. Darken the circles corresponding to the numbers. If lab range is not available in the medical record, record "9.9" in each of the spaces provided, i.e., "9.9" to "99.9." If the lab range uses operators such as > and <, report the range in a way that reflects the operator. For example, if the range is stated as "< 4.0" record the range as "0.0 to 3.9."
  - **Date of Test:** Record the month, day and year corresponding to each PSA blood test obtained. Month and day should be zero filled and four digits recorded for the year (e.g. 03/08/1994). If it is not clear from the record the day that the blood test was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number.
4. **Digital Rectal Examination (DRE):** This item refers to whether the participant had at least one *diagnostic* digital rectal examination for suspected prostate cancer. Record the date of the exam(s). A DRE may also be called a rectal exam.
- Do not record any DREs performed as part of the PLCO screening examinations or health screening exam.
  - Do not record any DRE unless it is part of the diagnostic evaluation for a suspected prostate cancer.
  - If 2 diagnostic DREs are done as part of the same procedure (i.e. ultrasound guided biopsy), record both of the DREs.
  - Do not record any DRE after a diagnosis of prostate cancer is confirmed.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any digital rectal exams. Darken the circle for "No" and go to Item A.5.

**Yes:** The record indicates that the participant had one or more digital rectal examinations. Darken the circle for "Yes" and complete the table for Item A.4. If space is needed to record additional DRE data, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional DRE in Comments would be the fourth DRE recorded:

Item E.24, Comments:

Item #	Comments
A.4	4; Date = __

**Unknown:** If there is no indication in the record whether digital rectal examinations were or were not performed, darken the circle for "Unknown" and go to Item A.5.

For each DRE performed, complete the following:

- **Date of Procedure:** Record the month, day, and year that the DRE was performed. If it is not clear from the record the day that the diagnostic/staging procedure was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day. Record four digits for year.
5. **Transrectal Ultrasonography (TRUS):** This item refers to whether the participant had at least one transrectal ultrasound examination, and if so, the date of the exam(s).
- Do not record any TRUS exam performed unless it is part of the diagnostic evaluation for a suspected prostate cancer.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any transrectal ultrasound examinations. Darken the circle for "No" and go to Item A.7.

**Yes:** The record indicates that the participant had one or more transrectal ultrasound examinations. Darken the circle for "Yes" and complete the table for Item A.5. If space is needed to record additional TRUS data, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional TRUS in Comments would be the fourth TRUS exam recorded.

Item E.24, Comments:

Item #	Comments
A.5	4; Dimensions = __, __, and __; Date = __

For each TRUS performed, complete the following items:

- **Prostate Dimensions:** Record the transverse (side to side), anteroposterior (front to back) and sagittal (top to bottom) dimensions of the prostate in centimeters, in the order in which they appear in the record.
  - Record only whole centimeters, not fractions. If rounding is necessary, use the rounding rules located in Appendix K of the MOOP.
  - Darken the circles corresponding to the numbers. If no information is available for one or more prostate dimensions, record "99" in the appropriate number of boxes.

- **Date of Procedure:** Record the month, day, and year that the TRUS was performed. If it is not clear from the record the day that the diagnostic/staging procedure was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**Unknown:** If there is no indication in the record whether transrectal ultrasonography examinations were or were not performed, darken the circle for "Unknown" and go to Item A.7.

6. **Pathologic Examination (Prostate Biopsy):** This item refers to whether the participant had at least one pathologic examination (biopsy of the prostate), and if so, the result and date of the exam(s).

- Record ALL biopsies related to the diagnostic evaluation for suspected prostate cancer, including any performed during the PLCO screening examinations. Consider a set of 6 or 10 part sampling biopsies as one collective biopsy, and record only once.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any biopsies of the prostate. Darken the circle for "No" and go to Item A.7.

**Yes:** The record indicates that the participant had one or more biopsies. Darken the circle for "Yes" and complete the table for Item A.6. If the record indicates that a biopsy was performed, but the tissue was lost, record the information in the table about the biopsy that is available. If space is needed to record information about more than three prostate biopsies, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional biopsy of the prostate in Comments would be the fourth biopsy recorded.

Item E.24, Comments:

Item #	Comments
A.6	4; Type = __; Location = __; Result = __; Date = __

**Unknown:** If there is no indication in the record whether or not biopsies of the prostate were or were not performed, darken the circle for "Unknown" and go to Item A.7.

For each biopsy performed, complete the following items:

- **Type of Biopsy:** Darken a circle to indicate the type of biopsy. Biopsy types are defined below:
  - 1 = **Cytological:** Cells obtained by needle aspiration, washings, smear, or scraping.
  - 2 = **Histological:** Tissue obtained by biopsy, such as a needle biopsy, core needle biopsy, or a tissue biopsy. This includes tissue biopsied from multiple sites. A histological biopsy may be obtained during a transrectal ultrasonography examination (TRUS) or when a transurethral resection of the prostate (TURP) is performed.

- 9 = **Not Available:** The type of biopsy was not available in the record.
- **Location of Biopsy:** Darken the circle(s) to indicate where the biopsy tissue was taken from as follows. Both "1" and "2" may be marked if applicable:
    - 1 = **Right Prostate:** Biopsy specimen was removed from the right side of the prostate.
    - 2 = **Left Prostate:** Biopsy specimen was removed from the left side of the prostate.
    - 9 = **Not available:** The prostate biopsy site was not available in the record.
  - **Result:** The way in which biopsy results are recorded in the participant's record may vary. Result codes, which may be used to record a biopsy result are located at the bottom of page 4 of the DEP form, and are defined below. Darken the circle corresponding to the result for each biopsy performed.
    - The result of biopsies of multiple sites of the prostate performed on the same date should be recorded as one biopsy procedure.
    - If the results of the biopsy differ for the different sites, the worst-case result should be recorded for the procedure.

If you are not able to assign a test result, place an asterisk beside Item A.6, and record the result verbatim in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.24, Comments:

Item #	Comments
A.6	Biopsy # _____ result stated as...

The Result Code definitions are as follows:

- 01 = Negative (normal):** The biopsy result was "negative," "normal", or "no indication of prostate cancer or other abnormality." The biopsy result may also be reported as "no evidence of prostate cancer seen at this time." A biopsy result of "benign" or "benign without hypertrophy" should also be coded as "Negative."
- 02 = Abnormal, not suspicious for prostate cancer:** The biopsy result was abnormal but not suspicious for prostate cancer. This includes dysplasia (not severe), prostatic intraepithelial neoplasia (PIN), granuloma, evidence of inflammation (chronic prostatitis), calcifications, stromal hyperplasia, focal glandular hyperplasia, or basal cell hyperplasia or benign prostatic hypertrophy (BPH). The pathology report may or may not state "no evidence of malignancy at this time."
- 04 = Abnormal, suspicious for prostate cancer:** The result of the biopsy was abnormal and suspicious for prostate cancer. This includes any abnormal or suspicious findings, such as severe dysplasia. This may also be reported as "not inconsistent with prostate cancer;" "cannot rule out prostate cancer, but not evident in specimen;" "R/O" (rule out) prostate cancer;" or "possible carcinoma of the prostate." A plan for additional testing, such as additional biopsies, and diagnostic

radiology procedures such as CT scans may indicate that there is a suspicion of cancer. In this situation, before recording a procedure result as "abnormal, suspicious for prostate cancer", be certain to review all supporting documentation in the medical record that additional tests were performed because cancer was suspected. The reasons for the additional tests will usually be recorded. If the reason is not recorded, however, the abstractor should code the result of the examination as "unknown." Just the fact of a biopsy is not sufficient to code the examination as abnormal-suspicious.

**05 = Abnormal, diagnostic of prostate cancer:** The biopsy result was diagnostic of prostate cancer. The report from the biopsy indicates carcinoma, adenocarcinoma, or malignancy.

**08 = Unsatisfactory (Inadequate):** The biopsy was inadequate to determine any abnormal or normal findings.

**09 = Inconclusive:** The result of the biopsy was inconclusive; the specimen was adequate but the physician/pathologist was unable to make a determination of the result.

**99 = Not available:** The result of the biopsy was not available in the record.

- **Date of Biopsy:** Record the month, day, and year that the biopsy was performed. Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

7. **Other Diagnostic/Staging Procedures:** This item is concerned with any diagnostic/staging procedures that the participant underwent during the evaluation for prostate cancer, other than PSA, DRE, TRUS or biopsy.

Darken the circle corresponding to whether the participant underwent other diagnostic/staging procedures as follows:

**No:** The record clearly states or indicates that the participant did not undergo any other diagnostic/staging procedures. Darken the circle for "No" and go to Item A.8.

**Yes:** The record states or indicates that the participant underwent one or more diagnostic/staging procedures for prostate cancer other than PSA, DRE, TRUS, or biopsy. Darken the circle for "Yes" and complete the table for Item A.7. If space is needed to record more than twelve diagnostic/staging procedures, use the Diagnostic/Staging Procedures Supplement (DSS) form (refer to Item A.7b).

**Unknown:** If there is no indication in the record whether other diagnostic/staging procedures were or were not performed, darken the circle for "Unknown" and go to Item A.8.

The following are general guidelines for identifying diagnostic and staging procedures in the medical record:

- Only procedures used to diagnose or stage a cancer that are clearly stated in the record (discharge summaries and operative reports) should be recorded. If the operative report and/or discharge summary is missing, procedures noted in doctor's notes or a history taken after the procedure may be used to record a diagnostic/staging procedure. The SC Lead Abstractor should contact the CC MRA Coordinator if there is any uncertainty about recording diagnostic/staging procedures.

- Only procedures, not approaches, should be recorded. The only time that an approach should be recorded is for a procedure that is strictly exploratory and which is not done for the purpose of a resection. The SC Lead Abstractor should contact the CC MRA Coordinator if there is any uncertainty about recording diagnostic/staging procedures.
- Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.
- Following a positive PLCO screening exam (DRE and PSA), the SC should collect information on diagnostic procedures until a conclusive diagnosis is made, or until 12 months from the date of the positive screen, or until the next screen, whichever comes first. If cancer is not diagnosed, and the clinician continues to order diagnostic PSAs and DREs within 12 months of the positive screen then a conclusive diagnosis has not been made (until the final test)
- All staging information related to the initial diagnosis of a primary prostate cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEP form.) Surgical resection of the primary organ, lymph nodes and other organs should be included. This also applies to the situation in which, after a diagnosis of prostate cancer, the next plan of action is other than therapy (i.e., watchful waiting). In this case, diagnostic/staging information would be collected up to the date when watchful waiting begins.
- Staging procedures performed after the start of the first definitive treatment should not be collected. Procedures to determine disease progression or the effect of treatment should not be recorded. The only exception would be surgery performed post neoadjuvant treatment. These post neoadjuvant procedures should be collected and the pathologic TNM staging should be completed using the Y-descriptor. Staging information in prostate cancer recurrence should not be collected.

For each diagnostic/staging procedure performed, complete the following items:

- **Type of Procedure:** Darken the circle corresponding to the type of diagnostic/staging procedure performed. Refer to the Procedure Codes for the list of diagnostic and staging procedures for prostate cancer. When the procedure on the Procedure Code list indicates "SPECIFY," describe the body site or the actual procedure, as appropriate. Refer to Appendix K-17-2 of the MOOP for an alphabetical listing of definitions and synonyms for the diagnostic/staging procedures listed on the DE forms. The following are guidelines for coding type of procedure:

- **Biopsy:**

Biopsies of the prostate should be recorded under Item A.6 (Pathologic Examination (Prostate Biopsy)). Both incisional and excisional biopsies of sites other than the prostate and lymph nodes should be recorded in Item A.7 as procedure type 10 = Other biopsy (SPECIFY). The specify line should be used to specify the site of the biopsy, not the method of the biopsy.

05 = Laparoscopic lymph node biopsy

10 = Other biopsy (SPECIFY): refers to biopsy of other organ excluding prostate and lymph nodes

- **Clinical Evaluation and Record Review:**

21 = Clinical evaluation: A clinical evaluation is defined as a visit to a health care provider for medical care and should include a history and physical exam related to the organ of interest. Generally this will be one of the first procedures recorded in the Diagnostic Evaluation for cancer. If a history includes information about the PLCO Screen only, this is to be considered a clinical evaluation. It does not include a telephone conversation to a health care provider. A clinical evaluation that only serves to repeat or confirm a previous finding should not be recorded. The following examples illustrate how the form should be completed to document a clinical evaluation:

- Although a visit to a health care provider that includes a history, as well as a digital rectal exam (DRE), is considered a clinical evaluation, this should be documented only once in Item A.4, Digital Rectal Examination. Do not make a separate entry in Item A.7, Other Diagnostic/Staging Procedures, as a clinical evaluation.
- If a visit to a health care provider includes a history and/or physical exam that contributes to ruling in or ruling out cancer and no DRE, then a clinical evaluation can be recorded using code 21 for the clinical evaluation in Item A.7, Other Diagnostic/Staging Procedures.

26 = Record review: This procedure should only be recorded when a review of the medical record is performed for the purpose of a second opinion of diagnosis, and a record review contributes to the diagnosis or staging of the cancer in question.

- **CT Scans:**

01 = CT scan - abdominal

22 = CT scan – abdomen and pelvis combined: If CT pelvic and CT abdominal procedures appear in the record as a combined procedure, they should be recorded as code 22 with one date. If they are performed on the same date, and appear in the record as separate procedures, the abstractor should record them separately, using codes 03 and 01 respectively.

02 = CT scan = other (SPECIFY)

03 = CT scan = pelvic

If a CT scan is performed as part of a diagnostic procedure, as in the case of a "CT guided biopsy," the CT scan should not be recorded as a separate procedure. In this case the CT scan is the approach or means to perform the biopsy.

- **Endoscopic Evaluation Procedures:**

17 = Cystoscopy

24 = Cystourethroscopy/Cystopanendoscopy

19 = Other endoscopy (SPECIFY)

18 = Proctosigmoidoscopy

- **Laboratory Tests:** PSA should be recorded in Item A.3. Preoperative prostatic acid phosphatase – PAP should be coded in Item A.7 as Procedure type “11” and the value obtained during the procedure should be recorded on the “Specify” line. If the value is not given, record “99” on the line. The normal values for PAP are 0.0 to 4.0 ng/ml. Do not record any other laboratory tests in Item A.7 including Free PSA or % Free PSA
- **MRI Scans:**
  - 07 = MRI scan – abdominal
  - 08 = MRI scan – other (SPECIFY)
  - 09 = MRI scan - pelvic
- **Other (SPECIFY) Procedures:** Use code 88 = Other (SPECIFY) to record procedures that cannot be listed using one of the other codes on the form.
- **Radiographic Procedures:**
  - 12 = Bone radiograph – Use this code for an x-ray of a bone, such as femur, or series of bones, such as lumbar spine or hip.
  - 13 = Chest radiograph: The first (chronological) chest radiograph found in the record, which contributes to the diagnosis or staging of the cancer in question, should be recorded. Additional chest radiographs should not be recorded unless they reveal a new abnormality that is diagnostic of cancer, which was not noted on the previous film.
  - 23 = Cystogram
  - 04 = Intravenous pyelography (IVP)/excretory urography
  - 06 = Lymphangiogram
  - 25 = Other radiograph (SPECIFY) – Use this code for x-rays of non -bone structures, such as a KUB or sinus series.
  - 14 = Radioisotope bone scan
  - 28 = Ureterogram
- **Surgical Procedures:**
  - 15 = TURP
  - 16 = Lymphadenectomy/Lymph node sampling:
    - If lymph node sampling and lymph node dissection are both performed, this should be considered as one procedure and
    - recorded only once as 16 = Lymphadenectomy/Lymph node sampling.
    - Lymph node removal accompanying surgical resection should be coded as two separate procedures. Use the appropriate code to record the resection and use 16 = Lymphadenectomy/Lymph node sampling to record the lymph node removal.
  - 20 = Prostatectomy
- **Ultrasound:**
  - 27 = Ultrasound (SPECIFY): Record the type of ultrasound performed on the specify line.

Please refer to Section A-8-6 of the MOOP, Diagnostic/Staging Procedures Supplement (DSS), for an additional listing of Diagnostic/Staging Procedures.

- **Date of Procedure:** Record the month, day, and year that the diagnostic/staging procedure was performed. If it is not clear from the record the day that the diagnostic/staging procedure was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year and the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**7b. Diagnostic/Staging Procedures Supplement Form Completed:** If space is needed for recording more than 12 diagnostic/staging procedures, darken the circle and go to the Diagnostic/Staging Procedures Supplement (DSS) form. Otherwise, do not darken the circle and go to Item A.8.

The DSS form provides eleven additional spaces for recording diagnostic/staging procedures, numbered 13 through 23. If there are more than 23 diagnostic/staging procedures, place an asterisk beside Item 4 (Diagnostic/Staging Procedures) on the DSS, and use the Comments section of the DEP to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example:

Item E.24, Comments:

Item#:	Comments:
A.7	24; Type = ___; Date =

Refer to the specifications for the DSS for additional information on completing the DSS.

**8. Medical Complications of Diagnostic Evaluation and Staging:** General guidelines for identifying selected medical complications from the medical record are given below:

- Only selected medical complications that were a result of the diagnostic evaluation or staging procedures and that required medical intervention should be recorded.
- Information on medical complications can usually be found in the discharge summary, or the doctor's or nurse's notes within the medical record.
- Medical complications should be collected up to 12 months after the time diagnostic procedures were initiated. In the event of a cancer diagnosis, medical complications should be collected through 6 months from the date of the cancer diagnosis.
- If more than one medical complication occurred during a particular event, record each selected medical complication, even if they occurred on the same date. Hospitalization, code 22, should be recorded only if the reason for hospitalization is not another selected medical complication. For example, in the case of fever requiring antibiotics and hospitalization, only record fever requiring antibiotics.

Darken the circle corresponding to medical complications as follows:

**No:** The record clearly states or indicates that none of the selected medical complications resulted from a diagnostic or staging procedure. Also mark this item if

no diagnostic/staging procedures were performed as part of the evaluation. Darken the circle for "No" and go to Item A.9.

**Yes:** The record states or indicates that one or more of the selected medical complications resulted from one of the diagnostic or staging procedures. If a participant had more than six medical complications, place an asterisk beside Item A.8, and use the Comments section to record the same data as requested in the table. In Comments, record the item numbers and labels followed by the data. Be certain to list the number associated with the complication next to "Type," rather than the text, which describes the complication. For example, fever requiring antibiotics was the seventh medical complication mentioned in the record:

Item E.24, Comments

Item #	Comments
A.8	7; Type = 2; Date = mm/dd/yyyy

Darken the circle for "Yes" and complete the table for Item A.8 as follows:

- **Type of Medical Condition:** Darken the circle corresponding to the type of medical complication that occurred. Refer to the Medical Complication Codes for the list of selected medical complications that required medical intervention for prostate cancer. Refer to Appendix K-17-2 of the MOOP for definitions and synonyms for the medical complications listed on the DE forms. The following are guidelines for recording some medical complications of Diagnostic Evaluation and Staging:

**1 = Infection (SPECIFY):** Specify the site or source of the infection on the line provided.

**22 = Hospitalization:** Use only if reason for hospitalization is not another selected medical complication.

**27 = Blood loss requiring transfusion:** Only record transfusion of blood if it involves giving red blood cells from a stored source, usually described as a unit of red blood cells. There can be a number of words that would apply - whole, packed, washed, irradiated, etc. The transfusion of red blood cells implies that the blood loss was significant enough to require a replacement of the red blood cells. Other types of fluids or blood products that do not include red blood cells, such as D5, saline (NaCl), platelets, albumin, or fresh frozen plasma should not be considered when recording blood loss requiring transfusion. The intra-operative recycling of blood lost, filtered, and returned immediately to participant will also not be considered equivalent to blood loss requiring transfusion and should not be recorded as a medical complication.

*The Lead Abstractor should consult with the CC MRA Coordinator if it cannot be determined if a medical complication should be recorded.*

- **Date of Complication:** Record the month, day and year that the medical complication began. If the day of the medical complication is not clear in the record, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**Unknown:** Only use this code when you may not have all of the medical record and you cannot reliably determine complications. Darken the circle for "Unknown" and go to Item A.9.

9. **Result of Diagnostic Evaluation for Prostate Cancer:** The purpose of this item is to record the overall results of the diagnostic evaluation for prostate cancer. This information should be found in the impression or conclusion sections of the various diagnostic and staging reports. It may also be found in a physician's note. Record the result of the diagnostic evaluation for prostate cancer as follows:

- **No malignancy:** The record indicates that no malignancy was found as a result of the diagnostic and staging procedures. A result of "No malignancy" should be coded in the following situations:
  - When a conclusive diagnosis is made following a positive screen and the diagnosis is not prostate or any other cancer. Include Prostatitis, BPH and Prostatic intraepithelial neoplasia (PIN). PIN and carcinoma in situ of the prostate are synonymous conditions.
  - When no diagnostic procedures are performed following a positive PLCO screening exam per documented physician recommendation (i.e., when Item A.1, Diagnostic Procedures Performed, is coded "No, physician report"), then no malignancy is assumed.
  - When diagnostic follow-up data have been abstracted for the period from a positive screen until 12 months past the positive screen or until the next screen (whichever came first) and the diagnosis was not conclusively malignant.
  - When the only diagnostic procedures performed during the 12-month follow-up were PSA tests and there is no cancer diagnosis.

Darken the circle and go to Part B: Diagnosis Information for Specific Conditions Other Than Prostate Cancer.

- **No malignancy and no diagnostic/staging procedures performed:** The participant reports that he/she had a follow-up visit with his/her physician who determined that there was no malignancy. No further diagnostic/staging procedures were performed. This information is not documented in the medical record and cannot be validated by the participant's physician. Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.
- **Prostate malignancy confirmed histologically (exclude carcinoma in situ):** The diagnosis of primary prostate cancer was confirmed by histologic examination (study of tissue). Histologic information can be found on the pathology report, sometimes called the histopathology report. Neoplasm of uncertain behavior of the prostate, carcinoid of the prostate, extranodal lymphoma arising in the prostate and sarcoma of the prostate should be recorded as a prostate malignancy. A diagnosis of carcinoma in situ of the prostate, also known as prostatic intraepithelial neoplasia (PIN), should not be recorded as a prostate malignancy. Darken the circle and go to Part C, Primary Prostate Cancer Diagnosis Information. Included in this response is when the basis of the prostate cancer diagnosis is from tissue obtained from a metastatic site.
- **Prostate malignancy confirmed cytologically:** The diagnosis of primary prostate cancer was confirmed by cytologic examination (study of cells). Cytologic information can be found on the cytology report, sometimes called a cytopathology report. Neoplasm of uncertain behavior of the prostate, carcinoid of the prostate, extranodal lymphoma arising in the prostate and sarcoma of the prostate

should be recorded as a prostate malignancy. A diagnosis of carcinoma in situ of the prostate, also known as prostatic intraepithelial neoplasia (PIN), should not be recorded as a prostate malignancy. Darken the circle and go to Part C, Primary Prostate Cancer Diagnosis Information.

**NOTE:** *If the prostate malignancy was confirmed by both histologic and cytologic examination, information should be abstracted only from the histopathology report (even if the cytology result is earlier). In such cases, the correct response to A.9, Result of the Diagnostic Evaluation, is "Prostate Malignancy Confirmed histologically". The histopathology pathology report is more definitive, and therefore, every attempt should be made to verify if one exists before utilizing cytologic confirmation.*

- **Prostate malignancy diagnosed by clinical examination only:** The record indicates that the participant was diagnosed with primary prostate cancer by clinical examination not confirmed by histologic examination (study of tissue) or cytologic examination (study of cells). This includes a prostate malignancy that is diagnosed secondary to bone metastasis. It is an extremely rare event, however, for a malignancy to be confirmed only by clinical examination and not histologically or cytologically. Darken the circle and go to Part C: Primary Prostate Cancer Diagnosis Information.

In these cases there will be a 12-month "holding period" to be sure that no pathologic confirmation followed. The following guidelines should be used to determine if the diagnosed "clinically" code is appropriate:

- If the initial response is "clinically" but within this 12-month period there is pathologic confirmation, the diagnosis should be changed to either "histologically" or "cytologically" and the diagnosis date should be updated.
- If the initial response is "clinically" and treatment is given right away, the clinically code becomes validated and should remain.
- If the initial response is "clinically" but after 12 months there is no follow-up or treatment, then the diagnosis is questionable and should be changed to "no malignancy".
- If the initial response is "clinically", but the lack of treatment is due to other reasons, such as advanced stage of disease, participant refusal, etc., the clinically diagnosed result should remain on the DE form.

Darken the circle and go to Part C, Primary Prostate Cancer Diagnosis Information.

- **Other malignancy confirmed histologically or cytologically:** The diagnosis of a malignancy *other* than primary prostate cancer was confirmed by histologic examination (study of tissue) and or cytologic examination (study of cells). Histologic information can be found on the pathology report, sometimes called the histopathology report, and cytologic information can be found on the cytology report, sometimes called a cytopathology report. Darken the circle and go to Part B: Diagnosis Information For Specific Conditions Other Than Prostate Cancer.

This answer category should also be coded if the diagnostic evaluation for primary prostate cancer reveals a malignancy (including a prostate malignancy) that is a metastasis from a primary cancer site other than the prostate. In this situation, the primary cancer site should be recorded in Part B: Diagnosis Information For Specific Conditions Other Than Prostate Cancer, Other Cancer Diagnosis.

NOTE:

- If the participant was diagnosed with another primary PLCO malignancy (lung, colorectal, or ovarian) while undergoing an evaluation for prostate cancer, the appropriate Diagnostic Evaluation form (DEL, DEC, or DEO) must also be completed, unless previously confirmed.
- If the participant was diagnosed with a malignancy other than one of the PLCO cancers, an Other Cancer Form (OCF) must also be completed, unless previously confirmed.

- **No information available:** There is equivocal or no information available in the record regarding the result of the diagnostic evaluation for prostate cancer. "No information available" should also be coded in the situation when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a prostate or other malignancy.

Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.

**Part B: Diagnosis Information for Specific Conditions Other Than Prostate Cancer:**

This section is to document specific prostate diagnoses and/or other cancer diagnoses, which resulted from the diagnostic evaluation. Other cancer diagnoses may include neoplasms of uncertain behavior, carcinoids, sarcomas, lymphomas, and other malignancies that have an origin other than the prostate. Specific prostate diagnoses include prostatitis, benign prostatic hypertrophy (BPH) and prostatic intraepithelial neoplasia (PIN). This information will most likely be obtained directly from the participant's physician when the SC contacts the physician during follow-up of a positive PLCO screening exam. Depending on the extent of the information available and the physician's preference, the requested information may be obtained either verbally by phone or via written documentation. The diagnosis should be recorded from documents in the medical record that are prefaced with "Diagnosis/Impression/Conclusion/Assessment." The physician diagnosis can be from a source other than the original diagnosing physician as long as the source states the physician's original diagnosis. One example is a progress note written by a follow-up physician. A pathology report documenting a benign condition is also an appropriate source. Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.

10. **Specific Prostate Diagnosis:** This item is concerned with benign conditions that are specific to the prostate. These include only prostatitis, benign prostatic hypertrophy (BPH), and prostatic intraepithelial neoplasia (PIN).

Darken the circle corresponding to a specific prostate diagnosis as follows:

**No:** The record clearly states or indicates that none of the specified prostate diagnoses were determined as a result of diagnostic or staging procedures. Use "No" if result of diagnostic evaluation is another conclusive non-cancer prostate diagnosis that is not listed on the form. Also mark this item if there is no information for physician diagnosis or if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to Item B.11.

**Yes:** The record states or indicates that one or more specific prostate diagnoses were determined as a result of diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for Item B.10 as follows:

- **Diagnosis:** Darken the circle corresponding to the type of specific prostate diagnosis that was found. Mark only one diagnosis per column. The types of specific prostate diagnoses, determined as a result of diagnostic/staging procedures for prostate cancer, are defined below:
  - 1 = Prostatitis:** The record indicates that the participant had either acute or chronic prostatitis, an inflammation of the prostate, determined as a result of diagnostic/staging procedures. Synonym: Chronic Inflammation.
  - 2 = Benign prostatic hypertrophy (BPH):** The record indicates that the participant had benign prostatic hypertrophy, a benign condition of the prostate whereby the prostate is enlarged, determined as a result of diagnostic/staging procedures.
  - 3 = Prostatic intraepithelial neoplasia (PIN):** The record indicates that the participant had prostatic intraepithelial neoplasia (PIN), a premalignant hyperplastic condition of the prostate, determined as a result of diagnostic/staging procedures. Use this code for carcinoma in situ of the prostate.
- **Date of Diagnosis:** Record the month, day and year that the specific prostate diagnosis was made. If the exact day of diagnosis cannot be determined from the record, year and month can usually be assessed. In this situation, record the exact month and year. Record the day as "99." Zero fill month and day, and record four digits for year. The diagnosis date should reflect the date that there is a conclusive diagnosis. For example, if a participant has a prostate biopsy that does not confirm cancer, and continues to get diagnostic PSA blood tests within 12 months of the positive screen, the date of diagnosis should be the final PSA (within the 12-month period).

11. **Other Cancer Diagnosis:** This item is concerned with cancer diagnoses other than the prostate. Other cancer diagnoses may also include neoplasms of uncertain behavior, carcinoids, sarcomas, lymphomas, and other malignancies that have an origin other than the prostate. Lung carcinoma in situ is also an other cancer, but do not include carcinoma in situ of the prostate and colon. These diagnoses must be classified according to ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification). ICD-9-CM coding for the PLCO Screening Trial must be consistent with the National ICD-9-CM coding standards and should not be influenced by specific institutional coding philosophies.

Darken the circle corresponding to an other cancer diagnosis as follows:

**No:** The record clearly states or indicates that no other cancers were diagnosed as a result of diagnostic or staging procedures. Also mark this item if there is no information for physician diagnosis or if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to Part D.

**Yes:** The record states or indicates that one or more other cancer diagnoses were determined as a result of diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for Item B.11 as follows:

- **ICD-9-CM Classification:** These items must be completed by a nosologist (a trained medical coder). The nosologist should code the five digit ICD-9-CM classification in the space provided and darken the circles corresponding to

each number or letter. When coding ICD-9-CM, always left justify the code and ignore the decimal place. If the ICD-9-CM code is a three or four digit code, record "X" for the remaining blank box(es). The following examples illustrate how the ICD-9-CM code boxes should be coded:

- The ICD-9-CM code for Hodgkin's disease, unspecified site is 201.90. This should be coded as "20190."
- The ICD-9-CM code for malignant neoplasm of the bladder is 188.9. This should be coded as "1889X."
- The ICD-9-CM code for malignant neoplasm of the thyroid gland is 193. This should be coded as "193XX."

**Note:** If the diagnostic evaluation results in an extranodal lymphoma of the lung or colorectum, assign the appropriate ICD-9-CM code for the type of lymphoma with "0" as the 5th digit denoting "extranodal." An "OCF" will be triggered. Complete an "MDF" for the OCF and manually set the expectation for the appropriate DE form. Complete the DEL or DEC for the lung or colorectal lymphoma.

- **Date of Other Cancer Diagnosis:** Record the month, day and year that the other cancer diagnosis was determined. If the day of the other cancer diagnosis is not clear in the record, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.
- **More Than Two "Other" Cancer Diagnoses:**  
Record codes for more than two "other" cancer diagnoses in Item E.24, Comments, as shown in the following example:

Item E.24, Comments:

Item #	Comments
B.11	3; ICD-9-CM Classification = ____; Date of Other Cancer Diagnosis = mm/dd/yyyy

Be sure to set an expectation in the SMS for any additional "other" cancers.

If Part B is completed, skip Part C and go to Part D.

**Part C: Primary Prostate Cancer Diagnosis Information:**

In this section we are interested in obtaining all relevant information pertaining to a primary prostate cancer diagnosis, including lymphoma arising in the prostate, sarcoma, neoplasm of uncertain behavior of the prostate, and/or a carcinoid of the prostate. This section is to be completed only by a CTR or CTR-eligible individual. Every attempt should be made to complete this form in a timely manner. For participants who have a positive PLCO screening result, the Medical Record Abstract-DEP Form should be completed within six months of the positive screening result. If specific items cannot be completed within the six - month time

frame (i.e., awaiting access to photocopy a document or awaiting TNM staging by the Tumor or Cancer Registrar), those items should be left blank and the information completed within nine to eleven months.

If the participant was diagnosed with more than one primary prostate cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For all subsequent primaries, use another DEP form. If more than one primary was diagnosed on the first date of diagnosis, record information about the most advanced cancer diagnosed on that day in Part C, and use additional DEP forms for any other cancers diagnosed on that day.

**12. Date of Primary Prostate Cancer Diagnosis:** Record the month, day and year of the primary prostate cancer diagnosis that was confirmed by histopathology (tissue) or by cytopathology (cells) if histopathology is not available. This is the date on the report that the actual procedure (biopsy, surgery, aspiration of cells, etc.) was performed that confirmed this primary prostate cancer diagnosis. Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report. For example, the date on the pathology report may be the date that the slides were read or the date that the diagnosis was determined or reported, rather than the date of the operative procedure.

If there are multiple reports that confirmed this primary cancer, *record the earliest date available that has an adequate histopathology specimen*. If a histopathology is not available, record the earliest date that has an adequate cytopathology specimen. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. In the rare situation in which prostate cancer was diagnosed by clinical examination only and not histologically or cytologically, the date of first prostate cancer diagnosis is the date of the clinical examination, which diagnosed the cancer.

Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year. *Month and year of prostate cancer diagnosis must be known*, however, if day is unknown, record "99."

**13. Verbatim Description of Primary Prostate Cancer Diagnosis:** This item is concerned with the actual physician diagnosis of prostate cancer. This item is optional except in the following situations:

- The diagnosis is based on clinical examination and not pathology (Item A.9 = Prostate malignancy diagnosed by clinical examination only); or
- The SC is unable to obtain a copy of the histology or cytology report that corresponds to the ICD-O-2 code in Item C.14 (Item C.15 = Not available).

Record the verbatim description of the primary prostate cancer diagnosis from the histopathology report (or cytopathology report if a histopathology report is not available). The verbatim description should come from the diagnosis section of the earliest (chronological) histopathology report (or cytopathology report if the histopathology report is not available) that had an adequate specimen and that confirms the cancer diagnosis.

- Occasionally, the diagnosis section will say "see above" or "see microscopic." In this situation record verbatim all of the information from the appropriate section of the report which pertains to the cancer diagnosis.
- Do not record any information about metastases or recurrent cancer.
- Do not record any information about benign conditions listed in the diagnosis section of the histopathology or cytopathology report.

- If the prostate cancer was diagnosed by clinical examination only, record the verbatim description as reported in the note of the clinical examination from the medical record.

**14. ICD-O-2 Cancer Classification:** This item is for classifying the physician diagnosis of the primary prostate cancer, according to ICD-O-2 (International Classification of Diseases for Oncology, Second edition, 1990). The CTR should code the ten digit ICD-O-2 classification in the space provided. Darken the circles corresponding to the letter and each number.

- The ICD-O-2 code/histopathology should reflect the diagnosis from the earliest (chronological) pathology report, that has an adequate tissue specimen, (or cytopathology report if the histopathology report is not available) which confirms the cancer diagnosis. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. This should be the same report that was used as a source for the date of diagnosis in Item C.12. If the basis for the diagnosis was tissue from a metastatic site such as lymph node or bone, record the grade as 9 (unknown).

- A neoplasm of uncertain behavior of the prostate is considered to be cancer by NCI and should be recorded in this section: Use the following guidelines for ICD-O-2 coding of neoplasm of uncertain behavior of the prostate:

- Assign the topography and morphology codes for this neoplasm according to ICD-O-2.
- The behavior code for neoplasms of uncertain behavior is "1." Under "Behavior," enter "1" in the box and darken the circle for "1" printed on the form.
- Grade will be coded "9" for neoplasms of uncertain behavior. Under "Grade", enter a "9" in the box and darken the circle for "9" printed on the form.

*If the medical record contains information about this neoplasm that would result in a behavior code other than "1" or a grade code other than "9," contact the CC MRA Coordinator.*

- If the record clearly indicates that prostate cancer was confirmed by a histopathology or cytopathology report, but the report is not available, code the diagnosis from other available documents, (i.e., physician's notes, progress reports, etc.) that reference the earliest procedure from an adequate specimen. Place an asterisk by Item C.15, and indicate in the Comments section the source of the diagnosis. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.24, Comments:

Item #	Comments
C.15	Histopathology/cytopathology report not available. Source of diagnosis is...

- If the prostate cancer was diagnosed by clinical examination only, code the diagnosis using the report from the clinical examination form, which diagnosed the cancer.
- The ICD-O-2 cancer classification should be coded by the CTR regardless of whether the ICD-O-2 code is available in the medical record.

- If there is no mention of Histopathologic Grade of the cancer from the prostate gland, but there is a Gleason's pattern or Gleason's score, you may use the following table to convert the Gleason's number to Histopathologic Grade.

<b>Gleason Pattern</b>	<b>Gleason Score</b>	<b>Histologic Grade</b>	<b>Histopathologic Grade for Primary Prostate Cancer</b>
1,2	2,3,4	I Well differentiated	G1
3	5,6,7	II Moderately differentiated	G2
4,5	8,9,10	III Poorly differentiated	G3-4

- Use the following guidelines to determine how to record a diagnosis of extranodal lymphoma of the prostate for PLCO. Refer to Appendix K-17-2 of the MOOP for explanation of Nodal vs. Extra-Nodal Lymphoma:
  - If an extranodal lymphoma of the prostate is designated as the primary, record this lymphoma on the DEP3 form and assign the ICD-O-2 topography code corresponding to the prostate. Be sure this is the primary site of origin and not just a site where a biopsy was taken. The TI form is required for each DE, as it is for any PLCO primary.
  - If the site or origin is determined to be the lymph node(s) obtained as part of the evaluation for prostate cancer, record this lymphoma in Part B.11. When scanned, this will set on expectation for an OCF.
  - If a lymphoma is diagnosed as both a nodal and an extranodal lymphoma of the prostate, consult the SC principal investigator to determine where the lymphoma originated and code the primary to that site.
  - If an extranodal lymphoma arising in another PLCO site is discovered during the diagnostic evaluation of the prostate, the ICD-9-CM code for lymphoma will be entered in Part B of the DE form. This code will trigger an OCF. The SC will complete an MDF (for the OCF) and manually set the expectation for the appropriate DE. For example, an extranodal lymphoma of the colon is discovered as a result of the diagnostic evaluation of a positive prostate screen. The ICD-9-CM code for the type of lymphoma will be entered in Part B of the DEP, with "0" as the 5th digit denoting "extranodal." An OCF will be triggered. Complete an MDF (for the OCF) and manually set the expectation for a DEC. Complete the DEC for the extranodal lymphoma arising in the colon. Complete the TIC also.
  - If an extranodal lymphoma arising in the prostate is reported on an ASU, the SC will need to use the three-digit PLCO code for the organ, rather than the three-digit code for lymphoma in order to trigger the appropriate DE form. Complete the DEP for the extranodal lymphoma arising in the prostate. Complete the TIP also.
- Extranodal lymphomas arising in the prostate may require the T-cell, B-cell, or NK cell designation. If so, enter the appropriate code from ICD-O-2 in the "Grade" space. The T-cell, B-cell or NK cell designation has priority over the grade when both are provided. NK cell designation = "8." A bubble for "8" does not exist on the form. Darken the space for "8" under "Grade" for NK cell if this applies.

- Do not code the descriptions “high grade,” “low grade,” or “intermediate grade” for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.

**15. Photocopy of Report Confirming Primary Prostate Cancer:** The purpose of this item is to document that the histopathology report (or cytopathology report if a histopathology report is not available) that confirmed the primary prostate cancer has been photocopied and attached to the Medical Record Abstract-DEP Form.

- If there are multiple pathology reports confirming this primary prostate cancer, the photocopy should be of the pathology or cytology report which was the source for recording the date of prostate cancer diagnosis recorded in Item C.12, and the ICD-O-2 code recorded in Item C.14. If the Date of Prostate Cancer Diagnosis and the ICD-O-2 Cancer Classification came from different reports, attach copies of both reports used to code Items C.12 and C.14.
- A situation may arise in which an institution does not allow the photocopying of records. Every reasonable attempt should be made to obtain permission to photocopy the histopathology or cytopathology report since it is a critical end-point of the screening trial. If special permission or approval is required, the abstractor should work with the SC Coordinator/Principal Investigator to obtain the necessary approval. If this item cannot be completed in a timely manner, leave it blank and attempt to obtain the information at a later date via data retrieval.

Darken the circle to indicate whether a photocopy of the histopathology or cytopathology report is available as follows:

- **Pathology/Histopathology:** The histopathology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEP Form. The photocopy should be labeled with the participant's ID number, the study year, titled “Medical Record Abstract-DEP/Pathology Report,” and inserted into the participant's folder.
- **Cytology/Cytopathology:** The Cytopathology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEP Form. The photocopy should be labeled with the participant's ID number, the study year, titled “Medical Record Abstract-DEP/Cytology Report,” and inserted into the participant's folder.
- **Not available:** The histopathology or cytopathology report exists in the medical record, but a photocopy cannot be obtained or there is no report in the medical record. Place an asterisk by Item C.15, and provide a detailed explanation in the Comments section of why the pathology or cytology report cannot be obtained. (In this situation, Item C.13 (Verbatim Description of Prostate Cancer Diagnosis) must be completed.) Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.24, Comments:

Item #	Comments
C.15	Pathology or cytology report cannot be obtained because...

**16. Histopathologic Type for Primary Prostate Cancer:** This item is to document the histopathologic type of the primary prostate cancer. This refers to the type of cell comprising the tumor, usually determined by the pathologist from a tissue specimen. This information can be obtained from the pathology report that confirmed the pros-

tate cancer and collected the most tissue. If a pathology report is not available, this information may be found in the discharge summary, operative report, or in a cytology report. If the histopathologic type is obtained from a source other than the pathology report, place an asterisk by Item C.16, and record the source of the information in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.24, Comments

Item #	Comments:
C.16	Source of histopathologic type of lesion is...

- If the cancer has two different histopathologic types, the diagnosis is usually based on the predominant type. This should be stated in the pathology report. In this situation, record the predominant histopathologic type. If the pathology report does not indicate a predominant type record both types in Other (SPECIFY) for Item C.16 as follows: "Histopathologic type is \_\_\_\_\_ and \_\_\_\_\_."
- **The abstractor should select the general category into which the result fits rather than using Other-specify to list a more detailed result.** For example, "Infiltrating adenocarcinoma," "Scirrhous adenocarcinoma," and "Superficial spreading adenocarcinoma" should all be included in the "Adenocarcinoma, NOS" category.
- **Neoplasm of uncertain behavior of the prostate:** Histopathologic Type for Neoplasm of uncertain behavior of the prostate will be designated as "Other". Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- **Extranodal lymphoma arising in the prostate:** Histopathologic Type for Extranodal lymphoma arising in the prostate will be designated as "Other". Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- **Primary sarcoma of the prostate:** Histopathologic Type for Primary sarcoma of the prostate will be designated as "Other". Darken the circle for "Other" and record the specific histopathologic type on the line provided.

Darken the circle corresponding to the histopathologic type of the prostate cancer. If the histopathologic type is other than those listed, darken the circle for "Other" and specify the histopathologic type. If the histopathologic type is unknown or not available in the record, darken the circle for "Unknown."

**17. Histopathologic Grade for Primary Prostate Cancer:** This item is to document the histopathologic grade of the primary prostate cancer. Grade refers to a system of classifying certain characteristics of the cell. This information can be obtained preferably from the histopathology report of the procedure that collected the most tissue. When that is not available, one may use a cytology report, a TNM form, a staging classification form, the discharge summary, or from doctor's notes.

- If the medical record states two different histopathologic grades, or a range of grades, record the most severe type. For example, "well differentiated (slight anaplasia)" is the least severe type and "poorly differentiated or undifferentiated (marked anaplasia)" is the most severe type. The most severe grade should be recorded from the primary site. Do not record the most severe grade from the metastatic site.

- If there is no mention of Histopathologic Grade, but there is a Gleason pattern or Gleason score, you may use the following table to convert the Gleason number to Histopathologic Grade.

Gleason Pattern	Gleason Score	Histologic Grade	Histopathologic Grade for Primary Prostate Cancer
1,2	2,3,4	I Well differentiated	G1
3	5,6,7	II Moderately differentiated	G2
4,5	8,9,10	III Poorly differentiated	G3-4

- **Neoplasm of uncertain behavior of the prostate:** Neoplasm of uncertain behavior of the prostate usually does not have a grade designation; therefore, "Grade cannot be assessed (GX)" should be recorded. If the medical record contains information about this neoplasm that would result in a specific grade, contact the CC MRA Coordinator.
- **Extranodal lymphoma arising in the prostate:** If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown". Do not code the descriptions "high grade", "low grade", or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.
- **Primary sarcoma of the prostate:** If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown."

Darken the circle corresponding to the histopathologic grade of the prostate cancer. Darken the circle for "Unknown" when there is no indication in the record of the histopathologic grade or if the basis for the diagnosis of prostate cancer is from a metastatic site such as bone or a lymph node.

18. **Gleason Score:** The Gleason score, also known as the Gleason grading system, is a measure of prostate cell growth and behavior. Gleason's system assigns histologic grade to predominant (primary) and lesser (secondary) pattern of tumor from 1-5: The grade numbers of the two patterns are added to obtain the Gleason score, which may range from 2 to 10. Darken the circle corresponding to the Gleason score as it appears in the record.

- If the medical record states two Gleason patterns numbers instead of the final Gleason score, the combined score should be recorded. (For example, if the medical record states a Gleason score of "4 + 5," record the combined score of "9.") 6. Or if only Gleason patterns are noted, and not added to derive the Gleason score, record the sum of the two predominant Gleason patterns. If only one Gleason pattern is noted, meaning there is only one pattern type noted, double the score to derive the Gleason score.
- If, during the diagnostic process, two different (total) Gleason scores are assigned as a result of two different procedures (example: initial biopsy and resection), the highest Gleason score should be recorded. An asterisk should be placed next to Items C.18 and the remaining Gleason score with the source such as biopsy or prostatectomy should be recorded in Comments. Also note the source. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.24, Comments

Item #	Comments:
C.18	Additional Gleason score = ____; source = prostate biopsy

- **Neoplasm of uncertain behavior of the prostate:** Darken the circle for "99 – Not available". Gleason's score is not assigned to a neoplasm of uncertain behavior. If the medical record contains information about this neoplasm that would result in a Gleason's score, contact the CC MRA Coordinator.
- **Extranodal lymphoma arising in the prostate:** Darken the circle for "99 – Not available". Gleason's score is not assigned to an extranodal lymphoma arising in the prostate. If the medical record contains information about this neoplasm that would result in a Gleason's score, contact the CC MRA Coordinator.
- **Primary sarcoma of the prostate:** Darken the circle for "99 – Not available". Gleason's score is not assigned to a primary sarcoma of the prostate. If the medical record contains information about this neoplasm that would result in a Gleason's score, contact the CC MRA Coordinator.

If the Gleason score is not available in the record, darken the circle for "99."

19. **TNM Staging for Primary Prostate Cancer:** This item refers to the TNM or AJCC (American Joint Committee on Cancer) Staging system. The AJCC Manual for Staging of Cancer provides the minimum requirements for clinical and pathologic staging. A list of relevant documentation, based on those requirements can be found below. If TNM staging was performed, darken the circle corresponding to the edition of the AJCC Cancer Staging Manual used, the 4th Edition or the 5th Edition.

**Note:** The 5th Edition of the AJCC manual was published in January 1998. This latest edition should be used to stage all cancers diagnosed on or after January 1, 1998. For all previous cases the 4th Edition should be used.

TNM staging describes the anatomic extent of disease based on three components:

- (1) the extent of the primary tumor (T),
- (2) the absence or presence and extent of regional lymph node metastases (N), and
- (3) the absence or presence of distant metastases (M).

The addition of numbers to these three components indicates the extent of the malignant disease, thus showing progressive increase in tumor size or involvement.

If the TNM staging is available in the medical record, the abstractor may record it directly from the record. This staging is often performed by a Tumor Registrar (also known as a Cancer Registrar) and, if not available in the medical record, it may be available in the tumor registry. If the TNM staging is not available in the tumor registry, the abstractor should attempt to have the stage classified by the Tumor Registrar at a later date. The Tumor Registrar must be a CTR or CTR-eligible. If the TNM staging is not in the records or if the abstractor disagrees with the staging, the CTR may assign the TNM stage when all relevant documentation from the patient's medical record is available to him/her. If an institution does not have a Tumor Registrar, then a physician can assign the TNM stage as long as all relevant patient documentation is

available to the physician. *The nosologist or abstractor should not assign the TNM staging, unless s/he is also a CTR (or CTR-eligible) and all relevant documentation is available.*

If a participant receives neoadjuvant therapy prior to surgical resection, NCI would like the abstractors to do Clinical Staging of the Primary Cancer. Then record the TNM Pathologic Staging, using surgical pathology. In this situation TNM Pathologic Staging should be recorded as follows:

- Complete the item for TNM Pathologic Staging using the surgical pathology report.
- Place an asterisk next to the item number and go to the Comments section in Part D.
- Record the item number in the left margin of the Comments section and begin with the phrase, "ypT\_N\_M", including the appropriate numerical stage of the carcinoma which was recorded in Part C, TNM Pathologic Staging. "y" is a TNM descriptor that indicates that staging was performed during or following multi-modal therapy and the "p" indicates pathologic staging. After the appropriate information has been included in the "ypTNM" format, briefly state what treatment was received prior to surgery.

Item E.24, Comments

Item #	Comments:
C.19.b	ypT_N_M_; Treatment received prior to surgery was...

### **General Guidelines for NX vs. N0 and MX vs. M0:**

The X category should be used when involvement of regional lymph nodes or distant metastatic sites was not evaluated or could not be evaluated. It is not sufficient to assume that an evaluation would have been negative (or positive). If there is a statement in the record documenting the physician's assessment of regional lymph nodes and/or metastatic sites as negative or not involved, without physical examination, imaging, or other diagnostic procedures, this may be used to assign 0 rather than X. The use of category 0, as in N0 or M0, means that no involvement was found after some type of evaluation including appropriate work-up and/or the physician's clinical impression.

**NOTE:** SCs should photocopy any documents from medical records that are used for TNM staging, and keep these with the participant's file.

#### **a. TNM Clinical Staging**

If both clinical and pathological staging are available, both should be recorded. Clinical staging is based on the assessment of the anatomic extent of disease before instituting definitive therapy. All information available prior to the first definitive treatment of primary prostate cancer may be used for TNM clinical staging. Enough information must be available about the primary tumor to determine if the tumor is confined to the prostate. Relevant documentation that is suggested to assign clinical staging includes:

- Physical examination;

- Digital rectal examination (DRE), to include the use of screening DRE to stage the tumor clinically - the CTRs will also use the worst result DRE to determine the clinical tumor stage;
- Imaging, including transrectal ultrasound (TRUS), intravenous pyelogram (IVP), kidney-ureters-bladder X-ray, abdominal and/or pelvic CT scans, lymphangiogram, and MRI;
- Endoscopy, including cystoscopy and proctosigmoidoscopy;
- Laboratory tests, including PSA, and acid phosphatase; and
- Histologic or cytologic confirmation.

Darken the circle to indicate whether the TNM clinical staging is available as follows:

**Yes:** If the TNM Clinical Staging is available, or *at least some part of it is available*, darken the circle for “Yes” and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to “Not available” in the column(s) for which the code is not available.

- Note that the TIC category is reserved for tumor unsuspected by the clinicians, so is not palpable on DRE examination. Those tumors that are not palpable on DRE examination but visible on TRUS will remain T1c for research purposes (as clinically undetected).
- Note that a clinically detected prostate cancer, e.g. T2a, would require an abnormal suspicious DRE that prompts the biopsy (for cancer confirmation).
- For a tumor to be clinically staged as T2a, the cancer that is confirmed must be on the same side as the abnormality that is noted on the DRE. Should the participant have an AS DRE exam, and the cancer is not found on the side of the abnormality, but on the opposite side that did not have palpable abnormality suspicious for cancer, then the tumor stage would remain clinically inapparent (T1c).

**No:** If no part of the TNM clinical staging is available, then darken the circle for “No” and skip to C.19b, TNM Pathologic Staging. “No” should also be recorded in the following situations:

- **Neoplasm of uncertain behavior of the prostate:** TNM clinical staging does not apply to neoplasms of uncertain behavior of the prostate.
- **Extranodal Lymphoma arising in the prostate:** TNM clinical staging does not apply to extranodal lymphoma arising in the prostate.
- **Primary sarcoma of the prostate:** TNM clinical staging does not apply to primary sarcoma of the prostate.

## b. TNM Pathologic Staging

Relevant documentation necessary to assign pathologic staging includes:

- Any data for clinical staging;
- Total prostatectomy; and
- Pelvic lymph node dissection.

*Note that transurethral resection of the prostate is not adequate surgery to use for pathologic staging. It may be possible to assign pathologic staging without total prostatectomy if a biopsy of the bladder neck, external sphincter,*

rectum, levator muscles, or any positive lymph node confirms the highest category for T or N.

Darken the circle to indicate whether the TNM pathologic staging is available as follows:

**Yes:** If the TNM Pathologic Staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available.

**No:** If no part of the TNM Pathologic Staging is available, then darken the circle for "No" and skip to Item C.20, Record Stage. "No" also applies to the following situations:

- **Neoplasm of uncertain behavior of the prostate:** TNM pathologic staging does not apply to neoplasms of uncertain behavior of the prostate.
- **Extranodal Lymphoma arising in the prostate:** TNM pathologic staging does not apply to extranodal lymphoma arising in the prostate.
- **Primary sarcoma of the prostate:** TNM pathologic staging does not apply to primary sarcoma of the prostate.

**20. Record Stage:** *If TNM Pathologic Staging is complete, this item must be skipped. If any part of the TNM Pathologic Staging is not available or is incomplete (i.e., "Tx", "Nx", or "Mx"), this item must be completed.* This item is to document the stage of disease (other than TNM staging) for primary prostate cancer. There are three stage classifications provided for prostate cancer: "Stage Only," "AUA Staging," and "Summary Staging." AUA staging is also known as Whitmore staging.

- If information about one or more of the stage classifications is not available in the medical record, it is not necessary to try to obtain it from another source.
- If a stage classification other than those provided on the form is available in the record and all or part of TNM Pathologic Staging is not available, place an asterisk beside Item C.20, and record in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.24, Comments

Item #	Comments
C.20	Other Stage Classification is _____. Stage = ____

- If stage is available for an extranodal lymphoma arising in the prostate, for a primary sarcoma of the prostate, or for any other type of primary prostate malignancy that cannot be staged using TNM, complete Item C.20.

Darken the circle to indicate whether stage of disease is available as follows:

**Yes:** If "Stage Only," "AUA Staging," and/or "Summary Staging" is available, darken the circle for "Yes" and then darken the circles corresponding to the code for each. If stage of disease is not available for any particular classification, darken the circle next to "Not available" in the appropriate column.

**No:** If no information is available about any of the three stage classifications, "Stage Only," "AUA Staging," or "Summary Staging" in the record, darken the circle for "No" and skip to Part D, Physician/Hospital Location Information.

- **Neoplasm of uncertain behavior of the prostate:** Darken the circle for "No." Typically, a neoplasm of uncertain behavior is not staged. If the medical record contains staging information about this neoplasm, contact the CC MRA Coordinator.
- If no stage of disease information is available, it is not necessary for the abstractor to obtain it from another source. Also, the abstractor should not attempt to code stage of disease unless s/he is a Certified Tumor Registrar (CTR) or CTR-eligible. If the abstractor is a CTR, or is CTR-eligible, and has all of the necessary documentation for determining the stage of disease, then s/he may code stage of disease and record it following the guidelines above.

#### **Part D: Date of Diagnostic Evaluation Determination:**

21. Complete this item by recording the month, day and year of the diagnostic evaluation determination if one of the following conditions is satisfied:

- Item A.9 = No malignancy and Items B.10 and B.11 = No. The date of diagnosis should correspond to the procedure with the latest date, or
- Item A.9 = No malignancy and no diagnostic procedures were performed (per participant self report) or
- Item A.9 = No information available

Darken the circle corresponding to each number. If the exact date of diagnostic evaluation determination cannot be determined from the record, the specific year and the month can be assessed and should be recorded. In this situation, record the exact month and year. Record the day as "99". Zero fill month and day, and record four digits for year.

#### **Part E: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant underwent diagnostic evaluation for prostate cancer, other than what was reported prior to abstracting. Items E.22 and E.23 are not required, but it is recommended they be completed to facilitate collection of additional medical record data, including pathology reports and slides. This section also includes the comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while information recorded in the comments item will be entered.

22. **Physician for Diagnostic Evaluation:** Record the name, address, and telephone number of the primary physician who provided care during the participant's diagnostic evaluation for prostate cancer and/or the physician who performed the diagnostic evaluation procedures. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise, record the physician's hospital address. Record the participant's medical record or chart number for each physician location.

23. **Hospital or Clinic for Diagnostic Evaluation:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent one or more diagnostic procedures for prostate cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.

24. **Comments:** Use this section to record any overflow information. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should review the discrepant information for the appropriate coding decision prior to contacting the CC MRA Coordinator.

*Do not darken the "Yes" or "No" circles at the top of page 12 if Comments continues on this page. Leave the circles blank. Comments "Yes" "No" circles should only be darkened on page 11 of the form.*

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as in the following example when a fourth PSA Blood Test should be collected:

Item #	Comment:
A.3	4; PSA level =__ ; PSA Assay Brand =__ ; Lab Range =__ to __ ; Date =__

- First enter the item number indicating the item to which the comments are related, and record the comments in the space provided to the right of the item number.
- Throughout these specifications, standard phrases are given to preface comments so they will be easier to locate during analysis. Please use these phrases at the beginning of the comments, if applicable.
- Place an asterisk next to the item number being referenced in the main body of the DEP form.
- If more space is needed, darken the circle next to "Continued" on the bottom of p. 12, and record additional comments on a Comments Continuation Form (CCF).

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM TREATMENT INFORMATION - PROSTATE (TIP2/TPQ2)

**1. Date Abstracted:**

MO.	DAY	YEAR
		20
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

**2. Abstractor ID #:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**3. CTR ID#:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**4. Study Year T0-T13:**

T	0	0
	1	1
	2	2
	3	3
	4	4
	5	5
	6	6
	7	7
	8	8
	9	9

**5. Purpose of Abstract:**

Initial abstract  
 Re-abstract for QA

### FOR OFFICE USE ONLY

**6. Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)**

**Data Entry of Non-Scannable Items:**      **Data Retrieval:**

Form Received into SMS       Completed       None Required       Attempted       None Required

Manual Review Completed

**Disposition:**

Interim Complete (ICM)       Final Complete (FCM)       Final Incomplete (FIC)

### PART A: INITIAL TREATMENT INFORMATION

**1. RADIATION TREATMENT FOR PROSTATE CANCER:**

No       Yes (COMPLETE TABLE BELOW)       Unknown

TREATMENT #	1	2																																																																		
DATE RADIATION TREATMENT BEGAN (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		

DesignExpert™ by NCS    Printed in U.S.A.    Mark Reflex® EW-153460-4-654321    HC05

PLEASE DO NOT WRITE IN THIS AREA



009037

**PART A CONTINUED . . .**

**2. SURGICAL TREATMENT FOR PROSTATE CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

PROCEDURE #	1	2	3	4																																																																																																																																				
<b>TYPE OF SURGICAL PROCEDURE</b>  (SEE SURGICAL PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 03 04 06 07 08 09 10 11 12 13 88  SPECIFY	01 02 03 04 06 07 08 09 10 11 12 13 88  SPECIFY	01 02 03 04 06 07 08 09 10 11 12 13 88  SPECIFY	01 02 03 04 06 07 08 09 10 11 12 13 88  SPECIFY																																																																																																																																				
<b>DATE OF SURGERY</b>  (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						

**SURGICAL PROCEDURE CODES**

- |  |  |
|--|--|
| 01 = Pelvic node dissection (lymphadenectomy), surgical          | 09 = Cryosurgery   |
| 02 = Pelvic node dissection (lymphadenectomy), laparoscopic      | 10 = Anatomic (unilateral nerve sparing) prostatectomy, retropubic |
| 03 = Radical prostatectomy, perineal                             | 11 = Anatomic (bilateral nerve sparing) prostatectomy, retropubic  |
| 04 = Radical prostatectomy, retropubic                           | 12 = Prostatectomy, NOS  |
| 06 = Subtotal/simple prostatectomy with lymph node dissection    | 13 = Laser prostatectomy   |
| 07 = Subtotal/simple prostatectomy without lymph node dissection | 88 = Other (SPECIFY)   |
| 08 = Transurethral resection                                     |  |

**3. HORMONAL TREATMENT FOR PROSTATE CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2	3																																																																																																			
<b>DATE HORMONAL TREATMENT BEGAN</b>  (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**PART A CONTINUED . . .**

**4. OTHER TYPE OF TREATMENT FOR PROSTATE CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2																																																																		
<p>DATE OTHER TREATMENT BEGAN</p> <p>(MO. - DAY - YEAR)</p>	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">MO.</th> <th style="width: 10%;">DAY</th> <th style="width: 10%;">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">MO.</th> <th style="width: 10%;">DAY</th> <th style="width: 10%;">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		

**5. ANY LOCAL OR REGIONAL RESIDUAL DISEASE LEFT AFTER SURGERY:**

No     Not applicable  
 Yes - Microscopic                       Unknown  
 Yes - Gross Tumor  
 Yes - Elevated PSA

**PART B: PHYSICIAN/HOSPITAL LOCATION INFORMATION**

**6. PHYSICIAN FOR TREATMENT:**

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City                      State                      ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City                      State                      ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

**7. HOSPITAL OR CLINIC FOR TREATMENT:**

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City                      State                      ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City                      State                      ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM: TREATMENT INFORMATION - PROSTATE**  
**VERSION 2 (TIP2/TPQ2)TIP SPECIFICATIONS**

This form is to be completed by the Medical Record Abstractor and the CTR or CTR - eligible individual. Specifically, the CTR will be required to complete Item A.5 (Any Local or Regional Residual Disease Left After Surgery).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- When abstracting date information for items with multiple treatments, record the dates in the order in which they are found in the medical record.
- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry. If the treatment is considered to be a non-traditional therapy that would not usually be mentioned in a medical record, it is acceptable to take the participant's self-report. In all other cases, a therapy that is not mentioned in the medical records should not be recorded.
- Information about treatment procedures should be collected for the first planned course of treatment (usually within 6 months of the cancer diagnosis). The maximum time period for which medical records could be collected for treatment information is about 1 year from the date of a cancer diagnosis.
- This form includes items, which require that data be entered verbatim, such as recording "other (specify)," and recording comments. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If additional space is needed to record treatment information, use the Comments section. Record the same type of data as requested in the treatment table.
- If any item has unclear, discrepant, or conflicting information, review the information with the SC Lead Abstractor, SC Coordinator or the Principal Investigator.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy black marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
  - Mark only one response for each question, unless the instructions tell you otherwise.
  - Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.
- 

**Administrative Section:**

Participant ID: Affix a Participant ID label to the space provided in the lower left corner of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled in. Darken the circle corresponding to each remaining number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized, erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the TI. If more than one abstractor completes the TI, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form-this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.
3. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item A.5. (Any Local or Regional Residual Disease Left After Surgery). Darken the circle corresponding to the four digits.
4. **Study Year:** Darken the circles corresponding to the study year, from T0 to T13. Zero-fill the number for T0 - T9 (e.g., T00, T01, T02, etc.).
5. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the "first" time to confirm the treatment of prostate cancer.

- **Re-abstract for QA:** Medical record information that has already been abstracted to confirm the treatment of prostate cancer is being re-abstracted for the purpose of quality assurance. Not yet implemented.
6. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except "Disposition" are optional. "Disposition" is required and may be marked on the form or entered directly into DEES. Dispositions of "Final Complete" (FCM) may also be set automatically in DEES when the form is edited (See DEES User's Guide).
- **Form Received into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)
  - **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)
  - **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
  - **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
  - **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
    - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data are abstracted, remove the ICM so that the appropriate disposition is assigned.
    - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
    - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **Part A: Initial Treatment Information:**

In this section, record all treatments that make up the first course of treatment the participant received for prostate cancer.

- If the treatment is intended as initial management, it should be recorded, regardless of the time frame or treatment site.
- If the first course of treatment is directed toward a metastatic site, it is appropriate to code this treatment.
- Combination Treatments: If multiple treatments are given in combination, enter the date treatment began for the combination treatments. If another treatment is added to the combination (or one is removed), the new combination should be considered a new treatment with a new start date.
- Time period Rules for First Course of Treatment (in order of precedence):
  1. If there is a documented, planned first course of treatment, first course ends at the completion of this treatment plan, regardless of the duration of the treatment plan.
  2. If the patient is treated according to a facility's standards of practice, first course ends at the completion of the treatment.
  3. If there is no documentation of a planned first course of treatment or standard of practice, first course of treatment includes all treatment received before disease progression or treatment failure. If it is undocumented whether there is disease progression/treatment failure and the treatment in question begins more than one year after diagnosis, assume that the treatment is not part of the first course.
  4. If a patient refuses all treatment modalities and does not change his/her mind within a reasonable time frame, or if the physician opts not to treat the patient, record that there was no treatment in the first course.
- If treatment is given for symptoms/disease progression after a period of "watchful waiting," this treatment is not considered part of the first course. For example, if a physician and patient choose a "wait and watch" approach to prostate cancer and the patient become symptomatic, consider the symptoms to be an indication that the disease has progressed and that any further treatment is not part of the first course.
- All modalities of the initial course of treatment are included regardless of sequence or the degree of completion of any component method.

Reference: SEER Program Code Manual, Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute; 1998, p.119.

- If there is a significant treatment that is not in the first course of treatment and the abstractor and the SC Principal Investigator feel it should be recorded, this will need to be sent to the CC MRA Coordinator. The relevant medical records should be copied (identifiers deleted) and sent to the CC MRA Coordinator with a memo describing the issue.
1. **Radiation Treatment for Prostate Cancer:** This item is concerned with the radiation treatment the participant received for prostate cancer. Radiation treatment most commonly consists of either external photon beam therapy or brachytherapy (intra-peritoneal implant). More rarely, radiation treatment may consist of either neutron or proton external beam therapy. Note that this item is concerned with radiation treatment and not diagnostic x-rays such as a CT scan.

External photon beam therapy is delivered by a machine, which generates x-rays or contains a large amount of a radioactive isotope (cobalt), or delivered by a linear accelerator. External beam treatments are given in one or more "series" or "courses." Each course of radiation is administered over a period of days or weeks in small daily doses.

Brachytherapy is a method of radiotherapy in which radioactive sources are applied on the external surface of the patient, implanted in tissue, or inserted into body cavities. Brachytherapy procedures usually are performed in an operating room since they require anesthesia. Although the brachytherapy treatment may be performed in a surgical suite and recorded in surgical notes, it is radiotherapy and should be recorded as such for purposes of describing the participant's treatment.

Some institutions may have the capability to deliver neutron beam therapy, via a hospital based high-energy cyclotron, or proton beam therapy, via a hospital-based synchrotron. Treatment via these modalities is usually administered in "courses" or "series" over a period of time. Most institutions, however, find these machines impractical for a hospital setting due to their cost and size.

Darken the circle corresponding to whether the participant received radiation treatment as follows:

**No:** The record clearly states that the participant did not receive radiation treatment, or there is no mention of radiation treatment (planned or given) in the records. Darken the circle for "No" and go to Item 2.

**Yes:** The record indicates that the participant received radiation treatment. Darken the circle for "Yes" and complete the table for Item 1. Record information for each course of radiation treatment received in a separate column. For each radiation treatment, complete the following:

- **Date Radiation Treatment Began:** Record the month, day and year that the radiation treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional radiation treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional radiation treatment in Comments would be the third radiation treatment recorded:

Item B.8, Comments:

Item #	Comments
A.1	3; Date = ____

**Unknown:** The record states that a radiation treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 2.

2. **Surgical Treatment for Prostate Cancer:** This item is concerned with the surgical treatment that the participant received, including TURP procedures, if appropriate. Complete this item as follows:

**No:** The record clearly states that the participant did not receive surgical treatment, or there is no mention of surgical treatment (planned or given) in the records. Darken the circle for "No" and go to Item 3.

**Yes:** The record indicates that the participant received surgical treatment. Darken the circle for "Yes" and complete the table for Item 2. For each surgical procedure performed, complete the following items:

- **Type of Surgical Procedure:** Darken the circle corresponding to the type of surgical procedure performed. Refer to the Surgical Procedure Codes for the list of common surgical procedures for prostate cancer and to Appendix K-17-2 of the MOOP for definitions of surgical procedures for the prostate. If the participant had a surgical procedure other than those listed, darken the circle for "Other (SPECIFY)" and record the surgical procedure performed on the line provided.

If the surgical procedure includes resection of the prostate with removal of lymph nodes is performed, this should be coded as two separate procedures using the appropriate code for surgical resection and code "01" or code "02" for the lymph node removal.

- **Date of Surgery:** Record the month, day and year that the surgical procedure was performed. If the date is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional surgical procedures, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional surgical treatment in Comments would be the fifth surgical treatment recorded:

Item B.8, Comments:

Item #	Comments
A.2	5; Type = ___; Date = ___

**Unknown:** The record states that a surgical treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 3.

3. **Hormonal Treatment for Prostate Cancer:** This item is concerned with any hormonal treatment the participant received for prostate cancer. Hormonal treatments attempt to deprive prostatic tumors of circulating androgens and thereby produce regression of both primary and metastatic lesions. Hormonal treatment may include orchiectomy (the excision of both testes), or administration of a hormone such as estrogens, antiandrogens (Flutamide), etc.

Hormonal therapy may be the primary treatment, prescribed in cases of advanced cancer, or may be an adjuvant treatment, given in addition to surgery and/or radiation.

The participant's medical record may or may not contain hormonal treatment data. Unlike surgery and radiation treatments, which must be performed at a hospital or clinic, hormonal treatment may be administered at a physician's office. In addition, it may be self-administered under the guidance and supervision of a physician. It is, therefore, especially important that the abstractor carefully review the record and, if necessary, contact the physician for information on hormonal treatment.

Darken the circle corresponding to whether the participant received hormonal treatment as follows:

**No:** The record clearly states that the participant did not receive hormonal treatment, or there is no mention of hormonal treatment (planned or given) in the records. Darken the circle for "No" and go to Item 4.

**Yes:** The record indicates that the participant received hormonal treatment. Darken the circle for "Yes" and complete the table for Item 3. For each type of hormonal treatment received, complete the following:

- **Date Hormonal Treatment Began:** Record the month, day and year that the hormonal therapy was begun for a particular course. If the date is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional hormonal treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional hormonal treatment in Comments would be the fourth hormonal treatment recorded:

Item B.8, Comments:

Item #	Comments
A.3	4; Date = ____

**Unknown:** The record states that a hormonal treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 4.

4. **Other Type of Treatment for Prostate Cancer:** This item is concerned with any treatment other than surgery, radiation and hormonal treatment that the participant received for prostate cancer. Other types of treatment include chemotherapy, hyperthermia, new drugs, biologic therapy, and alternative treatments. Do not record "Watchful Waiting" as a Type of Treatment for Prostate Cancer.

Darken the circle corresponding to whether the participant received some other type of treatment as follows:

**No:** The record clearly states that the participant did not receive any other type of treatment, or there is no mention of other treatments (planned or given) in the records. Darken the circle for “No” and go to Item 5.

**Yes:** The record indicates that the participant received some other type of treatment. Darken the circle for “Yes” and complete the table for Item 4. For each type of treatment received, complete the following:

- **Date Other Treatment Began:** Record the month, day and year that the other type of therapy began. If the date is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as “99”. Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record other type of treatments for prostate cancer, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional other type of treatment for prostate cancer in Comments would be the third other type of treatment for prostate cancer recorded:

Item B.8, Comments:

Item #	Comments
A.4	3; Date = ____

**Unknown:** The record states that an “other” treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for “Unknown” and go to Item 5.

5. **Any Local or Regional Residual Disease Left After Surgery:** This item is to be completed only by a CTR or a CTR-eligible individual. This item documents whether the participant had any local or regional residual disease left after surgery. Record information for this item for any attempted surgical procedure even if the procedure was not completed. Surgery is defined as any of the surgical procedures listed in Item 2. If there are multiple surgeries, use the results of the last surgery in the first course of treatment to answer the question. For prostate cancer only, “local” is defined as in the prostate bed. Regional residual disease is defined as a cancer that remains after surgery and is related to the original site by direct extension. This regional disease refers to the site of the surgery (not necessarily the site of the primary cancer). It does not apply to metastases. Information should be taken from the pathology report since this is the most definitive source for determining residual disease and the operative report may be used for further clarification. If neither pathology nor operative reports are available, a discharge summary or doctor's note with treatment plan may be used to record this item. “Perineural or vascular invasion” noted on a surgical pathology report does not infer that regional or residual disease is left after surgery. The pathology report refers only to the specimen or tissue removed during surgery, not to the tumor that remains following surgery. Darken the circle corresponding to whether the participant had any local or regional residual disease left after surgery as follows:

**No:** The record indicates that the participant had no local or regional residual disease left after surgery. Darken the circle for “No” and go to Item 6.

**Yes - Microscopic:** The record indicates that the participant had local or regional residual disease left after surgery which was microscopic (of minute size). The pathology report may state "tumor to surgical margin" or "involves capsule." Darken the circle for "Yes - Microscopic" and go to Item 6.

**Yes - Gross Tumor:** The record indicates that the participant had local or regional residual disease left after surgery which was a tumor remaining in the pelvic wall, colon, anus or rectum. The pathology report may state "gross residual disease remaining with nearby structural invasion." Darken the circle for "Yes - Gross Tumor" and go to Item 6.

**Yes - Elevated PSA:** The record indicates that the participant had local or regional residual disease left after surgery from an elevated PSA level that was performed after surgery. Participants who have undergone a radical prostatectomy should have an undetectable level of PSA in the blood. An elevated PSA is any measurable PSA detected in the blood following surgery. Darken the circle for "Yes - Elevated PSA" and go to Item 6. This is only recorded if there is no other evidence for gross or microscopic disease.

If a participant has had a transurethral resection, it is virtually certain that there is residual disease remaining after surgery.

The highest order of evidence should be coded. For example, if the operative report notes that gross disease remains, then "gross" should be coded. But if the report notes that there were positive surgical margins without gross evidence of disease, the "microscopic" response should be used.

**Not applicable:** The participant did not receive any surgical treatment for prostate cancer or Item A.2, Surgical Treatment for Prostate Cancer, is "No" or "Unknown". Darken the circle for "Not applicable" and go to Item 6.

**Unknown:** The record does not mention if the participant had local or regional residual disease left after surgery, or the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 6.

## **Part B: Physician/Hospital Location Information:**

In this section, record physician and hospital location information where the participant received treatment for prostate cancer. Items B.6 and B.7 are not required, but it is recommended that they be completed to facilitate collection of additional medical record data. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

6. **Physician for Treatment:** Record the name, address, and telephone number of the primary physician who provided care during the participant's treatment for prostate cancer and/or the physician who provided or administered the treatment. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.
7. **Hospital or Clinic for Treatment:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent treatment for prostate cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.
8. **Comments:** Use this section to record comments and any overflow information while abstracting from the participant's medical record. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or dis-

crepant information, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should review the discrepant information for the appropriate coding decision prior to contacting the CC MRA Coordinator.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as follows. First enter the item number indicating the item to which the comments are related. Record the comments in the space provided to the right of the item number as in the following example when a fifth Surgical Procedure for Prostate Cancer should be collected:

Item #	Comment:
A.2	5; Type = ____; Date = ____

Place an asterisk next to the item number being referenced in the main body of the TIP form. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

## **A-8-2**

A-8-2: Lung Cancer Medical Record Abstract Forms  
(DEL3, TIL2)

[Diagnostic Evaluation and Treatment Information]

Specifications for the Lung Cancer Medical Record  
Abstract Forms

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM DIAGNOSTIC EVALUATION - LUNG (DEL3/DLQ3)

1.	Date Abstracted:			2.	Abstractor ID #:	3.	Nosologist ID #:	4.	CTR ID#:	5.	Study Year T0-T13:	6.	Purpose of Abstract:
	MO.	DAY	YEAR										
		20								T		<input type="radio"/> Initial abstract <input type="radio"/> Re-abstract for QA	
	0 0 0 0		0 0										
	1 1 1 1		1 1										
	2 2 2 2		2 2										
	3 3 3 3		3 3										
	4 4 4 4		4 4										
	5 5 5 5		5 5										
	6 6 6 6		6 6										
	7 7 7 7		7 7										
	8 8 8 8		8 8										
	9 9 9 9		9 9										

**FOR OFFICE USE ONLY**

8. **Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)**

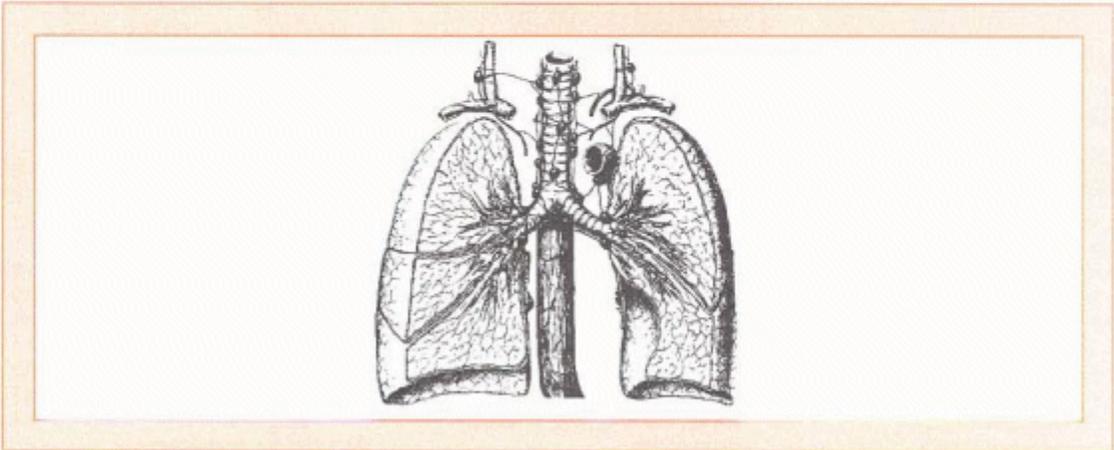
**Data Entry of Non-Scannable Items:** Form Received into SMS  Completed  Manual Review Completed

**Data Retrieval:** Attempted  None Required

**Disposition:** Interim Complete (ICM)  Final Complete (FCM)  Final Incomplete (FIC)

**PART A: DIAGNOSTIC EVALUATION AND STAGING**

1. <b>Diagnostic Procedures Performed:</b>	2. <b>Reason for Initial Visit for Clinical Assessment:</b>
<input type="radio"/> Yes <input type="radio"/> No, Physician report <input type="radio"/> No, Participant self-report } (GO TO A.5)	(MARK ALL THAT APPLY) <input type="radio"/> Symptomatic <input type="radio"/> Follow-up of positive PLCO screen <input type="radio"/> Other (SPECIFY) _____



**PART A CONTINUED . . .**

**3. Diagnostic/Staging Procedures: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**

No       Yes (COMPLETE TABLE BELOW)       Unknown

PROCEDURE #	1	2	3																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88																																																																																																			
	<b>SPECIFY</b>	<b>SPECIFY</b>	<b>SPECIFY</b>																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
	MO.	DAY	YEAR																																																																																																			
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
<b>PROCEDURE #</b>	<b>4</b>	<b>5</b>	<b>6</b>																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88																																																																																																			
	<b>SPECIFY</b>	<b>SPECIFY</b>	<b>SPECIFY</b>																																																																																																			
<b>DATE OF PROCEDURE</b> (MO.- DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
	MO.	DAY	YEAR																																																																																																			
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**PROCEDURE CODES**

- |   |  |  |   |
|---|--|--|---|
| 01 = Bronchoscopy<br>02 = Chest radiograph<br>04 = Clinical evaluation<br>05 = CT scan - brain<br>06 = CT scan - chest<br>07 = CT scan - liver<br>08 = CT scan - other (SPECIFY)<br>09 = Cytology (sputum, bronchial, washing/brushing)<br>10 = Mediastinoscopy/mediastinotomy<br>11 = MRI scan - brain<br>12 = MRI scan - chest<br>13 = MRI scan - liver | 14 = MRI scan - other (SPECIFY)<br>15 = Biopsy, needle aspiration (SPECIFY)<br>16 = Biopsy, lymph node - other (SPECIFY)<br>17 = Biopsy, other (SPECIFY)<br>18 = Pulmonary function tests/Spirometry<br>19 = Radionuclide scan - bone<br>20 = Radionuclide scan - brain<br>21 = Radionuclide scan - liver<br>22 = Biopsy, scalene (supraclavicular) lymph nodes<br>23 = Biopsy, surgical open<br>24 = Thoracotomy<br>25 = Biopsy, transthoracic needle aspiration (TBNA) | 26 = Biopsy, transthoracic needle aspiration (TNA)<br>27 = Resection<br>28 = Thoracoscopy<br>30 = Bone radiograph<br>31 = CT scan - chest and upper abdomen<br>32 = CT scan - abdomen and pelvis combined<br>33 = Biopsy, endobronchial<br>34 = Fluoroscopy<br>35 = Gallium scan<br>36 = Biopsy, liver | 37 = Lymphadenectomy/Lymph node sampling<br>38 = MRI scan - bone<br>39 = Radiograph, other (SPECIFY)<br>40 = CT scan, spiral - chest<br>41 = Thoracentesis<br>42 = Biopsy, transbronchial<br>43 = Ultrasound (SPECIFY)<br>44 = Ventilation perfusion lung scan/scintigraphy<br>45 = Internal referral<br>46 = Record review<br>88 = Other (SPECIFY) |
|---|--|--|---|

**PART A CONTINUED . . .**

PROCEDURE #	7	8	9																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse; text-align:center;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; text-align:center;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; text-align:center;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
	MO.	DAY	YEAR																																																																																																			
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
SPECIFY	SPECIFY	SPECIFY																																																																																																				
PROCEDURE #	10	11	12																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse; text-align:center;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; text-align:center;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; text-align:center;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
	MO.	DAY	YEAR																																																																																																			
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
SPECIFY	SPECIFY	SPECIFY																																																																																																				
<b>3b. DIAGNOSTIC/STAGING PROCEDURES SUPPLEMENT FORM COMPLETED</b> <input type="radio"/>																																																																																																						

**PROCEDURE CODES**

- |  |  |  |   |
|--|--|--|---|
| 01 = Bronchoscopy<br>02 = Chest radiograph<br>04 = Clinical evaluation<br>05 = CT scan - brain<br>06 = CT scan - chest<br>07 = CT scan - liver<br>08 = CT scan - other (SPECIFY)<br>09 = Cytology (sputum, bronchial, washing/brushing)<br>10 = Mediastinoscopy/mediastinotomy<br>11 = MRI scan - brain<br>12 = MRI scan - chest<br>13 = MRI scan - liver<br>14 = MRI scan - other (SPECIFY)<br>15 = Biopsy, needle aspiration (SPECIFY) | 16 = Biopsy, lymph node - other (SPECIFY)<br>17 = Biopsy, other (SPECIFY)<br>18 = Pulmonary function tests/Spirometry<br>19 = Radionuclide scan - bone<br>20 = Radionuclide scan - brain<br>21 = Radionuclide scan - liver<br>22 = Biopsy, scalene (supraclavicular) lymph nodes<br>23 = Biopsy, surgical open<br>24 = Thoracotomy<br>25 = Biopsy, transbronchial needle aspiration (TBNA) | 26 = Biopsy, transthoracic needle aspiration (TNA)<br>27 = Resection<br>28 = Thoracoscopy<br>30 = Bone radiograph<br>31 = CT scan - chest and upper abdomen<br>32 = CT scan - abdomen and pelvis combined<br>33 = Biopsy, endobronchial<br>34 = Fluoroscopy<br>35 = Gallium scan<br>36 = Biopsy, liver | 37 = Lymphadenectomy/Lymph node sampling<br>38 = MRI scan - bone<br>39 = Radiograph, other (SPECIFY)<br>40 = CT scan, spiral - chest<br>41 = Thoracentesis<br>42 = Biopsy, transbronchial<br>43 = Ultrasound (SPECIFY)<br>44 = Ventilation perfusion lung scan/scintigraphy<br>45 = Internal referral<br>46 = Record review<br>88 = Other (SPECIFY) |
|--|--|--|---|

PLEASE DO NOT WRITE IN THIS AREA



039237

**PART A CONTINUED . . .**

**4. Medical Complications of Diagnostic Evaluation and Staging:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

COMPLICATION #	1	2	3
TYPE OF COMPLICATION (SEE COMPLICATION CODES BELOW)	01 02 03 04 05 06 07 08 09 22 23 24 25 26 27 28 29 30 31 32 33 200 201 206 213 214 215	01 02 03 04 05 06 07 08 09 22 23 24 25 26 27 28 29 30 31 32 33 200 201 206 213 214 215	01 02 03 04 05 06 07 08 09 22 23 24 25 26 27 28 29 30 31 32 33 200 201 206 213 214 215
	SPECIFY	SPECIFY	SPECIFY
DATE OF COMPLICATION (MO. - DAY - YEAR)	MO. DAY YEAR 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 3 4 4 4 4 4 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 9 9	MO. DAY YEAR 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 3 4 4 4 4 4 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 9 9	MO. DAY YEAR 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 3 4 4 4 4 4 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 9 9
COMPLICATION #	4	5	6
TYPE OF COMPLICATION (SEE COMPLICATION CODES BELOW)	01 02 03 04 05 06 07 08 09 22 23 24 25 26 27 28 29 30 31 32 33 200 201 206 213 214 215	01 02 03 04 05 06 07 08 09 22 23 24 25 26 27 28 29 30 31 32 33 200 201 206 213 214 215	01 02 03 04 05 06 07 08 09 22 23 24 25 26 27 28 29 30 31 32 33 200 201 206 213 214 215
	SPECIFY	SPECIFY	SPECIFY
DATE OF COMPLICATION (MO. - DAY - YEAR)	MO. DAY YEAR 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 3 4 4 4 4 4 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 9 9	MO. DAY YEAR 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 3 4 4 4 4 4 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 9 9	MO. DAY YEAR 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 3 4 4 4 4 4 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 9 9

**MEDICAL COMPLICATION CODES**

- |                                  |  |  |
|----------------------------------|--|--|
| 01 = Infection (SPECIFY)         | 23 = Pulmonary embolus/emboli                | 33 = Hypokalemia   |
| 02 = Fever requiring antibiotics | 24 = Myocardial infarction                   | 200 = Vccal cord immobility/paralysis                                |
| 03 = Pneumothorax                | 25 = Cardiac arrhythmia                      | 201 = Rib fracture(s)  |
| 04 = Hemothorax                  | 26 = Cerebral vascular accident (CVA)/Stroke | 206 = Bronchopulmonary fistula                                       |
| 05 = Hemoptysis                  | 27 = Blood loss requiring transfusion        | 213 = Pain requiring referral to an anesthesiologist/pain specialist |
| 06 = Bronchospasm                | 28 = Deep venous thrombosis (DVT)            | 214 = Allergic reaction  |
| 07 = Respiratory arrest          | 29 = Acute/chronic respiratory failure       | 215 = Anaphylaxis  |
| 08 = Cardiac arrest              | 30 = Hypotension                             |  |
| 09 = Atelectasis                 | 31 = Congestive heart failure (CHF)          |  |
| 22 = Hospitalization             | 32 = Wound dehiscence                        |  |

**PART A CONTINUED . . .**

**5. Result of Diagnostic Evaluation for Lung Cancer:**

- No malignancy (GO TO PART B)
- No malignancy and no diagnostic/staging procedures performed (GO TO PART D)
- Lung malignancy confirmed histologically (exclude carcinoma in situ) (GO TO PART C)
- Lung malignancy confirmed cytologically (GO TO PART C)
- Lung malignancy diagnosed by clinical examination only (GO TO PART C)
- Other malignancy confirmed histologically or cytologically (GO TO PART B)
- No information available (GO TO PART D)

**PART B: DIAGNOSIS INFORMATION FOR SPECIFIC LUNG CONDITIONS**

**6. Specific Lung Diagnosis:**

- No       Yes (COMPLETE TABLE BELOW)

DIAGNOSIS #	1	2	3																																																																																																			
DIAGNOSIS (SEE DIAGNOSIS CODES BELOW)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>01</td><td>02</td><td>03</td><td>04</td><td>05</td><td>06</td></tr> <tr><td>07</td><td>08</td><td>09</td><td>10</td><td>11</td><td>12</td></tr> <tr><td>13</td><td>14</td><td>15</td><td>16</td><td>17</td><td></td></tr> </table>	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>01</td><td>02</td><td>03</td><td>04</td><td>05</td><td>06</td></tr> <tr><td>07</td><td>08</td><td>09</td><td>10</td><td>11</td><td>12</td></tr> <tr><td>13</td><td>14</td><td>15</td><td>16</td><td>17</td><td></td></tr> </table>	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>01</td><td>02</td><td>03</td><td>04</td><td>05</td><td>06</td></tr> <tr><td>07</td><td>08</td><td>09</td><td>10</td><td>11</td><td>12</td></tr> <tr><td>13</td><td>14</td><td>15</td><td>16</td><td>17</td><td></td></tr> </table>	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17																																														
01	02	03	04	05	06																																																																																																	
07	08	09	10	11	12																																																																																																	
13	14	15	16	17																																																																																																		
01	02	03	04	05	06																																																																																																	
07	08	09	10	11	12																																																																																																	
13	14	15	16	17																																																																																																		
01	02	03	04	05	06																																																																																																	
07	08	09	10	11	12																																																																																																	
13	14	15	16	17																																																																																																		
DATE OF DIAGNOSIS (MO. - DAY - YEAR)	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**SPECIFIC LUNG DIAGNOSIS CODES**

- |  |  |                                      |
|--|--|--------------------------------------|
| 01 = Lung carcinoma in situ                                    | 07 = Coccidioidomycosis                | 13 = Other mycobacterium of the lung |
| 02 = Aspergillosis   | 08 = Cryptococcosis                    | 14 = Pneumonia                       |
| 03 = Asthma  | 09 = Fungal infection of the lung, NOS | 15 = Sarcoidosis                     |
| 04 = Candidiasis   | 10 = Granuloma                         | 16 = Solitary lung nodule            |
| 05 = Chronic obstructive lung disease (COPD) without emphysema | 11 = Hamartoma                         | 17 = Tuberculosis                    |
| 06 = Chronic obstructive lung disease (COPD) with emphysema    | 12 = Histoplasmosis                    |                                      |

**7. Other Cancer Diagnosis:**

- No       Yes (COMPLETE TABLE BELOW)

OTHER CANCER DIAGNOSIS 1				OTHER CANCER DIAGNOSIS 2																																																																																																																																																													
ICD-9-CM CLASSIFICATION		DATE OF OTHER CANCER DIAGNOSIS		ICD-9-CM CLASSIFICATION		DATE OF OTHER CANCER DIAGNOSIS																																																																																																																																																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td></td><td></td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	X	X				<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td></td><td></td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	X	X				<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	
0	0	0	0																																																																																																																																																														
1	1	1	1																																																																																																																																																														
2	2	2	2																																																																																																																																																														
3	3	3	3																																																																																																																																																														
4	4	4	4																																																																																																																																																														
5	5	5	5																																																																																																																																																														
6	6	6	6																																																																																																																																																														
7	7	7	7																																																																																																																																																														
8	8	8	8																																																																																																																																																														
9	9	9	9																																																																																																																																																														
X	X																																																																																																																																																																
MO.	DAY	YEAR																																																																																																																																																															
0	0	0																																																																																																																																																															
1	1	1																																																																																																																																																															
2	2	2																																																																																																																																																															
3	3	3																																																																																																																																																															
4	4	4																																																																																																																																																															
5	5	5																																																																																																																																																															
6	6	6																																																																																																																																																															
7	7	7																																																																																																																																																															
8	8	8																																																																																																																																																															
9	9	9																																																																																																																																																															
0	0	0	0																																																																																																																																																														
1	1	1	1																																																																																																																																																														
2	2	2	2																																																																																																																																																														
3	3	3	3																																																																																																																																																														
4	4	4	4																																																																																																																																																														
5	5	5	5																																																																																																																																																														
6	6	6	6																																																																																																																																																														
7	7	7	7																																																																																																																																																														
8	8	8	8																																																																																																																																																														
9	9	9	9																																																																																																																																																														
X	X																																																																																																																																																																
MO.	DAY	YEAR																																																																																																																																																															
0	0	0																																																																																																																																																															
1	1	1																																																																																																																																																															
2	2	2																																																																																																																																																															
3	3	3																																																																																																																																																															
4	4	4																																																																																																																																																															
5	5	5																																																																																																																																																															
6	6	6																																																																																																																																																															
7	7	7																																																																																																																																																															
8	8	8																																																																																																																																																															
9	9	9																																																																																																																																																															

**PART C: PRIMARY LUNG CANCER DIAGNOSIS INFORMATION**

**8. Date of Primary Lung Cancer Diagnosis:**

MO.		DAY		YEAR		
0	0	0	0	0	0	0
1	1	1	1	1	1	1
2	2	2	2	2	2	2
3	3	3		3	3	
4		4		4	4	
5		5		5	5	
6		6		6	6	
7		7		7	7	
8		8		8	8	
9	9	9		9	9	9

**9. Verbatim Description of Primary Lung Cancer Diagnosis:**

---

---

---

---

---

---

---

---

---

---

**10. ICD-O-2 Cancer Classification:**

Topography	Morphology	Behavior	Grade
C 0 0 0	0 0 0 0		
1 1 1	1 1 1 1	1	1
2 2 2	2 2 2 2		2
3 3 3	3 3 3 3	3	3
4 4 4	4 4 4 4		4
5 5 5	5 5 5 5		5
6 6 6	6 6 6 6		6
7 7 7	7 7 7 7		7
8 8 8	8 8 8 8		
9 9 9	9 9 9 9	9	9

**11. Photocopy of Report Confirming Primary Lung Cancer: (MARK ONE)**

- Pathology/Histopathology (ATTACH COPY)
- Cytology/Cytopathology (ATTACH COPY)
- Not available

**12. Primary Tumor Location: (MARK ALL THAT APPLY)**

- |   |                                       |  |                               |
|---|---------------------------------------|--|-------------------------------|
| <input type="radio"/> Right upper lobe  | <input type="radio"/> Left upper lobe | <input type="radio"/> Right hilum        | <input type="radio"/> Carina  |
| <input type="radio"/> Right middle lobe | <input type="radio"/> Lingula         | <input type="radio"/> Left hilum         | <input type="radio"/> Unknown |
| <input type="radio"/> Right lower lobe  | <input type="radio"/> Left lower lobe | <input type="radio"/> Main stem bronchus |                               |

**13. Histopathologic Type for Primary Lung Cancer:**

- |  |  |
|--|--|
| <input type="radio"/> Squamous cell carcinoma (epidermoid carcinoma) | <input type="radio"/> Adenocarcinoma, solid carcinoma with mucus formation |
| <input type="radio"/> Adenocarcinoma                                 | <input type="radio"/> Giant cell carcinoma                                 |
| <input type="radio"/> Large cell carcinoma                           | <input type="radio"/> Clear cell carcinoma                                 |
| <input type="radio"/> Small cell carcinoma (oat cell)                | <input type="radio"/> Adenosquamous carcinoma                              |
| <input type="radio"/> Spindle cell carcinoma                         | <input type="radio"/> Carcinoid tumor                                      |
| <input type="radio"/> Intermediate cell type carcinoma               | <input type="radio"/> Bronchial gland carcinoma                            |
| <input type="radio"/> Combined oat cell carcinoma                    | <input type="radio"/> Adenoid cystic carcinoma                             |
| <input type="radio"/> Acinar adenocarcinoma                          | <input type="radio"/> Mucoepidermoid carcinoma                             |
| <input type="radio"/> Papillary adenocarcinoma                       | <input type="radio"/> Other (SPECIFY) _____                                |
| <input type="radio"/> Bronchiolo-alveolar adenocarcinoma             | <input type="radio"/> Unknown  |

PLEASE DO NOT WRITE IN THIS AREA



039237

**PART C CONTINUED . .**

**14. Histopathologic Grade for Primary Lung Cancer:**

- |  |  |
|--|--|
| <input type="radio"/> Grade cannot be assessed (GX)  | <input type="radio"/> Poorly differentiated (G3) |
| <input type="radio"/> Well differentiated (G1)       | <input type="radio"/> Undifferentiated (G4)      |
| <input type="radio"/> Moderately differentiated (G2) | <input type="radio"/> Unknown                    |

**15. TNM Staging for Primary Lung Cancer:**

If TNM Staging performed, what AJCC Cancer Staging Manual did you use?  4th Edition  5th Edition

**a. TNM Clinical Staging:**

- Yes (COMPLETE 15.a.1, 15.a.2, 15.a.3)  No (GO TO C.15.b)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
(T) Codes	(N) Codes	(M) Codes
<input type="radio"/> Tx <input type="radio"/> T0 <input type="radio"/> T1 <input type="radio"/> T2 <input type="radio"/> T3 <input type="radio"/> T4 <input type="radio"/> Not available	<input type="radio"/> Nx <input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2 <input type="radio"/> N3 <input type="radio"/> Not available	<input type="radio"/> Mx <input type="radio"/> M0 <input type="radio"/> M1 <input type="radio"/> Not available

**b. TNM Pathologic Staging:**

- Yes (COMPLETE 15.b.1, 15.b.2, 15.b.3)  No (GO TO C.16)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
(T) Codes	(N) Codes	(M) Codes
<input type="radio"/> Tx <input type="radio"/> T0 <input type="radio"/> T1 <input type="radio"/> T2 <input type="radio"/> T3 <input type="radio"/> T4 <input type="radio"/> Not available	<input type="radio"/> Nx <input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2 <input type="radio"/> N3 <input type="radio"/> Not available	<input type="radio"/> Mx <input type="radio"/> M0 <input type="radio"/> M1 <input type="radio"/> Not available

**16. Record Stage: (COMPLETE IF 15.b.1, 15.b.2, OR 15.b.3 IS NOT AVAILABLE, OTHERWISE SKIP)**

- Yes (COMPLETE 16.1, 16.2, 16.3)  No (GO TO PART E)

1. STAGE ONLY	2. VALCSG (small cell only)	3. SUMMARY STAGING										
<table border="0" style="width:100%;"> <tr> <td><input type="radio"/> I</td> <td><input type="radio"/> IIB</td> </tr> <tr> <td><input type="radio"/> IA</td> <td><input type="radio"/> IIIA</td> </tr> <tr> <td><input type="radio"/> IB</td> <td><input type="radio"/> IIIB</td> </tr> <tr> <td><input type="radio"/> II</td> <td><input type="radio"/> IV</td> </tr> <tr> <td><input type="radio"/> IIA</td> <td></td> </tr> </table> <input type="radio"/> Not available	<input type="radio"/> I	<input type="radio"/> IIB	<input type="radio"/> IA	<input type="radio"/> IIIA	<input type="radio"/> IB	<input type="radio"/> IIIB	<input type="radio"/> II	<input type="radio"/> IV	<input type="radio"/> IIA		<input type="radio"/> Limited <input type="radio"/> Extensive <input type="radio"/> Not available	<input type="radio"/> Localized <input type="radio"/> Regional <input type="radio"/> Distant <input type="radio"/> Not available
<input type="radio"/> I	<input type="radio"/> IIB											
<input type="radio"/> IA	<input type="radio"/> IIIA											
<input type="radio"/> IB	<input type="radio"/> IIIB											
<input type="radio"/> II	<input type="radio"/> IV											
<input type="radio"/> IIA												



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**DIAGNOSTIC EVALUATION - LUNG VERSION 3 (DEL3/DLQ3)**

This form is to be completed by the Medical Record Abstractor, a nosologist (trained medical coder), and a Tumor (or Cancer) Registrar who is also a Certified Tumor Registrar (CTR) or CTR – eligible. Items, which are to be completed by a nosologist or a CTR, are specified. The abstractor should complete all other items. Specifically, the nosologist will be required to complete Item B.7 (Other Cancer Diagnosis). The CTR will be required to complete Part C: Items C.8 (Date of Primary Lung Cancer Diagnosis), C.9 (Verbatim Description of Primary Lung Cancer Diagnosis), C.10 (ICD-O-2 Cancer Classification), C.11 (Photocopy of Report Confirming Primary Lung Cancer), C.12 (Primary Tumor Location), C.13 (Histopathologic Type for Primary Lung Cancer), C.14 (Histopathologic Grade for Primary Lung Cancer), C.15 (TNM Staging for Primary Lung Cancer), and C.16 (Record Stage).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry; it should not be obtained from the participant except for Item A.1, Diagnostic Procedures Performed, in which the information recorded may be based on participant self-report. Written documentation from the physician or the medical record, for example, is preferable to obtaining information verbally.
- Information about diagnostic procedures could possibly be collected up to 12 months after the date of a positive screen (if a conclusive diagnosis or the next screening exam does not come first). In addition, information about complications of diagnostic procedures should be collected up to 12 months from the time diagnostic procedures began. In the event of a cancer diagnosis, medical complications should be collected for an additional 6 months after the diagnosis.
- Before beginning abstraction, the medical record documents should be placed in chronological order and the diagnostic/staging procedures should be abstracted chronologically. If, however, a diagnostic or staging procedure is identified and added after the form has been completed, it is not necessary to shift all of the data to maintain the chronological order; the new procedure may be added at the end of the appropriate item.
- This form includes items, which require that data be entered verbatim, such as recording diagnoses, recording "other (specify)," and recording comments. Verbatim comments should be accurate and succinct. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If the medical record contains unclear, discrepant, or conflicting information for any item, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should first be consulted for a resolution and for making an appropriate coding decision, prior contacting the CC MRA Coordinator.
- When recording information in the Comments section, be sure to identify the item to which the comment refers. Appropriate identification will aid in the analysis of Comments data. Throughout the specifications, examples have been given for recording information in Comments.

Below are some guidelines for the collection of diagnostic evaluation information:

- Information regarding diagnostic procedures that occurred prior to the participant's randomization date should not be recorded.
- Procedures that occurred prior to the date of the initial visit for clinical assessment (i.e., the first visit to a doctor for clinical assessment) should not be recorded, with the exception of procedures that are part of the diagnostic evaluation for a suspected cancer. If a screening test is positive or a participant experiences symptoms and a diagnostic procedure is performed before the participant actually visits the doctor, this diagnostic procedure should be recorded on the DE form (even though it took place prior to the initial visit for clinical assessment).

For example, in the case of a positive PLCO screen with a biopsy performed, the screen is the event that led to the initiation of diagnostic follow-up and should not be recorded, but the biopsy is the first procedure in the diagnostic follow-up process, and should be recorded. Similarly, health screening tests in an asymptomatic participant would not be recorded, but follow-up evaluation (once cancer is suspected) should be recorded on a DE form.

- Following a positive screening exam, the SC should collect diagnostic evaluation information until:
  - a conclusive diagnosis (either malignant or non-malignant) is made, OR
  - 12 months after the date of the positive screen, OR
  - the next screening exam,

*whichever comes first.*

At the end of the 12 months or on the date of the next screen, if the diagnostic evaluation is not conclusively malignant, record the result of the diagnostic evaluation in Item A.5 as No malignancy."

- An exception to the above is when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a lung or other malignancy. In this situation it is not appropriate to record a conclusive diagnosis, but rather to record "No information available." If a Lead Abstractor cannot conclusively determine the result of a diagnostic evaluation from the medical record, contact the CC MRA Coordinator.

It is the SC's responsibility to encourage timely follow-up of positive screens. If, despite SC efforts, the participant does not initiate follow-up of a positive screen until late in the year, 10 months after the positive screen for example, the SC should still collect only the diagnostic evaluation data until 12 months after the positive screen or the next screen, whichever comes first. In the example given, this would mean two months of diagnostic evaluation data.

All staging information related to the initial diagnosis of primary lung cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEL form). Information to investigate lung cancer recurrence should not be recorded on the DEL form.

- If multiple primary lung cancers are diagnosed at the same time (i.e., as part of the same diagnostic evaluation process and prior to the first definitive treatment), it is necessary to complete portions of a separate DEL for each multiple primary. Item 7 (Multiple Primary Cancer #) allows the abstractor to indicate whether the DEL is being used for abstracting information about a multiple primary lung can-

cer. If there are multiple primary cancers, each cancer should be recorded on a separate DEL3 form.

- If a procedure such as surgical resection, is performed, that is used for diagnosis, staging, and treatment, that procedure should be abstracted onto both the Diagnostic Evaluation Form and the Treatment Information Form.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy black marks that fill the circle completely.**



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled, and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled in. Darken the circle corresponding to each remaining number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized ("Final Complete" or "Final Incomplete"), erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the DE. If more than one abstractor completes the DE, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form -- this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.

3. **Nosologist ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item B.7 (ICD-9-CM Classification of Other Cancer Diagnoses). Darken the circles corresponding to the four digits.
4. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting specific items related to ICD-O-2 Classification and cancer diagnosis/staging in Part C. Darken the circles corresponding to the four digits.
5. **Study Year:** Record the study year, T0 to T13. This is the study year in which the SC was notified of a suspicion of lung cancer. For example, if the cancer was reported on a T1 ASU, the study year for the DEL is T1. Darken the corresponding circles. Remember to right justify and zero-fill the number for study years T0 - T9 (e.g., T00, T01, T02, etc.).
6. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the “first” time to confirm a suspicion of lung cancer. This includes an initial abstract for a multiple primary cancer (see Item 7).
  - **Re-abstract for QA:** Medical record information, that has already been abstracted to confirm a suspicion of lung cancer, is being re-abstracted for the purpose of quality assurance. This includes a re-abstract for a multiple primary cancer (see Item 7). Not yet implemented.
7. **Multiple Primary Cancer #:** The purpose of this item is to indicate whether this form is being used to abstract information about an additional primary lung cancer that was diagnosed at the same time as the first primary lung cancer (i.e., as part of the same diagnostic evaluation and staging process, and before the first definitive treatment). Indicate the sequence number for the additional primary cancer(s). If this primary cancer is the second primary diagnosed (in chronological date order), darken the circle for “2”. If it is the third, darken the circle for “3,” etc. If only one primary cancer was diagnosed, this item should be skipped.

When the participant is diagnosed with more than one primary lung cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For the first primary, the DEL must be completed in full (all parts). For all subsequent primaries, use separate DEL forms and complete the administrative section, Item A.5 (Result of Diagnostic Evaluation for Lung Cancer), and Part C only. If more than one primary was diagnosed on the same date, designate the most advanced cancer diagnosed on that day as the “first primary” and complete the entire DEL form. Use additional DEL forms for any other cancers diagnosed on that day.

8. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except “Disposition” are optional. “Disposition” is required and may be marked on the form or entered directly into DEES. Dispositions of “Final Complete” (FCM) may also be set automatically in DEES when the form is edited (See DEES User’s Guide).
  - **Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)
  - **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is com-

plete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)

- **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 of the MOOP for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
- **Data Retrieval:** This item is optional. Complete this item to indicate status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
- **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
  - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data is abstracted, remove the ICM so that the appropriate disposition is assigned.
  - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report, or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
  - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A: Diagnostic Evaluation and Staging:**

This section refers to the diagnostic evaluation and staging for lung cancer. Abstracting this data will require careful review of the participant's medical records at one or more hospitals, clinics, or physicians' offices.

When abstracting information onto this form, do not include information from any physician/hospital visits or procedures that took place prior to the participant's date of randomization, even if these visits or procedures are related to a diagnosis which was made after the participant was enrolled in the trial.

1. **Diagnostic Procedures Performed:** The purpose of this item is to document whether or not a physician recommended and performed diagnostic procedures as part of the follow-up to a positive PLCO screening examination (chest x-ray). If the DEL is being completed in response to lung cancer being reported via an ASU, for example, if the participant was in fact diagnosed with cancer, it is assumed that diag-

nostic procedures were performed and this item should be coded "Yes." Darken the circle corresponding to the most appropriate response as follows:

**Yes:** The record indicates that diagnostic procedures were recommended by a physician and were performed. This includes situations when diagnostic procedures were performed to follow-up a positive PLCO screening exam (chest x-ray), or when an internal referral was done, or when lung cancer was reported to the SC via an ASU.

- If an internal referral is performed following a PLCO screening chest x-ray, this should be recorded as the first diagnostic and staging procedure in Item A.3 (Diagnostic/Staging Procedures).

**No, Physician Report:** The record indicated or the physician reported to the SC that based on review of the PLCO screening exam results, and possibly any medical history prior to the screening exam, no additional follow-up was deemed necessary. Complete Item A.5 (Result of Diagnostic Evaluation for Lung Cancer) and Parts B, D, and E of the form.

**No, Participant Self-Report:** The participant reported that the physician reviewed the PLCO screening exam results, and possibly other medical history prior to the screening exam, and deemed no additional follow-up was necessary. Complete Item A.5 (Result of Diagnostic Evaluation for Lung Cancer) and Parts D and E of the form.

- *Before accepting a participant self-report the SC should first attempt to obtain written documentation from the participant's physician. If written documentation cannot be obtained from the physician, the SC should then attempt to obtain verbal confirmation from the physician's office that the physician did not recommend additional follow-up of the positive PLCO screening exam. In cases where only the participant's report of the physician's recommendation can be obtained, this circle should be darkened.*

2. **Reason for Initial Visit for Clinical Assessment:** The purpose of this item is to identify the participant's motivation for seeking the initial clinical evaluation. Because motivation is sometimes not clearly stated in the record, NCI assumes that if a participant seeks medical care within 12 months of a positive screen, it is for the purpose of follow-up of that positive screen. If medical care is sought more than 12 months after a positive screen, NCI assumes that it is not for follow-up to a positive screen. Darken the circles corresponding to all the reasons that apply as follows:

- **Symptomatic:** The record indicates that symptoms prompted the participant to get the initial clinical evaluation.
- **Follow-up of positive PLCO screen:** The record indicates that the participant went for an initial clinical evaluation to follow up a positive PLCO screen, within 12 months of the positive screen.
- **Other (SPECIFY):** If the record indicates that the participant went for a clinical evaluation for a reason other than those listed, specify the reason in the space provided. Include here the non-PLCO health screen performed in an asymptomatic participant and indicate the specific examination preceded by "non-PLCO," as in "non-PLCO screening chest x-ray."

3. **Diagnostic/Staging Procedures:** This item is concerned with any diagnostic/staging procedures that the participant underwent during the evaluation for lung cancer.

Darken the circle corresponding to whether the participant underwent diagnostic/staging procedures as follows:

**No:** The record clearly states or indicates that the participant did not undergo any diagnostic/staging procedures. Darken the circle for “No” and go to Item A.4. Before darkening this circle, review what was completed in A.1. It is inconsistent to have “Yes” recorded in A.1 and “No” in A.3.

**Yes:** The record indicates that the participant underwent one or more of the diagnostic/staging procedures for lung cancer. Darken the circle for “Yes” and complete the table for Item A.3. If space is needed to record more than twelve diagnostic/staging procedures, use the Diagnostic/Staging Procedures Supplement (DSS) form (refer to Item A.3b).

**Unknown:** If there is no indication in the record whether or not diagnostic/staging procedures were or were not performed, darken the circle for “Unknown” and go to Item A.4.

The following are general guidelines for identifying diagnostic and staging procedures in the medical record:

- Only procedures used to diagnose or stage a cancer that are clearly stated in the record (discharge summaries and operative reports) should be recorded. If the operative report and/or discharge summary is missing, procedures noted in doctor’s notes or a history taken after the procedure was done may be used as documentation to record a diagnostic/staging procedure. The SC Lead Abstractor should contact the CC MRA Coordinator if there is any uncertainty about recording diagnostic/staging procedures.
- Surgical approaches should be recorded. The only time that an approach would not be recorded is for a procedure, such as a CT-directed biopsy, that is strictly for a localization of an abnormality to be biopsied and is not done for diagnostic purposes. The SC Lead Abstractor should contact the CC MRA Coordinator if there is any uncertainty about recording diagnostic/staging procedures.
- Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.
- Following a positive PLCO screening exam (chest x-ray), the SC should collect information on diagnostic procedures until a conclusive diagnosis is made, or until 12 months from the date of the positive screen, or until the next screen, whichever comes first.
- All staging information related to the initial diagnosis of a primary lung cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEL form.) Surgical resection of the primary organ, lymph nodes and other organs should be included. Staging procedures performed after the start of the first definitive treatment such as radiation therapy or chemotherapy should not be collected unless the treatment had been designated as neoadjuvant.
- Procedures to determine cancer progression should not be recorded.

For each diagnostic/staging procedure performed, complete the following items:

- **Type of Procedure:** Darken the circle corresponding to the type of diagnostic/staging procedure performed. Refer to the Procedure Codes for the list of diagnostic and staging procedures for lung cancer. When the procedure on the Procedure Code list indicates, “SPECIFY,” describe the body site or the actual procedure, as appropriate. Refer to Appendix K-17-2 of the MOOP for an alphabetical listing of definitions and synonyms for the diagnostic/staging pro-

cedures listed on the DE forms. The following are guidelines for coding type of procedure:

- Do not record any procedures that require testing of blood or serum.
- **Biopsy:**
  - 33 = Biopsy, endobronchial
  - 36 = Biopsy, liver
  - 16 = Biopsy, lymph node – other (SPECIFY): Specify lymph node site. Do not use this code to record biopsies of the scalene (supraclavicular) lymph nodes (code 22).
  - 15 = Biopsy, needle aspiration (SPECIFY): Also use this code if a needle aspiration was performed and none of the other needle aspiration procedure codes apply. Specify the site of the needle aspiration.
  - 17 = Biopsy, other (SPECIFY): Use this code to record other biopsies not listed as a procedure code on the DEL form. Record the site of the biopsy on the specify line, not the method of biopsy. Use this code to record both incisional and excisional biopsies of organs, except lymphadenectomy.
  - 22 = Biopsy, scalene (supraclavicular) lymph nodes
  - 23 = Biopsy, surgical open
  - 42 = Biopsy, transbronchial: Use this code when transbronchial biopsy was performed and it was not a transbronchial needle aspiration (code 25).
  - 25 = Biopsy, transbronchial needle aspiration (TBNA): Use this code if a “transaxillary oblique approach” is used and the biopsy was a needle aspiration.
  - 26 = Biopsy, transthoracic needle aspiration (TNA)
- **Clinical Evaluation and Record Review (includes Internal Referral):**
  - 04 = Clinical evaluation: A clinical evaluation is defined as a visit to a health care provider for medical care and usually includes a history and physical exam related to the organ of interest. If a clinic visit includes information about the PLCO Screen only, this is to be considered a clinical evaluation even if no physical exam is done. It does not include a telephone conversation to a health care provider. *A clinical evaluation that only serves to repeat or confirm previous findings should not be recorded.* The following examples illustrate how the form should be completed to document a clinical evaluation:
    - If a visit to a health care provider includes a history as well as a physical examination of the lungs, this is considered a clinical evaluation.
    - If a visit to a health care provider includes only a history and not a physical examination of the lungs, this is also considered a clinical evaluation.
    - Remember to record only those clinical evaluations, done after the initial evaluation, that provide additional information, by history or exam, to confirm or rule out cancer. A more detailed history and

physical, such as one performed by a consultant that does not specifically help to confirm or rule out cancer, should not be *recorded*.

45 = Internal referral: Use this code when the current PLCO screen is compared to a previous PLCO screen.

46 = Record review: Use this code when (1) when a provider makes a comparison of previous and/or serial chest x-rays, (2) when a review of the medical record is performed for the purpose of a second opinion of diagnosis, and a record review contributes to the diagnosis or staging of the cancer in question. A "comparison of chest x-rays", which is usually noted at the beginning of another study (i.e. chest x-ray or CT scan of the chest), should not be recorded as a Record Review. The SC Lead Abstractor should contact the CC MRA Coordinator if uncertain whether to include a record review.

- **CT Scans:**

32 = CT scan – abdomen and pelvis combined: If CT pelvic and CT abdominal procedures appear in the record as a combined procedure, they should be recorded as a single procedure.

05 = CT scan – brain

06 = CT scan – chest

31 = CT scan – chest and upper abdomen

40 = CT scan, spiral – chest

07 = CT scan – liver

08 = CT scan – other (SPECIFY)

- If a CT scan is performed as part of a diagnostic procedure, as in the case of a "CT guided biopsy", the CT scan should not be recorded as a separate procedure. In this case the CT scan is the approach or means to perform the biopsy.

- **Cytological Evaluation Procedures:**

09 = Cytology (sputum, bronchial, washing/brushing)

- **Endoscopic /Surgical Evaluation Procedures:**

01 = Bronchoscopy

10 = Mediastinoscopy/mediastinotomy

28 = Thoracoscopy

24 = Thoracotomy: This should be recorded if an end procedure only, as in an exploratory thoracotomy when no other procedure from it follows. Do not record thoracotomy if it is the approach to a definitive procedure, such as a wedge resection or pneumonectomy.

- **Gallium Scan: Use code 35**

- **MRI Scans:**

38 = MRI scan – bone

11 = MRI scan – brain

12 = MRI scan – chest

13 = MRI scan – liver

14 = MRI scan – other (SPECIFY)

- **Other (SPECIFY)**: Use code 88 = Other (SPECIFY) to record procedures that cannot be listed using one of the other codes on the form.
  - **"PET Scans: Use code 88 = Other (SPECIFY) and fill in "PET Scan"**
  - **Pulmonary Function Tests/Spirometry: Use code 18**
  - **Radiographic Procedures:**
    - 30 = Bone radiograph – Use this code for an x-ray of a bone or series of bones such as femur or lumbar spine.
    - 02 = Chest radiograph: Use this code when a chest x-ray is in the record, regardless of whether a particular view is specified such as PA, lateral, Bucky, kyphotic, or lordotic. Additional chest radiographs should not be recorded unless they reveal a new abnormality that is diagnostic of cancer, which was not noted on the previous film.
    - 34 = Fluoroscopy
    - 39 = Radiograph, other (SPECIFY) – Use this code for non-bone x-rays such as KUB or sinus series.
  - **Radionuclide Scans:**
    - 19 = Radionuclide scan – bone
    - 20 = Radionuclide scan – brain
    - 21 = Radionuclide scan – liver
- Tissue or Fluid-removing Procedures:
- 37 = Lymphadenectomy/Lymph node sampling: If lymph node sampling and lymph node dissection are both performed, this should be considered as one procedure and recorded only once. Lymph node removal accompanying surgical resection should be recorded as two separate procedures. Record the lymph node removal as "37" and the lung resection as "27."
  - 27 = Resection: While a lobectomy and pneumonectomy are treatments for lung cancer, record "27 = Resection" if a wedge resection, lobectomy, or pneumonectomy provides diagnostic/staging information.
  - 41 = Thoracentesis – Record if the thoracentesis is done for diagnostic reasons (so the fluid obtained is sent for culture and/or cytology). Do not record if the thoracentesis is done for therapeutic reasons only.
- **Ultrasound (SPECIFY)**: Use code 43. Specify the site of the ultrasound examination. Do not record ultrasound when used as an approach for a more definitive procedure, such as an ultrasound guided biopsy. In the latter example, record only the biopsy and not the ultrasound.
  - **Ventilation perfusion lung scan/scintigraphy**: Use code 44. This is also known as a VQ Scan.

Please refer to Section A-8-6 of the MOOP, Diagnostic/Staging Procedures Supplement (DSS), for an additional listing of Diagnostic/Staging Procedures.

- **Date of Procedure:** Record the month, day, and year that the diagnostic/staging procedure was performed. If it is not clear from the record the day that the diagnostic/staging procedure was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**3b. Diagnostic/Staging Procedures Supplement Form Completed:** If space is needed for recording more than 12 diagnostic/staging procedures, darken the circle and go to the Diagnostic/Staging Procedures Supplement (DSS) form. Otherwise, do not darken the circle and go to Item A.4.

The DSS form provides eleven additional spaces for recording diagnostic/ staging procedures, numbered 13 through 23. If there are more than 23 diagnostic/staging procedures, place an asterisk beside Item 4 (Diagnostic/Staging Procedures) on the DSS, and use the Comments section of the DEL to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example:

Item E.20, Comments:

Item #:	Comments:
A.3	24.; Type = _____; Date =

Refer to the specifications for the DSS for additional information on completing the DSS.

**4. Medical Complications of Diagnostic Evaluation and Staging:** General guidelines for identifying selected medical complications in the medical record are given below:

- Only selected medical complications that were a result of the diagnostic evaluation or staging procedures and that required medical intervention should be recorded.
- Information on medical complications can usually be found in the discharge summary, or the doctor's or nurse's notes within the medical record.
- Medical complications should be collected up to 12 months from the time diagnostic procedures were initiated. In the event of a cancer diagnosis, medical complications should be collected through 6 months after the date of the cancer diagnosis.
- If more than one medical complication occurred during a particular event, record each selected medical complication, even if they occurred on the same date. Hospitalization, code 22, should be recorded only if the reason for hospitalization is not another selected medical complication. For example, in the case of fever requiring antibiotics and hospitalization, only record fever requiring antibiotics.

Darken the circle corresponding to medical complications as follows:

**No:** The record clearly states or indicates that none of the selected medical complications resulted from a diagnostic or staging procedure. Also mark this item if no diagnostic/staging procedures were performed as part of the evaluation. Darken the circle for "No," and go to Item A.5.

**Yes:** The record states or indicates that one or more of the selected medical complications resulted from a diagnostic or staging procedure. If a participant had more than six medical complications, place an asterisk beside Item A.4, and use the Comments section to record the same data as requested in the table. In Comments, record the item numbers and labels followed by the data. Be certain to list the number associated with the complication next to "Type," rather than the text, which describes the complication. For example, fever requiring antibiotics was the seventh medical complication mentioned in the record:

Item E.20, Comments

Item #	Comments
A.4	7; Type = 02; Date = mm/dd/yyyy

Darken the circle for "Yes" and complete the table for Item A.4 as follows:

- **Type of Medical Complication:** Darken the circle corresponding to the type of medical complication that occurred. Refer to the Medical Complication Codes for the list of selected medical complications that required medical intervention for lung cancer. Refer to Appendix K-17-2 of the MOOP for definitions and synonyms for the medical complications listed on the DE forms. The following are guidelines for recording medical complications of Diagnostic Evaluation and Staging.

**1 = Infection (SPECIFY):** Specify the site or source of the infection on the line provided.

**22 = Hospitalization:** Use only if reason for hospitalization is not another selected medical complication.

**27 = Blood loss requiring transfusion:** Only record transfusion of blood if it involves giving red blood cells from a stored source, usually described as a unit of red blood cells. There can be a number of words that would apply - whole, packed, washed, irradiated, etc. The transfusion of red blood cells implies that the blood loss was significant enough to require a replacement of the red blood cells. Other types of fluids or blood products that do not include red blood cells, such as D5, saline, (NaCl), platelets, albumin, or fresh frozen plasma should not be considered when recording blood loss requiring transfusion. The intra-operative recycling of blood lost, filtered, and returned immediately to participant will also not be considered equivalent to blood loss requiring transfusion and should not be recorded as a medical complication.

*The Lead Abstractor should consult with the CC MRA Coordinator if it cannot be determined if a medical complication should be recorded.*

- **Date of Complication:** Record the month, day, and year that the medical complication began. If it is not clear from the record the day of the complication, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**Unknown:** Only use this code when you may not have all of the medical record and you cannot reliably determine complications. Darken the circle for "Unknown" and go to Item A.5.

5. **Result of Diagnostic Evaluation for Lung Cancer:** The purpose of this item is to record the overall results of the diagnostic evaluation for lung cancer. This information should be found in the impression/conclusion sections of the various diagnostic and staging reports. This information may also be found in a physician's note.

Record the result of the diagnostic evaluation for lung cancer as follows:

- **No malignancy:** The record indicates that no malignancy was found as a result of the diagnostic and staging procedures. A result of "No malignancy" should be coded in the following situations:
  - When a conclusive diagnosis is made following a positive screen and the diagnosis is not lung cancer, or any other cancer. Include aspergillosis, asthma, candidiasis, chronic obstructive lung disease (COPD) without emphysema, chronic obstructive lung disease (COPD) with emphysema, coccidioidomycosis, cryptococcosis, fungal infection of the lung, NOS, granuloma, hamartoma, histoplasmosis, other mycobacterium of the lung, pneumonia, sarcoidosis, solitary lung nodule, lung carcinoma in situ, and tuberculosis.
  - When no diagnostic procedures for further evaluation are recommended by the primary care provider/physician (i.e. when Item A.1, Diagnostic Procedures Performed, is coded "No Physician Report"), then "No Malignancy" is presumed. Documentation that the physician advised against any follow-up evaluation must be from the medical records or verified verbally from the medical clinic and not from the participant record only.
  - When diagnostic follow-up data have been abstracted for the period from a positive screen until 12 months past the positive screen or until the next screen (whichever came first) and the diagnosis was not conclusively malignant.

Darken the circle and go to Part B: Diagnosis Information For Specific Lung Conditions.

- **No malignancy and no diagnostic/staging procedures performed:** The participant reports that he/she had a follow-up visit with his/her health care provider who determined that there was no malignancy. No further diagnostic/staging procedures were performed. This information is not documented in the medical record and cannot be validated by the participant's health care provider. Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.
- **Lung malignancy confirmed histologically (exclude carcinoma in situ):** The record indicates that the participant has been diagnosed with primary lung cancer, confirmed by histologic examination (study of tissue). Histologic information may come from a biopsy, and can be found on the pathology report, sometimes called a histopathology report. Neoplasm of uncertain behavior of the lung, carcinoid of the lung, extranodal lymphoma arising in the lung and sarcoma of the lung should be recorded here. Darken the circle and go to Part C, Primary Lung Cancer Diagnosis Information. Included in this response is when the diagnosis of primary lung cancer is obtained from tissue from a metastatic site such as brain, bone, or a lymph node.

A diagnosis of carcinoma in situ of the lung, should not be recorded here. It should be recorded in Item B.6.

- **Lung malignancy confirmed cytologically:** The diagnosis of primary lung cancer was confirmed by cytologic examination (study of cells). Cytologic information may come from a bronchial brushing or washing, or a fine-needle aspiration, and can be found on the cytology report, sometimes called a cytopathology report. Neoplasm of uncertain behavior of the lung, carcinoid of the lung, extranodal lymphoma arising in the lung and sarcoma of the lung should be recorded here. Darken the circle and go to Part C, Primary Lung Cancer Diagnosis Information.

A diagnosis of carcinoma in situ of the lung based on cytology, should not be recorded here. It should be recorded in Item B.6.

**NOTE:** *If the lung malignancy was confirmed by both histologic and cytologic examination, information should be abstracted only from the pathology/histopathology report (even if the cytology report is earlier). The histopathology report is more definitive, and therefore, every attempt should be made to verify if one exists before utilizing cytologic confirmation. If the lung malignancy was confirmed by cytological examination alone, then cancer diagnosis information should be taken from the cytology/cytopathology report.*

- **Lung malignancy diagnosed by clinical examination only:** The record indicates that the participant has been diagnosed with primary lung cancer by clinical examination and not confirmed by histologic examination (study of tissue) or cytologic examination (study of cells). It is an extremely rare event, however, for a malignancy to be confirmed only by clinical examination and not histologically or cytologically. Darken the circle and go to Part C: Primary Lung Cancer Diagnosis Information.

In these cases there will be a 12-month "holding period" to be sure that no pathologic confirmation followed. The following guidelines should be used to determine if the diagnosed "clinically" code is appropriate:

- If the initial response is "clinically" and within this 12-month period there is pathologic confirmation, the diagnosis code should be changed to "histologically" or "cytologically" and the diagnosis date should be updated.
  - If the initial response is "clinically" and treatment is given right away, the "clinically" code becomes validated and should remain.
  - If the initial response is "clinically" but after 12 months there is no follow-up or treatment, then the diagnosis is questionable and should be changed to "no malignancy."
  - If the initial response is "clinically," but the lack of treatment is due to other reasons, such as advanced stage of disease, participant refusal, etc., the clinically diagnosed result should remain on the DE form.
- **Other malignancy confirmed histologically or cytologically:** The diagnosis of a malignancy other than primary lung cancer was confirmed by histologic examination (study of tissue) and or cytologic examination (study of cells). Histologic information can be found on the histopathology report, sometimes called the histopathology report, and cytologic information can be found on the cytology report, sometimes called a cytopathology report. Darken the circle and go to Part B: Diagnosis Information for Specific Lung Conditions.

This answer category should also be coded if the diagnostic evaluation for primary lung cancer reveals a malignancy (including a lung malignancy) that is a metasta-

sis from a primary cancer site other than the lung. In this situation, the primary cancer site should be recorded in Part B: Diagnosis Information for Specific Lung Conditions, Other Cancer Diagnosis.

**NOTE:**

- *If the participant was diagnosed with another PLCO malignancy (prostate, colorectal, or ovarian) as the result of a diagnostic evaluation for lung cancer, the appropriate Diagnostic Evaluation form (DEP, DEC, or DEO) must also be completed, unless previously confirmed.*
- *If the participant was diagnosed with a malignancy other than one of the PLCO cancers, an Other Cancer Form (OCF) must also be completed, unless previously confirmed.*

- **No information available:** There is equivocal or no information available in the record regarding the result of the diagnostic evaluation for lung cancer. For example: "No information available" should be coded in the situation when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a lung or other malignancy.

Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.

**Part B: Diagnosis Information for Specific Lung Conditions:**

This section is to document Specific Lung Diagnoses and/or Other Cancer Diagnoses, which resulted from the diagnostic evaluation. Specific Lung Diagnoses include lung carcinoma in-situ aspergillosis, asthma, candidiasis, chronic obstructive lung disease (COPD) without emphysema, chronic obstructive lung disease (COPD) with emphysema, coccidioidomycosis, cryptococcosis, fungal infection of the lung, NOS, granuloma, hamartoma, histoplasmosis, other mycobacterium of the lung, pneumonia, sarcoidosis, solitary lung nodule, and tuberculosis. Although lung carcinoma in-situ is a malignancy, it is confined and therefore for the purpose of this study will be recorded in Part B.. Other Cancer Diagnoses include any cancer other than lung and any neoplasm of uncertain behavior or carcinoid that is from a site other than the lung. This information will most likely be obtained directly from the participant's physician when the SC contacts the physician during follow-up of a positive PLCO screening exam. Depending on the extent of the information available and the physician's preference, the requested information may be obtained either verbally by phone or via written documentation. The diagnosis should be recorded from documents in the medical record that are prefaced with "Diagnosis/Impression/Conclusion/Assessment". The physician diagnosis can be from a source other than the original diagnosing physician as long as the source states the physician's original diagnosis. One example is a progress note written by a follow-up physician. A pathology report documenting a benign condition is also an appropriate source. Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.

6. **Specific Lung Diagnosis:** Lung carcinoma in situ and benign conditions that are specific to the lung are recorded here. They include aspergillosis, asthma, candidiasis, chronic obstructive lung disease (COPD) without emphysema, chronic obstructive lung disease (COPD) with emphysema, coccidioidomycosis, cryptococcosis, fungal infection of the lung, NOS, granuloma, hamartoma, histoplasmosis, other mycobacterium of the lung, pneumonia, sarcoidosis, solitary lung nodule, and tuberculosis.

Darken the circle corresponding to a specific lung diagnosis as follows:

**No:** The record clearly states or indicates that none of the specified lung diagnoses were determined as a result of diagnostic or staging procedures. Use "No" if result of diagnostic evaluation is another conclusive non-cancer lung diagnosis that is not listed on the form. Also mark this item if there is no information for physician diagnosis or if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to Item B.7.

**Yes:** The record states or indicates that one or more specific lung diagnoses were determined as a result of diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for Item B.6 as follows:

- **Diagnosis:** Darken the circle corresponding to the type of specific lung diagnosis that was found. The types of specific lung diagnoses, determined as a result of diagnostic/staging procedures for lung cancer, are defined below:

**01 = Lung carcinoma in situ:** The record indicates that the participant had lung carcinoma in situ, which is an early, non-invasive malignancy of the lung.

**02 = Aspergillosis:** The record indicates that the participant had aspergillosis, an opportunistic fungal infection of the lung, determined as a result of diagnostic/staging procedures.

**03 = Asthma:** The record indicates that the participant had asthma, a bronchial hypersensitivity disorder, determined as a result of diagnostic/staging procedures.

**04 = Candidiasis:** The record indicates that the participant had candidiasis, an opportunistic fungal infection of the lung, determined as a result of diagnostic/staging procedures.

**05 = Chronic obstructive lung disease (COPD) without emphysema:** The record indicates that the participant had COPD without emphysema, a restrictive airway disease, determined as a result of diagnostic/staging procedures.

**06 = Chronic obstructive lung disease (COPD) with emphysema:** The record indicates that the participant had COPD with emphysema, a restrictive airway disease, determined as a result of diagnostic/staging procedures.

**07 = Coccidioidomycosis:** The record indicates that the participant had coccidioidomycosis, an infectious fungal respiratory disease, determined as a result of diagnostic/staging procedures.

**08 = Cryptococcosis:** The record indicates that the participant had cryptococcosis, an infectious fungal respiratory disease, determined as a result of diagnostic/staging procedures.

**09 = Fungal infection of the lung, NOS:** The record indicates that the participant had a fungal infection of the lung, not otherwise specified, determined as a result of diagnostic/staging procedures.

**10 = Granuloma:** The record indicates that the participant had a granuloma, a nodular inflammatory lesion of the lung, determined as a result of diagnostic/staging procedures.

- 11 = Hamartoma:** The record indicates that the participant had a hamartoma, a focal malformation of the lung that resembles a neoplasm, determined as a result of diagnostic/staging procedures.
- 12 = Histoplasmosis:** The record indicates that the participant had histoplasmosis, an infectious fungal respiratory disease, determined as a result of diagnostic/staging procedures.
- 13 = Other mycobacterium of the lung:** The record indicates that the participant had a respiratory illness due to other mycobacterium of the lung, which was determined as a result of diagnostic/staging procedures.
- 14 = Pneumonia:** The record indicates that the participant had pneumonia, an inflammation of the lung parenchyma, determined as a result of diagnostic/staging procedures.
- 15 = Sarcoidosis:** The record indicates that the participant had sarcoidosis, a systemic granulomatous disease involving the lungs, determined as a result of diagnostic/staging procedures.
- 16 = Solitary lung nodule:** The record indicates that the participant had a solitary lung nodule determined as a result of diagnostic/staging procedures.
- 17 = Tuberculosis:** The record indicates that the participant had tuberculosis, an infectious disease caused by *Mycobacterium tuberculosis* and which most commonly involves the lungs, determined as a result of diagnostic/staging procedures.

- **Date of Diagnosis:** Record the month, day and year that the specific lung diagnosis was made. If the exact day of diagnosis cannot be determined from the record Record the exact month and year. Record the day as "99." Zero fill month and day, and record four digits for year.

7. **Other Cancer Diagnosis:** This item is concerned with cancer diagnoses other than the lung and neoplasms of uncertain behavior or carcinoids, sarcomas, lymphomas and other malignancies with an origin other than the lung. Do not include carcinoma in situ of the lung. These diagnoses must be classified according to ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification). ICD-9-CM coding for the PLCO Screening Trial must be consistent with the National ICD-9-CM coding standards and should not be influenced by specific institutional coding philosophies.

Darken the circle corresponding to an other cancer diagnosis as follows:

**No:** The record clearly states or indicates that no other cancers were diagnosed as a result of diagnostic or staging procedures. Also mark this item if there is no information for physician diagnosis or if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to Part D.

**Yes:** The record states or indicates that one or more other cancer diagnoses were determined as a result of diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for Item B.7 as follows:

- **ICD-9-CM Classification:** These items must be completed by a nosologist (a trained medical coder). The nosologist should code the five digit ICD-9-CM classification in the space provided and darken the circles corresponding to

each number or letter. When coding ICD-9-CM, always left justify the code and ignore the decimal place. If the ICD-9-CM code is a three or four digit code, record "X" for the remaining blank box(es). The following examples illustrate how the ICD-9-CM code boxes should be coded:

- The ICD-9-CM code for Hodgkin's disease, unspecified site is 201.90. This should be recorded as "20190."
- The ICD-9-CM code for malignant neoplasm of the esophagus is 150.9. This should be recorded as "1509X."
- The ICD-9-CM code for malignant neoplasm of the thyroid gland is 193. This should be recorded as "193XX."

**Note:** *If the diagnostic evaluation results in an extranodal lymphoma of the prostate, colorectum or ovary, assign the appropriate ICD-9-CM code for the type of lymphoma with "0" as the 5th digit denoting "extranodal". An "OCF" will be triggered. Complete an "MDF" for the OCF and manually set the expectation for the appropriate DE form. Complete the DEP, DEC or DEO for the prostate, colorectal or ovarian lymphoma.*

- **Date of Other Cancer Diagnosis:** Record the month, day, and year that the other cancer diagnosis was determined. If the day of the other cancer diagnosis is not clear in the record, then year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for the year.
- **More Than Two "Other" Cancer Diagnoses:**  
Record codes for more than two "other" cancer diagnoses in Item E.20, Comments, as shown in the following example:

Item E.20, Comments:

Item #	Comments
B.7	3; ICD-9-CM Classification = ____; Date of Other Cancer Diagnosis = mm/dd/yyyy

Be sure to set an expectation in the SMS for any additional "other" cancers.

If Part B is completed, skip Part C and go to Part D.

**Part C: Primary Lung Cancer Diagnosis Information:**

In this section, we are interested in obtaining all relevant information pertaining to a primary lung cancer diagnosis, including lymphoma arising in the lung, sarcoma, neoplasm of uncertain behavior of the lung, and/or a carcinoid of the lung. This section is to be completed only by a CTR or CTR-eligible individual. Every attempt should be made to complete this form in a timely manner. For participants who have a positive PLCO screening result, the Medical Record Abstract-DEL Form should be completed within six months of the positive screening result. If specific items cannot be completed within the six-month time frame (i.e., awaiting

access to photocopy a form or awaiting TNM staging by the Tumor or Cancer Registrar), those items should be left blank, and the information completed within nine to eleven months.

If the participant was diagnosed with more than one primary lung cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For all subsequent primaries use another DEL form. If more than one primary was diagnosed on the first date of diagnosis, record information about the most advanced cancer diagnosed on that day in Part C, and use additional DEL forms for any other cancers diagnosed on that day.

8. **Date of Primary Lung Cancer Diagnosis:** Record the month, day, and year of the primary lung cancer diagnosis that was confirmed by pathology/histopathology or cytology/cytopathology report if pathology/histopathology is not available. This is the date on the report that the actual procedure (biopsy, surgery, aspiration of cells, etc.) was performed that confirmed this primary lung cancer diagnosis. Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report. For example, the date on the pathology report may be the date that the slides were read or the date that the diagnosis was determined or reported, rather than the date of the procedure.

If there are multiple reports that confirmed this primary cancer, record the earliest date available that has an adequate pathology/histopathology specimen. If tissue confirmation a pathology/ histopathology is not available, record the earliest date that has an adequate cytology/cytopathology specimen. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. In the rare situation in which lung cancer was diagnosed by clinical examination only and not histologically or cytologically, the date of first lung cancer diagnosis is the date of the clinical examination, which diagnosed the cancer.

Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year. *Month and year of lung cancer diagnosis must be known*, however, if day is unknown, record "99."

9. **Verbatim Description of Primary Lung Cancer Diagnosis:** This item is concerned with the actual physician diagnosis of lung cancer. This item is optional except in the following situations:
- The diagnosis is based on clinical examination and not pathology (Item A.5 = Lung malignancy diagnosed by clinical examination only); or
  - The SC is unable to obtain a copy of the histopathology or cytology report that corresponds to the ICD-O-2 code in Item C.10 (Item C.11 = Not available).

Record the verbatim description of the primary lung cancer diagnosis from the pathology/histopathology report (or cytology/cytopathology report if a histopathology report is not available). The verbatim description should come from the diagnosis section of the earliest (chronological) histopathology report (or cytology report if the histopathology report is not available) that had an adequate specimen and that confirms the cancer diagnosis.

- Occasionally, the diagnosis section will say "see above" or "see microscopic." In this situation record verbatim all of the information from the appropriate section of the report which pertains to the cancer diagnosis.
- Do not record any information about metastases or recurrent cancer.
- Do not record any information about benign conditions listed in the diagnosis section of the histopathology or cytology report.

10. **ICD-O-2 Cancer Classification:** This item is for classifying the physician diagnosis of the primary lung cancer according to ICD-O-2 (*International Classification of Diseases for Oncology*, Second edition, 1990). The CTR should code the ten digit ICD-O-2 classification in the space provided. Darken the circles corresponding to the letter and each number.

- The ICD-O-2 code/histopathology should reflect the diagnosis from the earliest (chronological) pathology report, that has an adequate tissue specimen, (or cytology report if tissue was not the pathology report is not available) which confirms the cancer diagnosis. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. This should be the same report that was used as a source for the date of diagnosis in Item C.8.
- If the diagnosis of lung cancer is based on tissue obtained from a metastasis such as a lymph node or bone, record 9 (unknown) for the grade in the ICD-O-2 code.
- A neoplasm of uncertain behavior of the lung is considered to be a cancer by NCI and should be recorded in this section. Use the following guidelines for ICD-O-2 coding of neoplasms of uncertain behavior of the lung:
  - Assign the topography and morphology codes for this neoplasm according to ICD-O-2.
  - The behavior code for neoplasm of uncertain behavior is "1". Under "Behavior", enter "1" in the box and darken the circle for "1" printed on the form.
  - Grade will be coded "9" for neoplasm of uncertain behavior. Under "Grade", enter a "9" in the box and darken the circle for "9" printed on the form.

*If the medical record contains information about this neoplasm that would result in a behavior code other than "1" or a grade code other than "9", contact the CC MRA Coordinator.*

- Extranodal lymphomas arising in the prostate lung may require the T-cell, B-cell, or NK cell designation. If so, enter the appropriate code from ICD-O-2 in the "Grade" space. The T-cell, B-cell or NK cell designation has priority over the grade when both are provided. NK cell designation = "8." A bubble for "8" does not exist on the form. Darken the space for "8" under "Grade" for NK cell if this applies.
- Do not code the descriptions "high grade," "low grade," or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.
- If the record clearly indicates that lung cancer was confirmed by a pathology or cytology report, but the report is not available, code the diagnosis from other available documents, (i.e. physician's notes, progress reports, etc.) that reference the earliest procedure from an adequate specimen. Place an asterisk by Item C.10, and indicate in the Comments section the source of the diagnosis. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments:

Item #	Comments
C.10	Pathology/cytology report not available. Source of diagnosis is...

- If the lung cancer was diagnosed by clinical examination only, code the diagnosis using the report from the clinical examination form, which diagnosed the cancer.
- The ICD-O-2 cancer classification should be coded by the CTR regardless of whether the ICD-O-2 code is available in the medical record.
- Use the following guidelines to determine how to record a diagnosis of lymphoma for PLCO. Refer to Appendix K-17-2 of the MOOP for explanation of Nodal vs. Extra-Nodal Lymphomas:
  - If an extranodal lymphoma of the lung is designated as the primary, record the ICD-O-2 code per the site in the lung where the lymphoma is identified. Be sure this is the primary site of origin and not just a site where a biopsy was taken. The TIL form is required for each DEL as it is for any PLCO primary.
  - If the site of origin is determined to be the lymph node(s) in the chest rather than of lung tissue, record this lymphoma in B.7 as an Other Cancer Diagnosis. When the DEL3 form is scanned, an expectation for an OCF will be set. On the OCF, assign the ICD-O-2 topography code for lymph nodes (C77.\_\_\_).
  - If a lymphoma is diagnosed in both a nodal and an extranodal lymphoma of the lung, consult the SC principal investigator to determine where the lymphoma originated and code the primary to that site.
  - If an extranodal lymphoma arising in another PLCO site is discovered during the diagnostic evaluation of the lung, the ICD-9-CM code for lymphoma will be entered in Part B of the DE form. This code will trigger an OCF. The SC will complete an MDF (for the OCF) and manually set the expectation for the appropriate DE. For example, an extranodal lymphoma of the colon is discovered as a result of the diagnostic evaluation of positive lung screen. The ICD-9-CM code for the type of lymphoma will be entered in Part B of the DEL, with "0" as the 5th digit denoting "extranodal." An OCF will be triggered. Complete an MDF (for the OCF) and manually set the expectation for a DEC. Complete the DEC for the extranodal lymphoma arising in the colon. Complete the TIC also.
  - If an extranodal lymphoma arising in the lung is reported on an ASU, the SC will need to use the three-digit PLCO code for the lung, rather than the three-digit code for lymphoma in order to trigger the appropriate DE form. Complete the DEL for the extranodal lymphoma arising in the lung. Complete the TIL also.

**11. Photocopy of Report Confirming Primary Lung Cancer:** The purpose of this item is to document that the pathology/histopathology report (or cytology/cytopathology report if a pathology report is not available) that confirmed the primary lung cancer has been photocopied and attached to the Medical Record Abstract-DEL Form.

- If there are multiple pathology reports confirming this primary lung cancer, the photocopy should be of the first pathology or cytology report which was the source for recording the date of the lung cancer diagnosis recorded in Item C.8, and the ICD-O-2 code recorded in Item C.10. If the Date of Lung Cancer Diagnosis and the ICD-O-2 Cancer Classification came from different reports, attach copies of both reports used to code Items C.8 and C.10.
- A situation may arise in which an institution does not allow the photocopying of records. Every reasonable attempt should be made to obtain permission to photocopy the pathology or cytology report since it is a critical end-point of the screening trial. If special permission or approval is required, the abstractor should work with the SC Coordinator/Principal Investigator to obtain the necessary approval. If

this item cannot be completed in a timely manner, leave it blank and attempt to obtain the information at a later date via data retrieval.

Darken the circle to indicate whether a photocopy of the pathology or cytology report is available as follows:

- **Pathology/Histopathology:** The pathology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEL Form. The photocopy should be labeled with the participant's ID number, the study year, titled "Medical Record Abstract-DEL/Pathology Report," and inserted into the participant's folder.
- **Cytology/Cytopathology:** The cytology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEL Form. The photocopy should be labeled with the participant's ID number, the study year, titled "Medical Record Abstract-DEL/Cytology Report," and inserted into the participant's folder.
- **Not available:** The histo pathology or cytology report exists in the medical record, but a photocopy cannot be obtained or there is no report in the medical record. Place an asterisk by Item C.11, and provide a detailed explanation in the Comments section of why the pathology or cytology report cannot be obtained. (In this situation, Item C.9 (Verbatim Description of Lung Cancer Diagnosis) must be completed.) Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments:

Item #	Comments
C.11	Pathology or cytology report cannot be obtained because...

12. **Primary Tumor Location:** This item is to document the site of origin of the malignant lung tumor, as determined by a surgical report, pathology report, or radiology report. Darken one or more circles corresponding to the site of origin. If the primary tumor location is unknown or not mentioned in the record, darken the circle next to "Unknown."

13. **Histopathologic Type for Primary Lung Cancer:** This item is to document the histopathologic type of the primary lung cancer. This refers to the type of cell comprising the tumor, usually determined by the pathologist from a tissue specimen. This information can be obtained from the histopathology report or cytology report of the bronchial washing/brushing that confirmed the lung cancer and collected the most tissue. If neither a histopathology report nor a cytology report is available, this information may be found in the discharge summary, or an operative report. If the histopathologic type is obtained from a source other than the pathology report, place an asterisk by Item C.13, and record the source of the information in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments:

Item #	Comments
C.13	Source of histopathologic type of lesion is...

- If the cancer has two different histopathologic types, the diagnosis is usually based on the predominant type. This should be stated in the pathology report. In this situation, record the predominant histopathologic type. If the pathology report does not indicate a predominant type record both types in Other (SPECIFY) for Item C.13 as follows: "Histopathologic type is \_\_\_\_\_ and \_\_\_\_\_".
- **The abstractor should select the general category into which the result fits rather than using Other-specify to list a more detailed result.** For example, "nonkeratinizing squamous cell carcinoma" and "keratinizing squamous cell carcinoma" should be included in the "squamous cell carcinoma (epidermoid carcinoma)" category.
- **Neoplasm of uncertain behavior of the lung:** Histopathologic Type for Neoplasm of uncertain behavior of the lung will be designated as "Other." Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- **Extranodal lymphoma arising in the lung:** Histopathologic Type for Extranodal lymphoma arising in the lung will be designated as "Other." Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- **Primary sarcoma of the lung:** Histopathologic Type for Primary sarcoma of the lung will be designated as "Other". Darken the circle for "Other" and record the specific histopathologic type on the line provided.

Darken the circle corresponding to the histopathologic type of the lung cancer. If the histopathologic type is other than those listed and does not fit into a general category of a type listed, darken the circle for "Other" and specify the histopathologic type. If the histopathologic type is unknown or not available in the record, darken the circle for "Unknown."

**14. Histopathologic Grade for Primary Lung Cancer:** This item documents the histopathologic grade of the primary lung cancer. Grade refers to a system of classifying certain characteristics of the cell. This information can be obtained directly from the pathology report, which collected the most tissue, a cytology report, a TNM form, a staging classification form, the discharge summary, or from doctor's notes.

- If the medical record states two different histopathologic grades, or a range of grades, record the most severe type. For example, "well differentiated" is the least severe type and "undifferentiated" is the most severe type. The most severe grade should be recorded from the primary site. Do not record the most severe grade from the metastatic site.
- **Neoplasm of uncertain behavior of the lung:** Neoplasm of uncertain behavior of the lung usually does not have a grade designation; therefore, "Grade cannot be assessed (GX)" should be recorded. If the medical record contains information about this neoplasm that would result in a specific grade, contact the CC MRA Coordinator.
- **Extranodal lymphoma arising in the lung:** If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown." Do not code the descriptions "high grade," "low grade," or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.
- **Primary sarcoma of the lung:** If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown."

Darken the circle corresponding to the histopathologic grade of the lung cancer. Darken the circle for "Unknown" when there is no indication in the record of the histo-

pathologic grade or if the basis for the lung cancer diagnosis. is from tissue from a metastatic site (such as lymph node or bone).

15. **TNM Staging for Primary Lung Cancer:** This item refers to the TNM or AJCC (American Joint Committee on Cancer) staging system. The AJCC Manual for Staging of Cancer provides the minimum requirements for clinical and pathologic staging. A list of relevant documentation, based on those requirements can be found below. If TNM staging was performed, darken the circle corresponding to the edition of the AJCC Cancer Staging Manual used, the 4th Edition or the 5th Edition.

**Note:** The 5th Edition of the AJCC manual was published in January 1998. This latest edition should be used to stage all cancers diagnosed on or after January 1, 1998. For all previous cases the 4th Edition should be used.

TNM staging describes the anatomic extent of disease based on three components:

- (1) the extent of the primary tumor (T),
- (2) the absence or presence and extent of regional lymph node metastases (N), and
- (3) the absence or presence of distant metastases (M).

The addition of numbers to these three components indicates the extent of the malignant disease, thus showing progressive increase in tumor size or involvement.

If the TNM staging is available in the medical record, the abstractor may record it directly from the record. This staging is often performed by a Tumor Registrar (also known as a Cancer Registrar) and, if not available in the medical record, it may be available in the tumor registry. If the TNM staging is not available in the tumor registry, the abstractor should attempt to have the stage classified by the Tumor Registrar or a physician at a later date. The Tumor Registrar must be a CTR or CTR - eligible. If the TNM staging is not in the records or if the abstractor disagrees with the staging, the CTR may assign the TNM stage when all relevant documentation from the patient's medical record is available to him/her. If an institution does not have a Tumor Registrar, then a physician can assign the TNM stage as long as all relevant patient documentation is available to the physician. The nosologist or abstractor should not assign the TNM staging, unless s/he is also a CTR (or CTR-eligible) and all relevant documentation is available.

If a participant receives neoadjuvant therapy prior to surgical resection, NCI would like the abstractors to do Clinical Staging of the Primary Cancer. Then record the TNM Pathologic Staging, using surgical pathology. In this situation TNM Pathologic Staging should be recorded as follows:

- Complete the item for TNM Pathologic Staging using the surgical pathology report.
- Place an asterisk next to the item number and go to the Comments section in Part E.
- Record the item number in the left margin of the Comments section and begin with the phrase, "ypT\_N\_M", including the appropriate numerical stage of the carcinoma which was recorded in Part C, TNM Pathologic Staging. "y" is a TNM descriptor that indicates that staging was performed during or following multi-modal therapy and the "p" indicates pathologic staging. After the appropriate information has been included in the "ypTNM" format, briefly state what treatment was received prior to surgery.

Item E.20, Comments

Item #	Comments:
C.15.b	ypT_N_M_; Treatment received prior to surgery was...

**General Guidelines for NX vs. NO and MX vs. MO:**

The X category should be used when involvement of regional lymph nodes or distant metastatic sites was not evaluated or could not be evaluated. It is not sufficient to assume that an evaluation would have been negative (or positive). If there is a statement in the record documenting the physician's assessment of regional lymph nodes and/or metastatic sites as negative or not involved, without physical examination, imaging or other diagnostic procedures, this may be used to assign 0 rather than X. The use of category 0, as in NO or MO, means that no involvement was found after some type of evaluation including appropriate work-up and/or the physician's clinical impression.

**NOTE:** SCs should photocopy any documents from medical records that are used for TNM staging, and keep these with the participant's file.

**a. TNM Clinical Staging**

If both clinical and pathological staging are available, both should be recorded. Clinical staging is based on the assessment of the anatomic extent of disease before instituting definitive therapy. All information available prior to the first definitive treatment of primary lung cancer may be used for TNM clinical staging. Relevant documentation, which is suggested to assign clinical staging, includes:

- Physical examination and medical history;
- Imaging procedures;
- Endoscopy, including bronchoscopy, esophagoscopy, mediastinoscopy, thoracentesis, and thoracoscopy; and
- Other tests designed to demonstrate extrathoracic metastasis and regional extension.

Darken the circle to indicate whether the TNM clinical staging is available as follows:

**Yes:** If the TNM clinical staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available.

**No:** If no part of the TNM clinical staging is available, then darken the circle for "No" and skip to C.15b, TNM Pathologic Staging.

- **Neoplasm of uncertain behavior of the lung:** Darken the circle for "No." TNM clinical staging does not apply to neoplasms of uncertain behavior of the lung.
- **Extranodal lymphoma arising in the lung:** Darken the circle for "No." TNM clinical staging does not apply to an extranodal lymphoma arising in the lung.
- **Primary sarcoma of the lung:** Darken the circle for "No." TNM clinical staging does not apply to primary sarcoma of the lung.

## b. TNM Pathologic Staging

Relevant documentation necessary to assign pathologic staging includes:

- Any data for clinical staging;
- Examination of the resected specimen(s), including lymph nodes and lung tissue involving the primary tumor.

Darken the circle to indicate whether the TNM pathologic staging is available as follows:

**Yes:** If the TNM pathologic staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available.

**No:** If no part of the TNM pathologic staging is available, then darken the circle for "No" and skip to Item C.16, Record Stage.

- **Neoplasm of uncertain behavior of the lung:** Darken the circle for "No." TNM pathologic staging does not apply to neoplasms of uncertain behavior of the lung.
- **Extranodal lymphoma arising in the lung:** Darken the circle for "No." TNM pathologic staging does not apply to an extranodal lymphoma arising in the lung.
- **Primary sarcoma of the lung:** Darken the circle for "No." TNM pathologic staging does not apply to primary sarcoma of the lung.

**16. Record Stage:** *If TNM Pathologic Staging is complete, this item must be skipped. If any part of the TNM Pathologic Staging is not available or is incomplete (i.e. "Tx," "Nx," or "Mx" is missing), this item must be completed.* This item is to document the stage of disease (other than TNM) for primary lung cancer. There are three stage classifications provided for lung cancer: "Stage Only," "VALSCG" (Veterans Administration Lung Cancer Study Group) for small cell lung cancer only, and "Summary Staging."

- If information about one or more of the stage classifications is not available in the medical record, it is not necessary to try to obtain it from another source.
- If a stage classification other than those provided on the form is available in the record and all or part of the TNM Pathologic Staging is not available, place an asterisk beside Item C.16, and record in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments

Item #	Comments
C.16	Other Stage Classification is_____. Stage = _____.

- If stage is available for an extranodal lymphoma arising in the lung, for a primary sarcoma of the lung, or for any other type of primary lung malignancy, which cannot be staged using TNM, record the stage in Item C.16.

Darken the circle to indicate whether stage of disease is available as follows:

**Yes:** If "Stage Only," "VALCSG," and/or "Summary Staging" is available, darken the circle for "Yes" and then darken the circles corresponding to the code for each. If stage of disease is not available for any particular classification, darken the circle next to "Not available" in the appropriate column.

**No:** If none of the three stage classifications, "Stage Only," "VALCSG," or "Summary Staging" is available in the record, darken the circle for "No" and skip to Part E, Physician/Hospital Location Information.

- **Neoplasm of uncertain behavior of the lung:** Darken the circle for "No." Typically a neoplasm of uncertain behavior of the lung is not staged. If the medical record contains staging information about this neoplasm, contact the CC MRA Coordinator.
- If no stage of disease information is available, it is not necessary for the abstractor to obtain it from another source. Also, the abstractor should not attempt to code stage of disease unless s/he is a Certified Tumor Registrar (CTR) or CTR eligible. If the abstractor is a CTR, or is CTR eligible and has all of the necessary documentation for determining the stage of disease, then s/he may code stage of disease and record it following the guidelines above.
- If small cell lung cancer is diagnosed, even if pathologic TNM staging is complete, please record the VALCSG stage. This information will likely come from the radiation oncology consultation note. The Lung Subcommittee expects that for all small cell lung cancers that VALCSG stage be recorded.

#### **Part D: Date of Diagnostic Evaluation Determination:**

17. Complete this item by recording the month, day and year of the diagnostic evaluation determination if one of the following conditions is satisfied:

- Item A.5 = No malignancy and Items B.6 and B.7 = No or
- Item A.5 = No malignancy and no diagnostic procedures were performed per participant self-report or
- Item A.5 = No information available

Darken the circle corresponding to each number. If the exact day of diagnostic evaluation determination cannot be determined from the record, year and month can usually be assessed. In this situation, record the exact month and year. Record the day as "99." Zero fill month and day, and record four digits for year.

#### **Part E: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant underwent diagnostic evaluation for lung cancer, other than what was reported prior to abstracting. Items E.18 and E.19 are not required but it is recommended they be completed to facilitate collection of additional medical record data, including pathology reports and slides. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

18. **Physician for Diagnostic Evaluation:** Record the name, address, and telephone number of the primary physician who provided care during the participant's diagnostic evaluation for lung cancer or the physician who performed the diagnostic evaluation procedures. Space has been allotted for entry of one physician. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.

19. **Hospital or Clinic for Diagnostic Evaluation:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent one or more diagnostic procedures for lung cancer. Space has been allotted for entry of one hospital or clinic. Record the participant's medical record or chart number for each hospital or clinic location.

20. **Comments:** Use this section to record any overflow information. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or the Principal Investigator should review the discrepant information for the appropriate coding decision prior to calling the CC MRA Coordinator.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as in the following example when a seventh medical complication should be collected:

Item #	Comments
A.4	7; Type = ____; Date = ____

- First enter the item number indicating the item to which the comments are related, and record the comments in the space provided to the right of the item number.
- Throughout these specifications, standard phrases are given to preface comments so they will be easier to locate during analysis. Please use these phrases at the beginning of the comments, if applicable.
- Place an asterisk next to the item number being referenced in the main body of the DEL form.
- If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM TREATMENT INFORMATION - LUNG (TIL2/TLQ2)

**1. Date Abstracted:**

MO.	DAY	YEAR
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

MO: 20 DAY: 0 YEAR: 0

**2. Abstractor ID #:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**3. CTR ID#:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**4. Study Year T0-T13:**

T	0	0
	1	1
	2	2
	3	3
	4	4
	5	5
	6	6
	7	7
	8	8
	9	9

**5. Purpose of Abstract:**

Initial abstract

Re-abstract for QA

### FOR OFFICE USE ONLY

#### Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)

**6.**

**Data Entry of Non-Scannable Items:**

**Data Retrieval:**

Form Received into SMS   
Manual Review Completed

Completed  None Required

Attempted  None Required

**Disposition:**

Interim Complete (ICM)  Final Complete (FCM)  Final Incomplete (FIC)

### PART A: INITIAL TREATMENT INFORMATION

**1. RADIATION TREATMENT FOR LUNG CANCER:**

No  Yes (COMPLETE TABLE BELOW)  Unknown

TREATMENT #	1	2																																																																		
DATE RADIATION TREATMENT BEGAN (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		

PLEASE DO NOT WRITE IN THIS AREA



008811

**PART A CONTINUED . . .**

**2. SURGICAL TREATMENT FOR LUNG CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

PROCEDURE #	1	2	3	4																																																																																																																																				
<b>TYPE OF SURGICAL PROCEDURE</b>  (SEE SURGICAL PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 04 06 08 11 12 13 14 15 16 88  _____ SPECIFY	01 02 04 06 08 11 12 13 14 15 16 88  _____ SPECIFY	01 02 04 06 08 11 12 13 14 15 16 88  _____ SPECIFY	01 02 04 06 08 11 12 13 14 15 16 88  _____ SPECIFY																																																																																																																																				
<b>DATE OF SURGERY</b>  (MO. - DAY - YEAR)	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						

**SURGICAL PROCEDURE CODES**

- |  |  |                          |
|--|--|--------------------------|
| 01 = Exploratory thoracotomy without resection | 11 = Wedge resection                     | 16 = Partial pleurectomy |
| 02 = Mediansternotomy                          | 12 = Segmental resection                 | 88 = Other (SPECIFY)     |
| 04 = Lobectomy                                 | 13 = Lymphadenectomy/Lymph node sampling |                          |
| 06 = Bilobectomy                               | 14 = Chest wall resection                |                          |
| 08 = Pneumonectomy                             | 15 = Thoracentesis                       |                          |

**3. CHEMOTHERAPEUTIC TREATMENT FOR LUNG CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2	3	4																																																																																																																																				
<b>DATE CHEMOTHERAPEUTIC TREATMENT BEGAN</b>  (MO. - DAY - YEAR)	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						

**PART A CONTINUED . . .**

**4. OTHER TYPE OF TREATMENT FOR LUNG CANCER:**

- No
  Yes (COMPLETE TABLE BELOW)
  Unknown

TREATMENT #	1	2																																																																																																																																				
DATE OTHER TREATMENT BEGAN  (MO. - DAY - YEAR)	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR		0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	8	8	8	8	8	8	9	9	9	9	9	9	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR		0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	8	8	8	8	8	8	9	9	9	9	9	9
MO.		DAY		YEAR																																																																																																																																		
0	0	0	0	0	0																																																																																																																																	
1	1	1	1	1	1																																																																																																																																	
2	2	2	2	2	2																																																																																																																																	
3	3	3	3	3	3																																																																																																																																	
4	4	4	4	4	4																																																																																																																																	
5	5	5	5	5	5																																																																																																																																	
6	6	6	6	6	6																																																																																																																																	
7	7	7	7	7	7																																																																																																																																	
8	8	8	8	8	8																																																																																																																																	
9	9	9	9	9	9																																																																																																																																	
MO.		DAY		YEAR																																																																																																																																		
0	0	0	0	0	0																																																																																																																																	
1	1	1	1	1	1																																																																																																																																	
2	2	2	2	2	2																																																																																																																																	
3	3	3	3	3	3																																																																																																																																	
4	4	4	4	4	4																																																																																																																																	
5	5	5	5	5	5																																																																																																																																	
6	6	6	6	6	6																																																																																																																																	
7	7	7	7	7	7																																																																																																																																	
8	8	8	8	8	8																																																																																																																																	
9	9	9	9	9	9																																																																																																																																	

**5. ANY LOCAL OR REGIONAL RESIDUAL DISEASE LEFT AFTER SURGERY:**

- No
  Not applicable  
 Yes - Microscopic
  Unknown  
 Yes - Gross Tumor

**PART B: PHYSICIAN/HOSPITAL LOCATION INFORMATION**

**6. PHYSICIAN FOR TREATMENT:**

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

**7. HOSPITAL OR CLINIC FOR TREATMENT:**

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**TREATMENT INFORMATION – LUNG VERSION 2 (TIL2/TLQ2)**

This form is to be completed by the Medical Record Abstractor, and the CTR or CTR-eligible individual. Specifically, the CTR will be required to complete Item A.5 (Any Local or Regional Residual Disease Left After Surgery).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- When abstracting date information for items with multiple treatments, record the dates in the order in which they are found in the medical record.
- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital or tumor registry. If the treatment is considered to be a non-traditional therapy that would not usually be mentioned in a medical record, it is acceptable to take the participant's self-report. In all other cases, a therapy that is not mentioned in the medical record should not be recorded.
- Information about treatment procedures should be collected for the first planned course of treatment (usually within 6 months of the cancer diagnosis). The maximum time period for which medical records could be collected for treatment information is about 1 year from the date of a cancer diagnosis.
- This form includes items which require that data be entered verbatim, such as recording "other (specify)," and recording comments. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If additional space is needed to record treatment information, use the Comments section. Record the same type of data as requested in the treatment table.
- If any item has unclear, discrepant, or conflicting information, review this information with the SC Lead Abstractor, SC Coordinator or the Principal Investigator prior to contacting the CC MRA Coordinator.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy black marks that fill the circle completely.**



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

Participant ID: Affix a Participant ID label to the space provided in the lower left corner of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled in. Darken the circle corresponding to each remaining number.  
If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized, erase the interim date and record the date the form was completed.
2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the TI. If more than one abstractor completes the TI, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form— this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.
3. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item A.5. (Any Local or Regional Residual Disease Left After Surgery). Darken the circles corresponding to the four digits.
4. **Study Year:** Darken the circles corresponding to the study year, from T0 to T13. Zero fill the number for T0 - T9 (e.g., T00, T01, T02, etc.).
5. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the "first" time to confirm the treatment of lung cancer.

- **Re-abstract for QA:** Medical record information that has already been abstracted to confirm the treatment of lung cancer is being re-abstracted for the purpose of quality assurance. Not yet implemented.
6. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except "Disposition" are optional. "Disposition" is required and may be marked on the form or entered directly into DEES. Dispositions of "Final Complete" (FCM) may also be set automatically in DEES when the form is edited (See DEES User's Guide).
- **Form Received into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)
  - **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)
  - **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
  - **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
  - **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
    - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data are abstracted, remove the ICM so that the appropriate disposition is assigned.
    - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
    - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **Part A: Initial Treatment Information:**

In this section, record all treatments that make up the first course of treatment the participant received for lung cancer.

- If the treatment is intended as initial management, it should be recorded regardless of the timeframe or treatment site.
- If the first course of treatment is directed toward a metastatic site, it is appropriate to code this treatment.
- Combination Treatments: If multiple treatments are given in combination, enter the date treatment began for the combination treatments. If another treatment is added to the combination (or one is removed), the new combination should be considered a new treatment with a new start date.
- Time period Rules for First Course of Treatment (in order of precedence):
  1. If there is a documented, planned first course of treatment, first course ends at the completion of this treatment plan, regardless of the duration of the treatment plan.
  2. If the patient is treated according to a facility's standards of practice, first course ends at the completion of the treatment.
  3. If there is no documentation of a planned first course of treatment or standard of practice, first course of treatment includes all treatment received before disease progression or treatment failure. If it is undocumented whether there is disease progression/treatment failure and the treatment in question begins more than one year after diagnosis, assume that the treatment is not part of the first course.
  4. If a patient refuses all treatment modalities and does not change his/her mind within a reasonable time frame, or if the physician opts not to treat the patient, record that there was no treatment in the first course.
- All modalities of treatment are included regardless of sequence or the degree of completion of any component method.

Reference: SEER Program Code Manual, Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute; 1998, p.119.

- If there is a significant treatment that is not in the first course of treatment and the abstractor and the SC Principal Investigator feel it should be recorded, this will need to be sent to the CC MRA Coordinator. The relevant medical records should be copied (identifiers deleted) and sent to the CC MRA Coordinator with a memo describing the issue.
1. **Radiation Treatment for Lung Cancer:** This item is concerned with the radiation treatment the participant received for lung cancer. Radiation treatment most commonly consists of either external photon beam therapy or brachytherapy (interbronchial implant). More rarely, radiation treatment may consist of either neutron or proton external beam therapy. Note that this item is concerned with radiation treatment and not diagnostic x-rays such as a CT scan.

External photon beam therapy is delivered by a machine, which generates x-rays or contains a large amount of a radioactive isotope (cobalt), or delivered by a linear accelerator. External beam treatments are given in one or more "series" or "courses."

Each course of radiation is administered over a period of days or weeks in small daily doses.

Brachytherapy is a method of radiotherapy in which radioactive sources are applied on the external surface of the patient, implanted in tissue, or inserted into body cavities. Brachytherapy procedures usually are performed in an operating room since they require anesthesia. Although the brachytherapy treatment may be performed in a surgical suite and recorded in surgical notes, it is radiotherapy and should be recorded as such for purposes of describing the participant's treatment.

Some institutions may have the capability to deliver neutron beam therapy, via a hospital based high-energy cyclotron, or proton beam therapy, via a hospital-based synchrotron. Treatment via these modalities is usually administered in "courses" or "series" over a period of time. Hyperfractionated therapy refers to treatment with more than one fraction of radiation a day. Most institutions, however, find these machines impractical for a hospital setting due to their cost and size.

Darken the circle corresponding to whether the participant received radiation treatment as follows:

**No:** The record clearly states that the participant did not receive radiation treatment, or there is no mention of radiation treatment (planned or given) in the records. Darken the circle for "No" and go to Item 2.

**Yes:** The record indicates that the participant received radiation treatment. Darken the circle for "Yes" and complete the table for Item 1. Record information for each course of radiation treatment received in a separate column. For each radiation treatment, complete the following:

- **Date Radiation Treatment Began:** Record the month, day, and year that the radiation treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional radiation treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional radiation treatment in Comments would be the third radiation treatment recorded:

Item B.8, Comments:

Item #	Comments
A.1	3; Date =

**Unknown:** The record states that a radiation treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 2.

2. **Surgical Treatment for Lung Cancer:** This item is concerned with the surgical treatment that the participant received for lung cancer. Darken the circle corresponding to whether the participant received surgical treatment as follows:

**No:** The record clearly states that the participant did not receive surgical treatment, or there is no mention of surgical treatment (planned or given) in the records. Darken the circle for "No" and go to Item 3.

**Yes:** The record indicates that the participant received surgical treatment. Darken the circle for "Yes" and complete the table for Item 2. For each surgical procedure performed, complete the following items:

- **Type of Surgical Procedure:** Darken the circle corresponding to the type of surgical procedure performed. Refer to the Surgical Procedure Codes for the list of common surgical procedures for lung cancer and to Appendix K-17-2 of the MOOP for definitions of surgical procedures for the lung. If the participant had a surgical procedure other than those listed, darken the circle for "Other (SPECIFY)" and record the surgical procedure performed on the line provided.
  - If surgical resection with removal of lymph nodes is performed, this should be coded as two separate procedures using the appropriate code for surgical resection and code "13" for the lymph node removal.
  - Mediastinoscopy is not a treatment for lung cancer and should not be collected as a procedure.
  - If pleurodesis is done to treat the lung cancer, record under Thoracentesis, code 15.
- **Date of Surgery:** Record the month, day and year that the surgical procedure was performed. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional surgical procedures, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional surgical treatment in Comments would be the fifth surgical treatment recorded:

Item B.8, Comments:

Item #	Comments
A.2	5; Type = ____; Date = ____

**Unknown:** The record states that a surgical treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 3.

3. **Chemotherapeutic Treatment for Lung Cancer:** This item is concerned with any chemotherapeutic treatment the participant received for lung cancer. Chemotherapeutic treatment is the use of drugs given as treatment for cancer. Chemotherapeutic treatment may be the primary treatment, prescribed in cases of advanced cancer, or may be an adjuvant treatment, given in addition to surgery and/or radiation.

The participant's medical record may or may not contain chemotherapeutic treatment data. Unlike surgery and radiation, treatments that must be performed at a hospital or clinic, chemotherapeutic treatment may be administered at a physician's office or

self-administered under the guidance and supervision of a physician. It is, therefore, especially important that the abstractor carefully review the record and, if necessary, contact the physician for information on chemotherapeutic treatment.

Darken the circle corresponding to whether the participant received chemotherapeutic treatment as follows:

**No:** The record clearly states that the participant did not receive chemotherapeutic treatment, or there is no mention of chemotherapeutic treatment (planned or given) in the records. Darken the circle for "No" and go to Item 4.

**Yes:** The record indicates that the participant received chemotherapeutic treatment. Darken the circle for "Yes" and complete the table for Item 3. For each protocol of chemotherapeutic treatment received, complete the following:

- **Date Chemotherapeutic Treatment Began:** Record the month, day, and year that the chemotherapeutic treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional chemotherapeutic treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional chemotherapeutic treatment in Comments would be the fifth chemotherapeutic treatment recorded:

Item B.8, Comments:

Item #	Comments
A.3	5; Date = ____

**Unknown:** The record states that a chemotherapeutic treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 4.

4. **Other Type of Treatment for Lung Cancer:** This item is concerned with any treatment other than surgery, radiation and chemotherapeutic treatment that the participant received for lung cancer. Other types of treatment include autologous bone marrow transplant, gene therapy, and alternative treatments.

Darken the circle corresponding to whether the participant received some other type of treatment as follows:

**No:** The record clearly states that the participant did not receive any other type of treatment, or there is no mention of other treatments (planned or given) in the records. Darken the circle for "No" and go to Item 5.

**Yes:** The record indicates that the participant received some other type of treatment. Darken the circle for "Yes" and complete the table for Item 4. For each type of treatment received, complete the following:

- **Date Other Treatment Began:** Record the month, day, and year that the other type of therapy began. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation,

record the exact month and year. Record the day as "99". Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record other type of treatments for lung cancer, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional other type of treatment for lung cancer in Comments would be the third other type of treatment for lung cancer recorded:

Item B.8, Comments:

Item #	Comments
A.4	3; Date = ____

**Unknown:** The record states that an "other" treatment is planned but then there is no mention of whether or not it is actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 5.

5. **Any Local or Regional Residual Disease Left After Surgery:** This item is to be completed only by a CTR or a CTR-eligible individual. This item documents whether the participant had any local or regional residual disease left after surgery. Record information for this item for any attempted surgical procedure even if the procedure was not completed. Surgery is defined as any of the surgical procedures listed in Item 2. If there are multiple surgeries, use the last surgery in the first course of treatment. Regional residual disease is defined as a cancer that remains after surgery and is related to the original site by direct extension. This regional disease refers to the site of the surgery (not necessarily the site of the primary cancer). It does not apply to metastases. Information should be taken from the pathology report since this is the most definitive source for determining residual disease and the operative report may be used for further clarification. If neither pathology nor operative reports are available, a discharge summary or doctor's note with treatment plan may be used to record this item. "Perineural or vascular invasion" noted on a surgical pathology report, does not infer that regional or residual disease is left after surgery. The pathology report refers only to the specimen or tissue removed during surgery, not to tumor that remains following surgery. Darken the circle corresponding to whether the participant had any local or regional residual disease left after surgery as follows:

**No:** The record indicates that the participant had no local or regional residual disease left after surgery. Darken the circle for "No" and go to Item 6.

**Yes - Microscopic:** The record indicates that the participant had local or regional residual disease left after surgery which was microscopic (of minute size). The pathology report may state "tumor to surgical margin". Darken the circle for "Yes - Microscopic" and go to Item 6.

**Yes - Gross Tumor:** The record indicates that the participant had local or regional residual disease left after surgery, which was macroscopic (can be visualized with the naked eye). Darken the circle for "Yes - Gross Tumor" and go to Item 6.

The highest order of evidence should be coded. For example, if the operative report notes that gross disease remains, then "gross" should be coded. But if the

report notes that there were positive surgical margins without gross evidence of disease, the "microscopic" response should be used.

**Not applicable:** The participant did not receive any surgical treatment for lung cancer, or Item A.2, Surgical Treatment for Lung Cancer, is "No" or "Unknown." Darken the circle for "Not applicable" and go to Item 6.

**Unknown:** The record does not mention if the participant had local or regional residual disease left after surgery, or the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 6.

**Part B: Physician/Hospital Location Information:**

In this section, record physician and hospital location information where the participant received treatment for lung cancer. Items B.6 and B.7 are not required, but it is recommended that they be completed to facilitate collection of additional medical record data. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

- 6. **Physician for Treatment:** Record the name, address, and telephone number of the primary physician who provided care during the participant's treatment for lung cancer and/or the physician who provided or administered the treatment. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.
- 7. **Hospital or Clinic for Treatment:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent treatment for lung cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.
- 8. **Comments:** Use this section to record notes, comments and any overflow information while abstracting from the participant's medical record. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should review the discrepant information for the appropriate coding decision prior to contacting the CC MRA Coordinator.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as follows. First enter the item number indicating the item to which the comments are related, record the comments in the space provided to the right of the item number as in the following example when a fifth surgical procedure for lung cancer should be collected:

Item #	Comments:
A.2	5; Type = ____; Date = ____

Place an asterisk next to the item number being referenced in the main body of the TIL form. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

## **A-8-3**

**A-8-3: Colorectal Cancer Medical Record Abstract  
Forms (DEC3, TIC2)  
[Diagnostic Evaluation and Treatment Information]**

**Specifications for the Colorectal Cancer Medical  
Record Abstract Forms**



**PART A CONTINUED . . .**

**3. Sigmoidoscopy or Colonoscopy: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**

No

Yes (COMPLETE TABLE BELOW)

Unknown

PROCEDURE #	1	2	3																																																																																																			
<b>PROCEDURE TYPE</b> 1 = Sigmoidoscopy 3 = Colonoscopy 4 = Endoscopy (NOS)	(1) (3) (4)	(1) (3) (4)	(1) (3) (4)																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
<b>CECUM VISUALIZATION</b> (SKIP FOR SIGMOIDOSCOPY)  0 = No 1 = Yes 9 = Not available	(0) (1) (9)	(0) (1) (9)	(0) (1) (9)																																																																																																			
<b>BOWEL PREPARATION</b>  0 = Inadequate 1 = Adequate 9 = Not available	(0) (1) (9)	(0) (1) (9)	(0) (1) (9)																																																																																																			
<b>HYPERPLASTIC POLYPS</b>  0 = None 1 = One 2 = Multiple	(0) (1) (2)	(0) (1) (2)	(0) (1) (2)																																																																																																			

**PART A CONTINUED . . .**

**4. Adenomas on Sigmoidoscopy or Colonoscopy: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**  
 No       Yes (COMPLETE TABLE BELOW)       Unknown

PATHOLOGY OR SPECIMEN JAR #	1	2	3	4	5																																																																																							
<b>MULTIPLE POLYPS IN SPECIMEN JAR?</b> 0 = No    1 = Yes	0 1	0 1	0 1	0 1	0 1																																																																																							
<b>PROCEDURE</b> 1 = Sigmoidoscopy 2 = Colonoscopy 3 = Endoscopy (NOS)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3																																																																																							
<b>LOCATION</b> a. Anatomic (MARK ALL THAT APPLY FOR MULTIPLE ADENOMAS) 01 = Cecum 02 = Ascending colon 03 = Hepatic flexure 04 = Transverse colon 05 = Splenic flexure 06 = Descending colon 07 = Sigmoid colon 08 = Rectum 09 = Appendix 99 = Not available b. Distance in cm 99 = Not available	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>01 02</td><td>0 0</td></tr> <tr><td>03 04</td><td>1 1</td></tr> <tr><td>05 06</td><td>2 2</td></tr> <tr><td>07 08</td><td>3 3</td></tr> <tr><td>09 99</td><td>4 4</td></tr> <tr><td></td><td>5 5</td></tr> <tr><td></td><td>6 6</td></tr> <tr><td></td><td>7 7</td></tr> <tr><td></td><td>8 8</td></tr> <tr><td></td><td>9 9</td></tr> </table>	a.	b.	01 02	0 0	03 04	1 1	05 06	2 2	07 08	3 3	09 99	4 4		5 5		6 6		7 7		8 8		9 9	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>01 02</td><td>0 0</td></tr> <tr><td>03 04</td><td>1 1</td></tr> <tr><td>05 06</td><td>2 2</td></tr> <tr><td>07 08</td><td>3 3</td></tr> <tr><td>09 99</td><td>4 4</td></tr> <tr><td></td><td>5 5</td></tr> <tr><td></td><td>6 6</td></tr> <tr><td></td><td>7 7</td></tr> <tr><td></td><td>8 8</td></tr> <tr><td></td><td>9 9</td></tr> </table>	a.	b.	01 02	0 0	03 04	1 1	05 06	2 2	07 08	3 3	09 99	4 4		5 5		6 6		7 7		8 8		9 9	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>01 02</td><td>0 0</td></tr> <tr><td>03 04</td><td>1 1</td></tr> <tr><td>05 06</td><td>2 2</td></tr> <tr><td>07 08</td><td>3 3</td></tr> <tr><td>09 99</td><td>4 4</td></tr> <tr><td></td><td>5 5</td></tr> <tr><td></td><td>6 6</td></tr> <tr><td></td><td>7 7</td></tr> <tr><td></td><td>8 8</td></tr> <tr><td></td><td>9 9</td></tr> </table>	a.	b.	01 02	0 0	03 04	1 1	05 06	2 2	07 08	3 3	09 99	4 4		5 5		6 6		7 7		8 8		9 9	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>01 02</td><td>0 0</td></tr> <tr><td>03 04</td><td>1 1</td></tr> <tr><td>05 06</td><td>2 2</td></tr> <tr><td>07 08</td><td>3 3</td></tr> <tr><td>09 99</td><td>4 4</td></tr> <tr><td></td><td>5 5</td></tr> <tr><td></td><td>6 6</td></tr> <tr><td></td><td>7 7</td></tr> <tr><td></td><td>8 8</td></tr> <tr><td></td><td>9 9</td></tr> </table>	a.	b.	01 02	0 0	03 04	1 1	05 06	2 2	07 08	3 3	09 99	4 4		5 5		6 6		7 7		8 8		9 9
a.	b.																																																																																											
01 02	0 0																																																																																											
03 04	1 1																																																																																											
05 06	2 2																																																																																											
07 08	3 3																																																																																											
09 99	4 4																																																																																											
	5 5																																																																																											
	6 6																																																																																											
	7 7																																																																																											
	8 8																																																																																											
	9 9																																																																																											
a.	b.																																																																																											
01 02	0 0																																																																																											
03 04	1 1																																																																																											
05 06	2 2																																																																																											
07 08	3 3																																																																																											
09 99	4 4																																																																																											
	5 5																																																																																											
	6 6																																																																																											
	7 7																																																																																											
	8 8																																																																																											
	9 9																																																																																											
a.	b.																																																																																											
01 02	0 0																																																																																											
03 04	1 1																																																																																											
05 06	2 2																																																																																											
07 08	3 3																																																																																											
09 99	4 4																																																																																											
	5 5																																																																																											
	6 6																																																																																											
	7 7																																																																																											
	8 8																																																																																											
	9 9																																																																																											
a.	b.																																																																																											
01 02	0 0																																																																																											
03 04	1 1																																																																																											
05 06	2 2																																																																																											
07 08	3 3																																																																																											
09 99	4 4																																																																																											
	5 5																																																																																											
	6 6																																																																																											
	7 7																																																																																											
	8 8																																																																																											
	9 9																																																																																											
<b>SIZE</b> a. Longest dimension in cm 99.9 = Not available  OR b. 1 = Diminutive 2 = Small 3 = Large 9 = Not available	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>0 0</td><td>0</td></tr> <tr><td>1 1</td><td>1</td></tr> <tr><td>2 2</td><td>2</td></tr> <tr><td>3 3</td><td>3</td></tr> <tr><td>4 4</td><td>4</td></tr> <tr><td>5 5</td><td>5</td></tr> <tr><td>6 6</td><td>6</td></tr> <tr><td>7 7</td><td>7</td></tr> <tr><td>8 8</td><td>8</td></tr> <tr><td>9 9</td><td>9</td></tr> </table>	a.	b.	0 0	0	1 1	1	2 2	2	3 3	3	4 4	4	5 5	5	6 6	6	7 7	7	8 8	8	9 9	9	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>0 0</td><td>0</td></tr> <tr><td>1 1</td><td>1</td></tr> <tr><td>2 2</td><td>2</td></tr> <tr><td>3 3</td><td>3</td></tr> <tr><td>4 4</td><td>4</td></tr> <tr><td>5 5</td><td>5</td></tr> <tr><td>6 6</td><td>6</td></tr> <tr><td>7 7</td><td>7</td></tr> <tr><td>8 8</td><td>8</td></tr> <tr><td>9 9</td><td>9</td></tr> </table>	a.	b.	0 0	0	1 1	1	2 2	2	3 3	3	4 4	4	5 5	5	6 6	6	7 7	7	8 8	8	9 9	9	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>0 0</td><td>0</td></tr> <tr><td>1 1</td><td>1</td></tr> <tr><td>2 2</td><td>2</td></tr> <tr><td>3 3</td><td>3</td></tr> <tr><td>4 4</td><td>4</td></tr> <tr><td>5 5</td><td>5</td></tr> <tr><td>6 6</td><td>6</td></tr> <tr><td>7 7</td><td>7</td></tr> <tr><td>8 8</td><td>8</td></tr> <tr><td>9 9</td><td>9</td></tr> </table>	a.	b.	0 0	0	1 1	1	2 2	2	3 3	3	4 4	4	5 5	5	6 6	6	7 7	7	8 8	8	9 9	9	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">a.</td><td style="width: 50%;">b.</td></tr> <tr><td>0 0</td><td>0</td></tr> <tr><td>1 1</td><td>1</td></tr> <tr><td>2 2</td><td>2</td></tr> <tr><td>3 3</td><td>3</td></tr> <tr><td>4 4</td><td>4</td></tr> <tr><td>5 5</td><td>5</td></tr> <tr><td>6 6</td><td>6</td></tr> <tr><td>7 7</td><td>7</td></tr> <tr><td>8 8</td><td>8</td></tr> <tr><td>9 9</td><td>9</td></tr> </table>	a.	b.	0 0	0	1 1	1	2 2	2	3 3	3	4 4	4	5 5	5	6 6	6	7 7	7	8 8	8	9 9	9
a.	b.																																																																																											
0 0	0																																																																																											
1 1	1																																																																																											
2 2	2																																																																																											
3 3	3																																																																																											
4 4	4																																																																																											
5 5	5																																																																																											
6 6	6																																																																																											
7 7	7																																																																																											
8 8	8																																																																																											
9 9	9																																																																																											
a.	b.																																																																																											
0 0	0																																																																																											
1 1	1																																																																																											
2 2	2																																																																																											
3 3	3																																																																																											
4 4	4																																																																																											
5 5	5																																																																																											
6 6	6																																																																																											
7 7	7																																																																																											
8 8	8																																																																																											
9 9	9																																																																																											
a.	b.																																																																																											
0 0	0																																																																																											
1 1	1																																																																																											
2 2	2																																																																																											
3 3	3																																																																																											
4 4	4																																																																																											
5 5	5																																																																																											
6 6	6																																																																																											
7 7	7																																																																																											
8 8	8																																																																																											
9 9	9																																																																																											
a.	b.																																																																																											
0 0	0																																																																																											
1 1	1																																																																																											
2 2	2																																																																																											
3 3	3																																																																																											
4 4	4																																																																																											
5 5	5																																																																																											
6 6	6																																																																																											
7 7	7																																																																																											
8 8	8																																																																																											
9 9	9																																																																																											
<b>HISTOLOGY</b> 2 = Tubular adenoma 3 = Tubular villous adenoma 4 = Villous adenoma 5 = Adenoma (NOS)	2 3 4 5	2 3 4 5	2 3 4 5	2 3 4 5	2 3 4 5																																																																																							
<b>DYSPLASIA</b> 0 = None 1 = Mild (low grade) 2 = Moderate (low grade) 3 = Severe (high grade) 9 = Not available	0 1 2 3 9	0 1 2 3 9	0 1 2 3 9	0 1 2 3 9	0 1 2 3 9																																																																																							
<b>4a. NUMBER OF NON-ADVANCED AND/OR ADVANCED ADENOMAS</b>  <b>ADVANCED ADENOMA CRITERIA:</b> (must fulfill at least one to be classified as advanced)  - greater than or equal to 1 cm - villous elements in histology - severe or high-grade dysplasia	Total # of confirmed non-advanced adenomas	Total # of confirmed advanced adenomas	<b>4b. CAN EXACT # OF ADENOMAS BE DETERMINED?</b>  0 = No      0 1 1 = Yes																																																																																									
	<table style="width: 100%; border-collapse: collapse;"> <tr><td>0 0</td></tr> <tr><td>1 1</td></tr> <tr><td>2 2</td></tr> <tr><td>3 3</td></tr> <tr><td>4 4</td></tr> <tr><td>5 5</td></tr> <tr><td>6 6</td></tr> <tr><td>7 7</td></tr> <tr><td>8 8</td></tr> <tr><td>9 9</td></tr> </table>	0 0	1 1	2 2	3 3	4 4	5 5	6 6	7 7	8 8	9 9	<table style="width: 100%; border-collapse: collapse;"> <tr><td>0 0</td></tr> <tr><td>1 1</td></tr> <tr><td>2 2</td></tr> <tr><td>3 3</td></tr> <tr><td>4 4</td></tr> <tr><td>5 5</td></tr> <tr><td>6 6</td></tr> <tr><td>7 7</td></tr> <tr><td>8 8</td></tr> <tr><td>9 9</td></tr> </table>	0 0	1 1	2 2	3 3	4 4	5 5	6 6	7 7	8 8	9 9																																																																						
0 0																																																																																												
1 1																																																																																												
2 2																																																																																												
3 3																																																																																												
4 4																																																																																												
5 5																																																																																												
6 6																																																																																												
7 7																																																																																												
8 8																																																																																												
9 9																																																																																												
0 0																																																																																												
1 1																																																																																												
2 2																																																																																												
3 3																																																																																												
4 4																																																																																												
5 5																																																																																												
6 6																																																																																												
7 7																																																																																												
8 8																																																																																												
9 9																																																																																												

**PART A CONTINUED . . .**

**5. Other Diagnostic/Staging Procedures: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**  
 No  Yes (COMPLETE TABLE BELOW)  Unknown

PROCEDURE #	1	2	3																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF CEA, RECORD VALUE; IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 _____ SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

PROCEDURE #	4	5	6																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF CEA, RECORD VALUE; IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 _____ SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 _____ SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**PROCEDURE CODES**

- |  |   |  |
|--|---|--|
| 01 = Abdominal flat plate (plain film) | 11 = Intravenous pyelography (IVP)/excretory urography          | 19 = Abdominal ultrasound                          |
| 02 = Barium enema radiograph           | 12 = MRI scan - abdominal                                       | 20 = CT scan - abdomen and pelvis combined         |
| 03 = Biopsy (SPECIFY)                  | 13 = MRI scan - other (SPECIFY)                                 | 21 = Hemicolectomy                                 |
| 04 = Chest radiograph                  | 14 = MRI scan - pelvic  | 22 = Laparoscopy                                   |
| 05 = Clinical evaluation               | 15 = Preoperative carcinoembryonic antigen (CEA) (RECORD VALUE) | 23 = Laparotomy                                    |
| 06 = CT scan - abdominal               | 16 = Stool occult blood   | 24 = Lymphadenectomy/Lymph node sampling           |
| 07 = CT scan - other (SPECIFY)         | 17 = Record review  | 25 = Other radiograph (SPECIFY)                    |
| 08 = CT scan - pelvic                  | 18 = Resection (SPECIFY)  | 26 = Ultrasound (SPECIFY)                          |
| 09 = Cystoscopy                        |   | 27 = Upper GI evaluation - endoscopic/radiographic |
| 10 = DRE                               |   | 88 = Other (SPECIFY)                               |

PLEASE DO NOT WRITE IN THIS AREA



054417

**PART A CONTINUED . . .**

PROCEDURE #	7	8	9																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF CEA, RECORD VALUE; IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 <hr/> SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
PROCEDURE #	10	11	12																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF CEA, RECORD VALUE; IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 88 <hr/> SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**5b.** DIAGNOSTIC/STAGING PROCEDURES SUPPLEMENT FORM COMPLETED

**PROCEDURE CODES**

- |  |   |  |
|--|---|--|
| 01 = Abdominal flat plate (plain film) | 11 = Intravenous pyelography (IVP)/excretory urography          | 19 = Abdominal ultrasound                          |
| 02 = Barium enema radiograph           | 12 = MRI scan - abdominal                                       | 20 = CT scan - abdomen and pelvis combined         |
| 03 = Biopsy (SPECIFY)                  | 13 = MRI scan - other (SPECIFY)                                 | 21 = Hemicolectomy                                 |
| 04 = Chest radiograph                  | 14 = MRI scan - pelvic  | 22 = Laparoscopy                                   |
| 05 = Clinical evaluation               | 15 = Preoperative carcinoembryonic antigen (CEA) (RECORD VALUE) | 23 = Laparotomy                                    |
| 06 = CT scan - abdominal               | 16 = Stool occult blood   | 24 = Lymphadenectomy/Lymph node sampling           |
| 07 = CT scan - other (SPECIFY)         | 17 = Record review  | 25 = Other radiograph (SPECIFY)                    |
| 08 = CT scan - pelvic                  | 18 = Resection (SPECIFY)  | 26 = Ultrasound (SPECIFY)                          |
| 09 = Cystoscopy                        |   | 27 = Upper GI evaluation - endoscopic/radiographic |
| 10 = DRE                               |   | 88 = Other (SPECIFY)                               |

PLEASE DO NOT WRITE IN THIS AREA



054417

**PART A CONTINUED . . .**

**6. Medical Complications of Diagnostic Evaluation and Staging:**

No       Yes (COMPLETE TABLE BELOW)       Unknown

COMPLICATION #	1	2	3																																																																																																			
TYPE OF COMPLICATION (SEE COMPLICATION CODES BELOW)	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 6 <input type="radio"/> 20 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30 <input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 300 <input type="radio"/> 301 <input type="radio"/> 302 <input type="radio"/> 304 <input type="radio"/> 305	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 6 <input type="radio"/> 20 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30 <input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 300 <input type="radio"/> 301 <input type="radio"/> 302 <input type="radio"/> 304 <input type="radio"/> 305	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 6 <input type="radio"/> 20 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30 <input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 300 <input type="radio"/> 301 <input type="radio"/> 302 <input type="radio"/> 304 <input type="radio"/> 305																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
DATE OF COMPLICATION (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
COMPLICATION #	4	5	6																																																																																																			
TYPE OF COMPLICATION (SEE COMPLICATION CODES BELOW)	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 6 <input type="radio"/> 20 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30 <input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 300 <input type="radio"/> 301 <input type="radio"/> 302 <input type="radio"/> 304 <input type="radio"/> 305	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 6 <input type="radio"/> 20 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30 <input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 300 <input type="radio"/> 301 <input type="radio"/> 302 <input type="radio"/> 304 <input type="radio"/> 305	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 6 <input type="radio"/> 20 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30 <input type="radio"/> 31 <input type="radio"/> 32 <input type="radio"/> 33 <input type="radio"/> 300 <input type="radio"/> 301 <input type="radio"/> 302 <input type="radio"/> 304 <input type="radio"/> 305																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
DATE OF COMPLICATION (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**MEDICAL COMPLICATION CODES**

- |                                 |  |   |
|---------------------------------|--|---|
| 1 = Infection (SPECIFY)         | 25 = Cardiac arrhythmia                      | 300 = Diarrhea                                    |
| 2 = Fever requiring antibiotics | 26 = Cerebral vascular accident (CVA)/Stroke | 301 = Small bowel obstruction/partial or complete |
| 3 = Perforation                 | 27 = Blood loss requiring transfusion        | 302 = Ileus                                       |
| 4 = Hemorrhage                  | 28 = Deep venous thrombosis (DVT)            | 306 = Rectal damage                               |
| 6 = Respiratory arrest          | 29 = Acute/chronic respiratory failure       | 307 = Blood in stool                              |
| 20 = Cardiac arrest             | 30 = Hypotension                             |   |
| 22 = Hospitalization            | 31 = Congestive heart failure (CHF)          |   |
| 23 = Pulmonary embolus/emboli   | 32 = Wound dehiscence                        |   |
| 24 = Myocardial infarction      | 33 = Hypokalemia                             |   |

**PART A CONTINUED . . .**

**7. Result of Diagnostic Evaluation for Colorectal Cancer:**

- No malignancy (GO TO PART D)
- No malignancy and no diagnostic/staging procedures performed (GO TO PART D)
- Colorectal malignancy confirmed histologically (exclude carcinoma in situ) (GO TO PART C)
- Colorectal malignancy confirmed cytologically (GO TO PART C)
- Colorectal malignancy diagnosed by clinical examination only (GO TO PART C)
- Other malignancy confirmed histologically or cytologically (GO TO PART B)
- No information available (GO TO PART D)

**PART B: DIAGNOSIS INFORMATION FOR CANCERS OTHER THAN COLORECTAL CANCER**

**8. Other Cancer Diagnosis:**

- No
- Yes (COMPLETE TABLE BELOW)

OTHER CANCER DIAGNOSIS 1				OTHER CANCER DIAGNOSIS 2			
<b>ICD-9-CM CLASSIFICATION</b>		<b>DATE OF OTHER CANCER DIAGNOSIS</b>				<b>DATE OF OTHER CANCER DIAGNOSIS</b>	
		<b>MO.</b>	<b>DAY</b>	<b>YEAR</b>			
0 0 0 0					0 0 0 0		
1 1 1 1					1 1 1 1		
2 2 2 2					2 2 2 2		
3 3 3 3					3 3 3 3		
4 4 4 4					4 4 4 4		
5 5 5 5					5 5 5 5		
6 6 6 6					6 6 6 6		
7 7 7 7					7 7 7 7		
8 8 8 8					8 8 8 8		
9 9 9 9					9 9 9 9		
X X					X X		

**GO TO PART D**

**PART C: PRIMARY COLORECTAL CANCER DIAGNOSIS INFORMATION**

**9. Description of Colorectal Carcinoma:**

- No
- Yes (COMPLETE TABLE BELOW)
- Unknown

	1	2	3																																																											
<p><b>PROCEDURE (MARK ALL THAT APPLY)</b></p> <p>1 = Sigmoidoscopy                      2 = Colonoscopy                      3 = Polypectomy                      4 = Surgical resection                      5 = Lccal transanal or other resection                      8 = Endoscopy (NOS)</p>	1 2 3 4 5 8	1 2 3 4 5 8	1 2 3 4 5 8																																																											
<p><b>LOCATION</b></p> <p>a. Anatomic (MARK ALL THAT APPLY)</p> <p>01 = Cecum                      02 = Ascending colon                      03 = Hepatic flexure                      04 = Transverse colon                      05 = Splenic flexure                      06 = Descending colon                      07 = Sigmoid colon                      08 = Rectum                      09 = Appendix                      99 = Not available</p> <p>b. Distance in cm                      99 = Not available</p>	<p>a.</p> <table style="margin-left: 20px;"> <tr><td>01</td><td>02</td></tr> <tr><td>03</td><td>04</td></tr> <tr><td>05</td><td>06</td></tr> <tr><td>07</td><td>08</td></tr> <tr><td>09</td><td>99</td></tr> </table> <p>b.</p> <table style="margin-left: 20px;"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	01	02	03	04	05	06	07	08	09	99	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<p>a.</p> <table style="margin-left: 20px;"> <tr><td>01</td><td>02</td></tr> <tr><td>03</td><td>04</td></tr> <tr><td>05</td><td>06</td></tr> <tr><td>07</td><td>08</td></tr> <tr><td>09</td><td>99</td></tr> </table> <p>b.</p> <table style="margin-left: 20px;"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	01	02	03	04	05	06	07	08	09	99	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9
01	02																																																													
03	04																																																													
05	06																																																													
07	08																																																													
09	99																																																													
0	0																																																													
1	1																																																													
2	2																																																													
3	3																																																													
4	4																																																													
5	5																																																													
6	6																																																													
7	7																																																													
8	8																																																													
9	9																																																													
01	02																																																													
03	04																																																													
05	06																																																													
07	08																																																													
09	99																																																													
0	0																																																													
1	1																																																													
2	2																																																													
3	3																																																													
4	4																																																													
5	5																																																													
6	6																																																													
7	7																																																													
8	8																																																													
9	9																																																													
<p><b>GROSS MORPHOLOGY</b></p> <p>1 = Exophytic                      2 = Endophytic                      3 = Annular                      4 = Diffusely infiltrative                      9 = Not available</p>	1 2 3 4 9	1 2 3 4 9	1 2 3 4 9																																																											

**PART C CONTINUED . . .**

**10. Date of Primary Colorectal Cancer Diagnosis:**

MO.		DAY		YEAR	
0	0	0	0	0	0
1	1	1	1	1	1
2	2	2	2	2	2
3	3	3	3	3	3
4	4	4	4	4	4
5	5	5	5	5	5
6	6	6	6	6	6
7	7	7	7	7	7
8	8	8	8	8	8
9	9	9	9	9	9

**11. Verbatim Description of Primary Colorectal Cancer Diagnosis:**

---

---

---

---

---

---

---

---

---

---

**12. ICD-O-2 Cancer Classification:**

Topography	Morphology	Behavior	Grade
C 0 0 0 0	0 0 0 0		
1 1 1 1	1 1 1 1	1	1
2 2 2 2	2 2 2 2		2
3 3 3 3	3 3 3 3	3	3
4 4 4 4	4 4 4 4		4
5 5 5 5	5 5 5 5		5
6 6 6 6	6 6 6 6		6
7 7 7 7	7 7 7 7		7
8 8 8 8	8 8 8 8		
9 9 9 9	9 9 9 9	9	9

**13. Photocopy of Report Confirming Primary Colorectal Cancer: (MARK ONE)**

- Pathology/Histopathology (ATTACH COPY)
- Cytology/Cytopathology (ATTACH COPY)
- Not available

**14. Histopathologic Type for Primary Colorectal Cancer:**

- Adenocarcinoma
- Mucinous (colloid) adenocarcinoma
- Signet ring cell carcinoma
- Squamous cell (epidermoid) carcinoma
- Adenosquamous carcinoma
- Undifferentiated carcinoma
- Carcinoma
- Other (SPECIFY) \_\_\_\_\_
- Unknown

**15. Histopathologic Grade for Primary Colorectal Cancer:**

- Grade cannot be assessed (GX)
- Well differentiated (G1)
- Moderately differentiated (G2)
- Poorly differentiated (G3)
- Undifferentiated (G4)
- Unknown

**16. TNM Staging for Primary Colorectal Cancer:**

If TNM Staging performed, what AJCC Cancer Staging Manual did you use?  4th Edition  5th Edition

**a. TNM Clinical Staging:**  Yes (COMPLETE 16.a.1, 16.a.2, 16.a.3)  No (GO TO C.16.b)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
(T) Codes	(N) Codes	(M) Codes
<input type="radio"/> Tx <input type="radio"/> T2 <input type="radio"/> T0 <input type="radio"/> T3 <input type="radio"/> T1 <input type="radio"/> T4 <input type="radio"/> Not available	<input type="radio"/> Nx <input type="radio"/> N2 <input type="radio"/> N0 <input type="radio"/> N3 <input type="radio"/> N1 <input type="radio"/> Not available	<input type="radio"/> Mx <input type="radio"/> M0 <input type="radio"/> M1 <input type="radio"/> Not available

PLEASE DO NOT WRITE IN THIS AREA



054417

**PART C CONTINUED . .**

**b. TNM Pathologic Staging:**

Yes (COMPLETE 16.b.1, 16.b.2, 16.b.3)  No (GO TO C.17)

<b>1. PRIMARY TUMOR (T)</b>	<b>2. NODAL INVOLVEMENT (N)</b>	<b>3. DISTANT METASTASES (M)</b>
(T) Codes <input type="radio"/> Tx <input type="radio"/> T2 <input type="radio"/> T0 <input type="radio"/> T3 <input type="radio"/> T1 <input type="radio"/> T4 <input type="radio"/> Not available	(N) Codes <input type="radio"/> Nx <input type="radio"/> N2 <input type="radio"/> N0 <input type="radio"/> N3 <input type="radio"/> N1 <input type="radio"/> Not available	(M) Codes <input type="radio"/> Mx <input type="radio"/> M0 <input type="radio"/> M1 <input type="radio"/> Not available

**17. Record Stage: (COMPLETE IF 16.b.1, 16.b.2, OR 16.b.3 IS NOT AVAILABLE, OTHERWISE SKIP)**  
 Yes (COMPLETE 17.1, 17.2, 17.3, 17.4)  No (GO TO PART E)

<b>1. STAGE ONLY</b>	<b>2. DUKES</b>	<b>3. MODIFIED DUKES (ASTLER-COLLER)</b>	<b>4. SUMMARY STAGING</b>
<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV <input type="radio"/> Not available	<input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> Not available	<input type="radio"/> A <input type="radio"/> C1 <input type="radio"/> B1 <input type="radio"/> C2 <input type="radio"/> B2 <input type="radio"/> D <input type="radio"/> Not available	<input type="radio"/> Localized <input type="radio"/> Regional <input type="radio"/> Distant <input type="radio"/> Not available

**GO TO PART E**

**PART D: DATE OF DIAGNOSTIC EVALUATION DETERMINATION**

**18.** Complete this item if:  
 Item A.7 = No malignancy **OR**  
 Item A.7 = No malignancy and no diagnostic procedures performed **OR**  
 Item A.7 = No information available

MO.		DAY		YEAR		
0	0	0	0	0	0	0
1	1	1	1	1	1	1
2	2	2	2	2	2	2
3	3	3	3	3	3	3
4	4	4	4	4	4	4
5	5	5	5	5	5	5
6	6	6	6	6	6	6
7	7	7	7	7	7	7
8	8	8	8	8	8	8
9	9	9	9	9	9	9

**PART E: PHYSICIAN/HOSPITAL LOCATION INFORMATION**

**19. Physician for Diagnostic Evaluation:**

a. Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Telephone: (\_\_\_\_) \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_  
 Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Telephone: (\_\_\_\_) \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_  
 Medical Record/Chart # \_\_\_\_\_

**20. Hospital or Clinic for Diagnostic Evaluation:**

a. Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Telephone: (\_\_\_\_) \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_  
 Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Telephone: (\_\_\_\_) \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_  
 Medical Record/Chart # \_\_\_\_\_







**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**DIAGNOSTIC EVALUATION - COLORECTUM VERSION 3 (DEC3/DCQ3)**

This form is to be completed by the Medical Record Abstractor, a nosologist (trained medical coder), and a Tumor (or Cancer) Registrar who is also a Certified Tumor Registrar (CTR) or CTR-eligible. Items, which are to be completed by a nosologist or a CTR, are specified. The abstractor should complete all other items. Specifically, the nosologist will be required to complete Item B.8 (Other Cancer Diagnosis). The CTR will be required to complete Part C: Items C.9 (Description of Colorectal Carcinoma), C.10 (Date of Primary Colorectal Cancer Diagnosis), C.11 (Verbatim Description of Primary Colorectal Cancer Diagnosis), C.12 (ICD-O-2 Cancer Classification), C.13 (Photocopy of Report Confirming Primary Colorectal Cancer), C.14 (Histopathologic Type for Primary Colorectal Cancer), C.15 (Histopathologic Grade for Primary Colorectal Cancer), C.16 (TNM Staging for Primary Colorectal Cancer) and C.17 (Record Stage).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry; it should not be obtained from the participant, except in Item A1, Diagnostic Procedures Performed, in which the information recorded may be based on participant self-report. Written documentation from the physician or the medical record, for example, is preferable to obtaining information verbally.
- Information about diagnostic procedures could possibly be collected up to 12 months after the date of a positive screen (if a conclusive diagnosis or the next screening exam does not come first). In addition, information about complications of diagnostic procedures should be collected up to 12 months from the time diagnostic procedures began. In the event of a cancer diagnosis, medical complications should be collected for an additional 6 months after the diagnosis.
- Before beginning abstraction, the medical record documents should be placed in chronological order and the diagnostic/staging procedures should be abstracted chronologically. If, however, a diagnostic or staging procedure is identified and added after the form has been completed, it is not necessary to shift all of the data to maintain the chronological order; the new procedure may be added at the end of the appropriate item.
- This form includes items, which require that data be entered verbatim, such as recording diagnoses, recording "Other (specify)," and recording comments. Verbatim comments should be accurate and succinct. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If the medical record contains unclear, discrepant, or conflicting information for any item, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should first be consulted for a resolution and for making an appropriate coding decision, prior contacting the CC MRA Coordinator.
- When recording information in the Comments section, be sure to identify the item to which the comment refers. Appropriate identification will aid in the analysis of

Comments data. Throughout the specifications, examples have been given for recording information in Comments.

Below are some guidelines for the collection of diagnostic evaluation information:

- Information regarding diagnostic procedures that occurred prior to the participant's randomization date should not be recorded.
- Procedures that occurred prior to the date of the initial visit for clinical assessment (i.e., the first visit to a doctor for clinical assessment) should not be recorded, with the exception of procedures that are part of the diagnostic evaluation for a suspected cancer. If a screening test is positive or a participant experiences symptoms and a diagnostic procedure is performed before the participant actually visits the doctor, this diagnostic procedure should be recorded on the DE form (even though it took place prior to the initial visit for clinical assessment).

For example, in the case of a positive PLCO screen with a biopsy performed, the screen is the event that led to the initiation of diagnostic follow-up and should not be recorded, but the biopsy is the first procedure in the diagnostic follow-up process, and should be recorded.

- Following a positive FSG screening exam, the SC should collect diagnostic evaluation information until:
  - a conclusive diagnosis (either malignant or non-malignant) is made, OR
  - 12 months after the date of the positive screen

*whichever comes first.*

At the end of the 12 months, if the diagnostic evaluation is not conclusively malignant, record the result of the diagnostic evaluation in Item A.7 as "No malignancy."

- An exception to the above is when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a colorectal or other malignancy. In this situation it is not appropriate to record a conclusive diagnosis, but rather to record "No information available." If a Lead Abstractor cannot conclusively determine the result of a diagnostic evaluation from the medical record, contact the CC MRA Coordinator.

It is the SC's responsibility to encourage timely follow-up of positive screens. If, despite SC efforts, the participant does not initiate follow-up of a positive screen until late in the year, 10 months after the positive screen for example, the SC should still collect only the diagnostic evaluation data until 12 months after the positive screen or the next screen, whichever comes first. In the example given, this would mean two months of diagnostic evaluation data.

- All staging information related to the initial diagnosis of primary colorectal cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEC form). Staging information on colorectal cancer recurrence should not be collected.
- If multiple primary colorectal cancers are diagnosed at the same time (i.e., as part of the same diagnostic evaluation process and prior to the first definitive treatment), it is necessary to complete portions of a separate DEC for each multiple primary. Item 7 (Multiple Primary Cancer #) allows the abstractor to indicate whether the DEC is being used for abstracting information about a multiple pri-

mary colorectal cancer. If there are multiple primary cancers, each cancer should be recorded on a separate DEC3 form.

- If a procedure such as a hemicolectomy is done and considered to be diagnostic, staging, and initial treatment it should be abstracted onto both the Diagnostic Evaluation forms.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy black marks that fill the circle completely.**



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled. Darken the circle corresponding to each remaining number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized ("Final Complete" or "Final Incomplete"), erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the DE. If more than one abstractor completes the DE, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form -- this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.

3. **Nosologist ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item B.8 (ICD-9-CM Classification of Other Cancer Diagnoses). Darken the circles corresponding to the four digits.
4. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting specific items related to ICD-O-2 Classification and cancer diagnosis/staging in Part C. Darken the circles corresponding to the four digits.
5. **Study Year:** Record the study year, T0 to T13. This is the study year in which the SC was notified of a suspicion of colorectal cancer. For example, if the cancer was reported on a T1 ASU, the study year for the DEC is T1. Darken the corresponding circles. Remember to right justify and zero-fill the number for study years T0 - T9 (e.g., T00, T01, T02, etc.).
6. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the "first" time to confirm a suspicion of colorectal cancer. This includes an initial abstract for a multiple primary cancer (see Item 7).
  - **Re-abstract for QA:** Medical record information that has already been abstracted to confirm a suspicion of colorectal cancer is being re-abstracted for the purpose of quality assurance. This includes a re-abstract for a multiple primary cancer (see Item 7). Not yet implemented.
7. **Multiple Primary Cancer #:** The purpose of this item is to indicate whether this form is being used to abstract information about an additional primary colorectal cancer that was diagnosed at the same time as the first primary colorectal cancer (i.e., as part of the same diagnostic evaluation and staging process, and before the first definitive treatment). If this primary cancer is the second primary diagnosed (in chronological date order), darken the circle for "2." If it is the third, darken the circle for "3," etc. *If only one primary cancer was diagnosed, this item should be skipped.* Only information on one carcinoma should be recorded per each DE. This is because it would be unlikely for separate primary carcinomas to have data that matched exactly for questions C.10 through C.17.
 

If the participant was diagnosed with more than one primary colorectal cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For the first primary, the DEC must be completed in full (all parts). For all subsequent primaries, use another DEC form and complete the administrative section, Item A.7 (Result of Diagnostic Evaluation for Colorectal Cancer), and Part C only. If more than one primary was diagnosed on the first date of diagnosis, designate the most advanced cancer diagnosed on that day as the "first primary" and complete the entire DEC form. Use additional DEC forms for any other cancers diagnosed on that day.
8. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except "Disposition" are optional. "Disposition" is required and may be marked on the form or entered directly into DEES. Dispositions of "Final Complete" (FCM) may also be set automatically in DEES when the form is edited (See DEES User's Guide).
  - **Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)

- **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)
- **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 of the MOOP for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
- **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
- **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
  - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data is abstracted, remove the ICM so that the appropriate disposition is assigned.
  - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report, or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional form processing items.
  - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A: Diagnostic Evaluation and Staging:**

This section refers to the diagnostic evaluation and staging for colorectal cancer. Abstracting this data will require careful review of the participant's medical records at one or more hospitals, clinics, or physicians' offices.

When abstracting information onto this form, do not include information from any physician/hospital visits or procedures that took place prior to the participant's date of randomization, even if these visits or procedures are related to a diagnosis which was made after the participant was enrolled in the trial.

1. **Diagnostic Procedures Performed:** The purpose of this item is to document whether or not a physician recommended and performed diagnostic procedures as part of the follow-up to a positive PLCO screening examination (FSG). *If the DEC is*

being completed in response to colorectal cancer being reported via an ASU, for example, if the participant was in fact diagnosed with cancer, it is assumed that diagnostic procedures were performed and this item should be coded "Yes." Darken the circle corresponding to the most appropriate response as follows:

**Yes:** The record indicates that diagnostic procedures were recommended by a physician and were performed. This includes situations when diagnostic procedures were performed to follow up a positive PLCO screening exam and when colorectal cancer was reported to the SC via an ASU.

**No, Physician Report:** The record indicated or the physician reported to the SC that based on review of the PLCO screening exam results, and possibly any medical history prior to the screening exam, no additional follow-up was deemed necessary. Complete Item A.7 (Result of Diagnostic Evaluation for Colorectal Cancer) and Parts D and E of the form.

**No, Participant Self-Report:** The participant reported that his/her physician reviewed the PLCO screening exam results, and possibly other medical history prior to the screening exam, and deemed no additional follow-up was necessary. Complete Item A.7 (Result of Diagnostic Evaluation for Colorectal Cancer) and Parts D and E of the form.

- *Before accepting a participant self-report the SC should first attempt to obtain written documentation from the participant's physician. If written documentation cannot be obtained from the physician, the SC should then attempt to obtain verbal confirmation from the physician's office that the physician did not recommend additional follow-up of the positive PLCO screening exam. In cases where only the participant's report of the physician's recommendation can be obtained, this circle should be darkened.*

2. **Reason for Initial Visit for Clinical Assessment:** The purpose of this item is to identify the participant's motivation for seeking clinical evaluation. Because motivation is sometimes not clearly stated in the record, NCI assumes that if a participant seeks medical care within 12 months of a positive screen, it is for the purpose of follow-up of that positive screen. If medical care is sought more than 12 months after a positive screen, NCI assumes that it is not for follow-up to a positive screen. Darken the circles corresponding to all the reasons that apply as follows:

- **Symptomatic:** The record indicates that symptoms prompted the participant to go for a clinical evaluation.
- **Follow-up of positive PLCO screen:** The record indicates that the participant went for a clinical evaluation to follow up a positive PLCO screen, within 12 months of the positive screen.
- **Other (SPECIFY):** If the record indicates that the participant went for a clinical evaluation for a reason other than those listed, specify the reason in the space provided. This would include the participant who is asymptomatic and has a positive non-PLCO screening exam that prompts for the evaluation. If the motivation for evaluation is a non-PLCO screening exam, the details of the test and results should be recorded on the "Specify" line.

3. **Sigmoidoscopy or Colonoscopy:** The purpose of this item is to document whether the participant had at least one endoscopy procedure (sigmoidoscopy or colonoscopy), as part of the diagnostic evaluation for colorectal cancer. If so, specific information about each procedure performed, as described below, should be recorded. Information regarding these procedures will usually be found in an endoscopy (sigmoidoscopy or colonoscopy) report in the medical record.

- Do not record information about flexible sigmoidoscopies performed as part of the PLCO screening examinations.
- Do not record screening non-PLCO flexible sigmoidoscopies.
- Do not record any sigmoidoscopy or colonoscopy performed unless it is part of the diagnostic evaluation for a suspected colorectal cancer.
- Do not record anoscopy in this section. Anoscopy should be recorded in A.5, "Other diagnostic/staging procedures", under code 88 "other", and specified.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any endoscopies. Darken the circle for "No" and go to Item A.5.

**Yes:** The record states or indicates that the participant had one or more endoscopies. Darken the circle for "Yes" and complete the table for Item A.3.

- If a participant had more than three endoscopy procedures, place an asterisk beside Item A.3 and use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example:

Item E.21, Comments:

Item#:	Comments:
A.3	4; Type =___; Date =___; Cecum visualization =___; Bowel prep =___; Hyperplastic polyps =___

**Unknown:** If there is no indication in the record whether Sigmoidoscopy or Colonoscopy was or was not performed, darken the circle for "Unknown" and go to Item A.4.

For each endoscopy performed, complete the following items:

- **Procedure Type:** Darken the circle corresponding to the type of procedure performed. The procedure types are defined below:

**1 = Sigmoidoscopy:** Visual examination of the sigmoid colon with either a flexible endoscope (flexible sigmoidoscopy) or a rigid endoscope (rigid sigmoidoscopy). If this code is marked, skip "Cecum Visualization" and go to "Bowel Preparation."

**3 = Colonoscopy:** Visual examination of the entire colon with a flexible endoscope.

**Note:** *If depth of insertion is in the record it may be used to help determine whether an endoscopy was a sigmoidoscopy or colonoscopy, when not specified. Unless there is a complication or obstruction (which should be noted in the record), a sigmoidoscope will reach approximately 60 cm, without cecum visualization, whereas a colonoscope will reach approximately 120 cm, and usually the cecum is visualized.*

**4 = Endoscopy (NOS):** The abbreviation "NOS" represents "not otherwise specified." The record does not specify, or it is questionable, whether the endoscopy performed was a sigmoidoscopy or a colonoscopy, and it cannot be determined using the guidelines above.

- **Date of Procedure**: Record the month, day and year that the endoscopy procedure was performed. [Month and day should be zero filled and four digits recorded for the year (e.g., 03/08/1994).] Even if it is not clear from the medical record the day that the procedure was performed, one should be able to record the specific month and year. Record the day as "99." Darken the circle corresponding to each number.
- **Cecum Visualization**: This item applies to colonoscopy procedures only. If a participant had a flexible or rigid sigmoidoscopy, skip this item and go to "Bowel Preparation." In the medical record, the gastroenterologist who performed the colonoscopy will have noted whether or not the cecum was visualized. If the colonoscopy report states that the colonoscope was advanced to the terminal ileum, it can be assumed that the cecum was visualized, even if the report does not specifically mention cecum visualization. Other phrases which might be used in a colonoscopy report which indicate that the cecum was visualized include "...the entire colon was visualized" or "...colonoscopy to cecum." Darken the circle corresponding to whether or not the cecum was visualized as follows:
  - 0 = No**: The record states that the cecum was not visualized.
  - 1 = Yes**: The record states that the cecum was visualized.
  - 9 = Not available**: Information on cecum visualization is either not mentioned or is stated as unknown in the record.
- **Bowel Preparation**: Bowel preparation for endoscopy involves the emptying of the bowels of all fecal matter. In many cases, the bowel preparation and the endoscopy procedure will be repeated in the same visit. We are interested in recording the outcome of the final bowel preparation for each endoscopy visit.
 

Darken the circle corresponding to whether or not the bowel preparation was adequate or inadequate as follows:

  - 0 = Inadequate (Unsatisfactory)**: The record states or indicates that the bowel preparation was inadequate. This may be recorded in the record as "poor prep," "inadequate prep," "inadequate view," "large amounts of residual stool" or some other terms as less than ideal. For example, if the physician states explicitly that the bowel preparation was inadequate or unsatisfactory, code "Inadequate" regardless of whether the physician was able to visualize some or all of the colonic mucosa.
  - 1 = Adequate**: The record states or indicates that the bowel preparation was adequate. For example, if the physician states that, "a good view was obtained of the entire colonic mucosa," or that the prep was "excellent," "good," "adequate" or "fair", the bowel preparation should be considered adequate.
  - 9 = Not available**: Information on bowel preparation is either not mentioned or is stated as unknown in the record.
- **Hyperplastic Polyps**: Record the number of hyperplastic polyps, which were found during endoscopy. This information should be taken from the endoscopy report. The diagnosis of hyperplastic polyp may be confirmed by the pathologic review or may be determined by clinical observation that is documented in the endoscopy report (when pathology review is not obtained). If, for example, the endoscopist categorizes "two hyperplastic polyps" without sending them to pathology for confirmation, one may use

the clinical impression from the endoscopist to answer this question. Use code 2 = Multiple if more than one hyperplastic polyp was found during endoscopy.

4. **Adenomas on Sigmoidoscopy or Colonoscopy:** This item refers to only adenomatous polyps identified during sigmoidoscopy or colonoscopy. Note that information about malignant abnormalities will be recorded later, in Section C, Primary Colorectal Cancer Diagnosis Information, but the biopsy of malignancy would be recorded in A.5 under biopsy, code 3.

Information on location, size, histology, and dysplasia is to be recorded for up to the 5 largest adenomas (villous adenoma, tubular villous adenoma, tubular adenoma, or adenoma NOS). (*Do not record information about adenomas identified as part of the PLCO flexible sigmoidoscopy or non-PLCO screening exam unless the adenoma was biopsied*). Information on the number, size, and location of adenomas will usually be found in an endoscopy report. Information on histology and dysplasia will usually be found in the pathology report.

The endoscopy report should be reviewed first to note the number, size and location of the adenomas seen. Next, the pathology report should be reviewed to determine the classification of the tissue collected. If there is a discrepancy between the two reports, for items such as number of adenomas seen, the location, and the size, the endoscopy report takes precedence over the pathology report. If the information on number, size or location is missing on the endoscopy report, it should be coded as "not available" and not taken from the pathology report.

Complete this item as follows:

**No:** The record indicates that the participant did not have any adenomas identified. Darken the circle for "No" and go to Item A.5.

**Yes:** The record indicates that the participant had one or more adenomas identified.

**Unknown:** It is unknown or not mentioned in the record whether adenomas were identified during the endoscopy procedure. Darken the circle for "Unknown" and go to Item A.5

Instructions for completing Table in Item A.4:

Darken the circle for "Yes" and complete the table for Item A.4.

- If a participant had more than 5 adenomas, record information for only the five largest.
- If an adenoma was seen and/or treated on more than one endoscopy, the abstractor must determine whether or not an adenoma noted on more than one procedure is the same adenoma. If it is the same adenoma, it should be recorded *only once* on the DEC form, in Item A.4 (Adenomas on Sigmoidoscopy or Colonoscopy).
- Adenomas should be recorded only once in either Item A.4 (Adenomas on Sigmoidoscopy or Colonoscopy) or Item C.9 (Description of Colorectal Carcinoma) depending on the result of the biopsy.

For example, a polyp is found and removed by polypectomy because it is thought to be benign. When the tissue was biopsied, a carcinoma is diagnosed. A subsequent surgical resection is performed to ensure that all of the carcinoma has been removed, but the resection does not remove additional malignant tissue. The description of the carcinoma should be recorded on the DEC

form in Item A.5, other Diagnostic/Staging Procedures, as code 03, and in item C.9, Description of Colorectal Carcinoma, Procedure, Polypectomy = 3. If the surgical resection had also removed malignant tissue, Item C.9 Procedure should be completed as Polypectomy = 3 and Surgical resection = 4. The surgical resection would also be recorded in A.5, code 18 "Resection", specified.

For each adenoma complete the following items:

- **Pathology Or Specimen Jar #:** Each column contains a number, 1-5, which represents up to five pathology or specimen jars, for which there is information. Record information on each adenoma according to the pathology or specimen jar # in which it was stored. **Note:** If information is clearly given for each adenoma within a specimen jar, record the information about the adenomas in separate columns.
- **Multiple Polyps In Specimen Jar?:** If there was only one adenoma in the specimen jar, record "0 = No." If there was more than one adenoma described in the same specimen jar, record "1 = Yes."
- **Procedure:** Darken the circle corresponding to the type of procedure performed where the adenomas were identified. The procedure types are defined as follows:
  - 1 = Sigmoidoscopy:** Visual examination of the sigmoid colon with either a flexible or rigid endoscope.
  - 2 = Colonoscopy:** Visual examination of the entire colon with a flexible endoscope.
  - 3 = Endoscopy (NOS):** The abbreviation "NOS" represents "not otherwise specified." The record does not specify, or it is questionable, whether the endoscopy performed was a sigmoidoscopy or a colonoscopy, and it cannot be determined using the guidelines provided in the specifications in Item A.3, Procedure Type.
- **Location:** Information about the anatomic location and/or the distance in centimeters from the anal verge where the adenoma was located will be found on the endoscopy report. *Complete both Parts, a and b.*
  - a. **Anatomic (Mark all that apply):** Darken the circle(s) corresponding to the anatomic location of the adenoma. If one adenoma overlaps two anatomic sites, mark all sites that apply. If there are multiple adenomas in a jar, mark all sites that apply.
    - If the anatomic location given is "rectosigmoid" or "sigmoid descending," record "07" for "Sigmoid colon."
    - If the anatomic location given is "right colon," record "02 = Ascending colon."
    - If the anatomic location given is "left colon," record "06 = Descending colon."
    - If the procedure is a sigmoidoscopy, the following anatomic location codes are not acceptable: 01, 02, 03 and 04.
    - If the anatomic location is not given or is unknown, record "99."
    - If the information is unclear or questionable, consult the SC Lead Abstractor, SC Coordinator and/or Principal Investigator for a resolution prior to contacting the CC MRA Coordinator.

If the operative report does not state the location of an adenoma, however, there is a diagram of the colon with the adenoma noted, the anatomic location of the adenoma can be coded using the diagram.

- b. **Distance in cm:** Record the distance in centimeters where the adenoma was located. If a range of measurements is given for a distance, record the median or the midpoint of the range. If the median is a decimal, round to the nearest centimeter using the rounding rules in Appendix K of the MOOP. Darken the circles corresponding to the numbers recorded. If the location is greater than or equal to 99cm, 99 should be entered.

**For multiple adenomas in the same pathology or specimen jar:** If more than one distance is given for the group, record the longest distance in the space provided. Do not record the distance for additional adenomas in the same specimen jar.

If the distance in centimeters for the location is not given or is unknown, record "99."

If the information is unclear or questionable, consult the SC Lead Abstractor, SC Coordinator, and/or Principal Investigator for a resolution prior to contacting the CC MRA Coordinator.

- **Size:** Information about the size of the adenoma at visualization during the endoscopy should be recorded from the endoscopy report. Size may be given in the report in millimeters or centimeters, and/or may be described as diminutive, small, or large. Complete this item following the guidelines below.
- a. **Longest dimension in cm:** Record the appropriate measurement given for the adenoma following the guidelines below. Record the size in centimeters, rounding to the nearest one tenth of a centimeter using the rounding rules in Appendix K of the MOOP. If the size is stated in millimeters, convert millimeters to centimeters (1 mm = 0.1 cm).

*If the size of the adenoma is given as a measurement (i.e., in millimeters or centimeters), record this lesion in Part a, and skip Part b (i.e., leave it blank). If the size is not given as a measurement, record "99.9" for "Not available" in Part a, and go to Part b.*

Record the longest dimension given for the adenoma, and then darken the circles corresponding to the numbers. The following guidelines should also be followed:

- If a range of measures is given for the size of an adenoma in which there is a difference of only one increment in size, record the largest size in the range; e.g. the size of an adenoma given as 0.3 to 0.4 cm would be recorded as 00.4 cm.
- If a range of measures is given for the size of an adenoma in which there is a difference of greater than one increment in size, record the average of the measures; e.g. the size of a polyp given as 0.4 to 0.7 cm would have an average of 0.55 cm, and would be recorded as 00.6 cm because of rounding.

For multiple adenomatous polyps in the same pathology or specimen jar: If more than one measurement is given because there are multiple adenomas in one pathology or specimen jar, record the dimension for the largest adenoma in the jar. Darken the circles corresponding to the numbers recorded. Do not record the size of additional adenomas in the same specimen jar.

- b. **Diminutive, small, large:** Only complete Part b if "Not available" is recorded in Part a, otherwise, leave Part b blank and go to "Histology." Darken the circle corresponding to the size given for the adenoma. If there are multiple adenomas in the same pathology or specimen jar, record the size for the largest adenoma.

The following are additional guidelines for recording size:

- If the size of the adenoma is given as diminutive to small, record "2" for small.
- If the size of the adenoma is given as diminutive to large, record "3" for large.
- If the size of the adenoma is given as diminutive, this is the same as "extremely small in size" or "tiny."
- When the endoscopy report does not give a specific size or range of sizes for an adenoma because the size of the polyp is described as "< \_\_mm" or "> \_\_mm", use the following table to record the polyp size:

Diminutive < or = 5 mm

Small 5.01-10 mm

Large > 10 mm (1 cm)

- If the size of the adenoma is not described as diminutive, small, or large, record "9" for "Not available."
- If more than one size (diminutive, small, large) is given for an adenoma, record the largest size noted.
- **Histology:** Darken the circle corresponding to the histological type of the adenoma. If there are multiple adenomas in the same pathology or specimen jar, record the histology for the adenoma with the highest level of classification.

The level of classification from highest to lowest is as follows: villous adenoma, tubular villous adenoma, tubular adenoma and adenoma (NOS). For example, a result of adenomatous hyperplastic polyp should be recorded as "adenoma (NOS)." This information can be found on the pathology report. The histological classifications are as follows:

**2 = Tubular adenoma**

**3 = Tubular villous adenoma:** This may also be called a tubular papillary adenoma or villoglandular.

**4 = Villous adenoma:** This may also be called a villous papilloma.

**5 = Adenoma (NOS):** The abbreviation "NOS" represents "not otherwise specified"; unusual adenomas such as serrated or flat adenomas should be recorded in this category.

- **Dysplasia:** This item refers to the degree of cellular atypia of the adenoma. Record the level of dysplasia for the adenoma recorded under histology above. If the adenoma or group of adenomas is noted to have a range of dysplasia, record the most severe type. For example, "mild to moderate" should be recorded as "moderate." Darken the circle corresponding to the degree of dysplasia as follows:

**0 = None:** The record clearly states that the abnormality had no dysplasia (i.e., no atypia or "no significant atypia").

**1 =Mild (low grade)**

**2 =Moderate (low grade)**

**3 =Severe (high grade)**

**9 = Not available:** The degree of dysplasia is stated as unknown or is not available in the record. If dysplasia is not mentioned in the record, use this code.

**4a. Number Of Non-Advanced And/Or Advanced Adenomas:** Record the total number of confirmed non-advanced adenomas and total number of confirmed advanced adenomas found on endoscopy for all procedures documented in the medical record. The criteria for an advanced adenoma is noted below and an adenoma must fulfill at least one criterion to be classified as advanced:

- greater than or equal to 1 centimeter
- villous elements in histology
- severe or high-grade dysplasia

This item cannot be left blank. If the total number of non-advanced adenomas or the total number of advanced adenomas is "none" or "0," record "00."

**4b. Can Exact Number Of Adenomas Be Determined?** Record whether or not the exact number of adenomas can be determined.

**5. Other Diagnostic/Staging Procedures:** This item is concerned with any other diagnostic/staging procedures that the participant underwent during evaluation for colorectal cancer other than sigmoidoscopy, colonoscopy, or endoscopy (NOS).

Darken the circle corresponding to whether the participant underwent other diagnostic/staging procedures as follows:

**No:** The record clearly states or indicates that the participant did not undergo any other diagnostic/staging procedures. Darken the circle for "No" and go to Item A.6.

**Yes:** The record states or indicates that the participant underwent one or more diagnostic/staging procedures for colorectal cancer other than sigmoidoscopy, colonoscopy or endoscopy (NOS). This may include a colon biopsy performed during a PLCO screen or a colon biopsy performed during an endoscopy to rule out cancer. Darken the circle for "Yes" and complete the table for Item A.5. If space is needed to record more than twelve diagnostic/staging procedures, use the Diagnostic/Staging Procedures Supplement (DSS) form (refer to Item A.5b).

**Unknown:** If there is no indication in the record whether or not diagnostic/staging procedures were or were not performed, darken the circle for "Unknown" and go to Item A.6.

The following are general guidelines for identifying diagnostic and staging procedures in the medical record:

- Only procedures used to diagnose or stage a cancer that are clearly stated in the record (discharge summaries and operative reports) should be recorded. If the operative report and/or discharge summary is missing, procedures noted in doctor's notes or a history taken after the procedure may be used to record

a diagnostic/staging procedure. *Please call the CC MRA Coordinator if there is any uncertainty about recording diagnostic/staging procedures.*

- Only procedures, not approaches, should be recorded. The only time that an approach should be recorded is for a procedure that is strictly exploratory and which is not done for the purpose of a resection. *The SC Lead Abstractor should contact the CC MRA Coordinator if there is any uncertainty about recording diagnostic/staging procedures.*
- Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.
- All staging information related to the initial diagnosis of a primary colorectal cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEC form.) Surgical resection of the primary organ, lymph nodes and other organs should be included. Staging procedures performed after the start of the first definitive treatment such as chemotherapy or radiation therapy, unless the treatment had been designated neoadjuvant, should not be collected.
- Procedures done to assess for disease progression or to assess for effect of treatment should not be collected.

For each diagnostic/staging procedure performed, complete the following items:

- **Type of Procedure:** Darken the circle corresponding to the type of diagnostic/staging procedure performed. Refer to the Procedure Codes for the list of diagnostic and staging procedures for colorectal cancer. When the procedure on the Procedure Code list indicates "SPECIFY," describe the body site or the actual procedure, as appropriate. Refer to Appendix K-17-2 of the MOOP for an alphabetical listing of definitions and synonyms for the diagnostic/staging procedures listed on the DE forms. The following are guidelines for coding type of procedure:
  - **Biopsy:**
    - 03 = Biopsy (Specify) includes all biopsies performed, including a colon biopsy that have been accounted for in A.3 or A.4 (the biopsy of noncancer polyps should not be recorded in A.5). The "specify" refers to the site of the biopsy not the method of biopsy. It should be used to record both incisional and excisional biopsies of organs except lymphadenectomy/lymph node sampling (code 24).
  - **Clinical Evaluation, DRE, and Record Review:**
    - 05 = Clinical Evaluation: A clinical evaluation is defined as a visit to a health care provider for medical care and should include a history and physical exam related to the colorectum. If a history includes information about the PLCO Screen only, this is to be considered a clinical evaluation. It does not include a telephone conversation to a health care provider. The following examples illustrate how the form should be completed to document a clinical evaluation:
      - If a visit to a health care provider includes a history as well as a physical examination of the abdomen and/or rectum, this is considered a clinical evaluation.

- If a visit to a health care provider includes only a history and not a physical examination of the abdomen and/or rectum, this is also considered a clinical evaluation.
  - If a visit to a health care provider includes a history and a physical exam and a DRE is performed as part of the physical examination, this should be considered as one procedure and recorded only once using code 10 = DRE.
  - A clinical evaluation that only serves to repeat or confirm previous finding should not be recorded.
- 10 = DRE: If the findings or description in a sigmoidoscopy or colonoscopy report begin with, "following a normal rectal examination," this may mean that the endoscopist was checking to see if a scope could be passed. This does not mean that a diagnostic Digital Rectal Examination (DRE) was performed prior to sigmoidoscopy or colonoscopy. If a diagnostic DRE is performed just prior to endoscopy and detailed separately, this may be recorded as a separate Diagnostic/Staging procedure. Do not record any DREs performed after the diagnosis of colorectal cancer is confirmed.
- 17 = Record Review: This procedure should only be recorded when a review of the medical record is performed for the purpose of a second opinion of diagnosis, and a record review contributes to the diagnosis or staging of the cancer in question.
- **CT Scans:**
    - 06 = CT scan abdominal
    - 07 = CT scan – other (SPECIFY)
    - 08 = CT scan – pelvic
    - 20 = CT scan – abdomen and pelvis combined: If CT pelvic and CT abdominal procedures appear in the record as a combined procedure, they should be recorded as a single procedure under "20 = CT scan – abdomen and pelvis combined" with one date. If they are performed on the same date, and appear in the record as separate procedures, the abstractor should record them under 08 and 06 respectively.
      - If a CT scan is performed as part of a diagnostic procedure, as in the case of a "CT guided biopsy," the CT scan should not be recorded as a separate procedure. In this case the CT scan is the approach or means to perform the biopsy.
  - **Endoscopic/Surgical Evaluation Procedures:**
    - 09 = Cystoscopy
    - 22 = Laparoscopy – Record if exploratory only and not if an approach to another procedure.
    - 23 = Laparotomy – Record if exploratory only and not if an approach to another procedure.
    - 27 = Upper GI evaluation – endoscopic/radiographic
  - **Procto Exams:**

A procto exam, which is usually a rigid sigmoidoscopy, should be coded under Item A.3, Sigmoidoscopy or Colonoscopy, as a sigmoidoscopy.

- **Anoscopy: Use code 88, Other (specify) and note "Anoscopy"**
- **Laboratory Tests:**
  - 15 = Preoperative carcinoembryonic antigen (CEA): Preoperative carcinoembryonic antigen – CEA should be coded as "15" and the value obtained during the procedure should be recorded on the "Specify" line. If the value is not given, record "99" on the line. The normal values for CEA are 0.0 to 3.0 ng/ml.
  - 16 = Stool occult blood, also known as Fecal Occult Blood Test (FOBT) or stool guaiacs
- **MRI Scans:**
  - 12 = MRI scan – abdominal
  - 13 = MRI scan – other (SPECIFY)
  - 14 = MRI scan - pelvic
- **Other (SPECIFY):** Use code 88 = Other (SPECIFY) to record procedures that cannot be listed using one of the other codes on the form.
- **Radiographic Procedures:**
  - 01 = Abdominal flat plate (plain film). A KUB film would be synonymous.
  - 02 = Barium enema radiograph. A hypaque enema study is not equivalent and should be recorded under 25=Other radiograph, and specified as "hypaque enema."
  - 04 = Chest radiograph: The first (chronological) chest radiograph found in the record should be recorded. Additional chest radiographs should not be recorded unless they reveal a new abnormality that confirms the spread of cancer.
  - 11 = Intravenous pyelography (IVP)/excretory urography
  - 25 = Other radiograph (SPECIFY)
  - 27 = Upper GI evaluation – endoscopic/radiographic. A barium swallow would be recorded using this code.
- **Surgical Procedures:**
  - 18 = Resection (SPECIFY):
    - A surgical resection should be recorded as 18 = Resection (Specify). Specify what was removed.
    - If the surgical procedures "diverting sigmoid colectomy" (a type of surgical resection) or "abdominal perineal resection (APR)" were performed for diagnostic evaluation, record them under "18=Resection (Specify)" and record the type of the resection on the specify line.
    - If the participant underwent a hemicolectomy, record this as code 21. Do not record a hemicolectomy under 18 = Resection (SPECIFY).

21 = Hemicolectomy: If the colon resection involves the removal of the left or right side of the colon, the procedure should be recorded as a hemicolectomy. This procedure means that approximately half of the colon was removed.

24 = Lymphadenectomy/lymph node sampling: If lymph node sampling and lymph node dissection are both performed, this should be considered as one procedure and recorded only once as code 24.

- Lymph node removal accompanying surgical resection should be coded as two separate procedures. Code each procedure separately, using either code 18 = Resection (SPECIFY) or code 21 = Hemicolectomy for the resection and code 24 = Lymphadenectomy/Lymph node sampling for the lymph node removal.

- **Ultrasound:**

19 = Abdominal ultrasound

26 = Ultrasound (SPECIFY)

Please refer to Section A-8-6 of the MOOP, Diagnostic/Staging Procedures Supplement (DSS), for an additional listing of Diagnostic/Staging Procedures.

- **Date of Procedure:** Record the month, day, and year that the diagnostic/staging procedure was performed. If it is not clear from the record the day that the procedure was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

5b. Diagnostic/Staging Procedures Supplement Form Completed: If space is needed for recording more than 12 diagnostic/staging procedures, darken the circle and complete the Diagnostic/Staging Procedures Supplement (DSS) form. Otherwise, do not darken the circle and go to Item A.6.

The DSS form provides eleven additional spaces for recording diagnostic/staging procedures, numbered 13 through 23. If there are more than 23 diagnostic/staging procedures, place an asterisk beside Item 4 (Diagnostic/Staging Procedures) on the DSS, and use the Comments section of the DEC to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example:

Item E.21, Comments:

<u>Item #:</u>	<u>Comments:</u>
A.5	4; Type = ____; Date = ____

Refer to the specifications for the DSS for additional information on completing the DSS.

6. **Medical Complications of Diagnostic Evaluation and Staging:** General guidelines for identifying selected medical complications in the medical record are given below:

- Only those selected medical complications that were a result of the diagnostic evaluation or staging procedures and that required medical intervention should be recorded.

- Information on medical complications can usually be found in the discharge summary, or the doctor's or nurse's notes within the medical record.
- Medical complications should be collected up to 12 months from the time diagnostic procedures were initiated. In the event of a cancer diagnosis, medical complications should be collected through 6 months after the date of the cancer diagnosis.
- If more than one medical complication occurred during a particular event, record each selected medical complication, even if they occurred on the same date. Hospitalization, code 22, should be recorded only if the reason for hospitalization is not another selected medical complication. For example, in the case of fever requiring antibiotics and hospitalization, only record fever requiring antibiotics.

Darken the circle corresponding to medical complications as follows:

**No:** The record clearly states or indicates that none of the selected medical complications resulted from a diagnostic or staging procedure. Also mark this item if no diagnostic/staging procedures were performed as part of the evaluation. Darken the circle for "No" and go to Item A.7.

**Yes:** The record states or indicates that one or more of the selected medical complications resulted from a diagnostic or staging procedure. If a participant had more than six medical complications, place an asterisk beside Item A.6, and use the Comments section to record the same data as requested in the table. In Comments, record the item numbers and labels followed by the data. Be certain to list the number associated with the complication next to "Type," rather than the text, which describes the complication. For example, fever requiring antibiotics was the seventh medical complication mentioned in the record:

Item E.21, Comments

Item #	Comments
A.6	7; Type = 2; Date = mm/dd/yyyy

Darken the circle for "Yes" and complete the table for Item A.6 as follows:

- **Type of Medical Complication:** Darken the circle corresponding to the type of medical complication that occurred. Refer to the Medical Complication Codes for the list of selected medical complications that required medical intervention for colorectal cancer. Refer to Appendix K-17-2 of the MOOP for definitions and synonyms for the medical complications listed on the DE forms. The following are guidelines for recording medical complications of Diagnostic Evaluation and Staging:
  - 1 = Infection (SPECIFY):** Specify the site or source of the infection on the line provided.
  - 22 = Hospitalization:** Use only if reason for hospitalization is not another selected medical complication.
  - 27 = Blood loss requiring transfusion:** Only record transfusion of blood if it involves giving red blood cells from a stored source, usually described as a unit of red blood cells. There can be a number of words that would apply - whole, packed, washed, irradiated, etc. The transfusion of red blood cells implies that the blood loss was significant enough to require a replacement of the red blood cells. Other types of

fluids or blood products that do not include red blood cells, such as D5, saline (NaCl), platelets, albumin, or fresh frozen plasma should not be considered when recording blood loss requiring transfusion. The intra-operative recycling of blood lost, filtered, and returned immediately to participant will also not be considered equivalent to blood loss requiring transfusion and should not be recorded as a medical complication.

*The Lead Abstractor should consult with the CC MRA Coordinator if it cannot be determined if a medical complication should be recorded.*

- **Date of Complication:** Record the month, day and year that the medical complication began. If it is not clear from the record the day of the complication, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**Unknown:** Only use this code when you may not have all of the medical record and you cannot reliably determine complications. Darken the circle for "Unknown" and go to Item A.7.

7. **Result of Diagnostic Evaluation for Colorectal Cancer:** The purpose of this item is to record the overall results of the diagnostic evaluation for colorectal cancer. This information should be found in the impression or conclusion sections of the various diagnostic and staging reports. It may also be found in a physician's note. Record the result of the diagnostic evaluation for prostate cancer as follows:

- **No malignancy:** The record states or indicates that no malignancy was found as a result of the diagnostic and staging procedures. A result of "No malignancy" should be coded in the following situations:
  - When a conclusive diagnosis is made following a positive screen and the diagnosis is not colorectal or any other cancer. Include an advanced adenoma that meets one or more of the following criteria: greater than or equal to 1 centimeter, villous elements in histology, and/or severe or high-grade dysplasia. Carcinoma in situ of the colorectum and an advanced adenoma as described above are synonymous conditions. Intramucosal carcinoma and carcinoma limited to the mucosa are equivalent to colon carcinoma in situ and included in the result of "No Malignancy".
  - When there is a diagnosis of severe diverticulosis and a small polyp.
  - When there is a diagnosis of adenomatous polyps with a recommendation to follow-up with a colonoscopy in one year
  - When no diagnostic procedures are performed following a positive PLCO screening exam per documented physician recommendation - (i.e., when Item A.1, Diagnostic Procedures Performed, is coded "No, physician report"), then no malignancy is assumed.
  - When diagnostic follow-up data have been abstracted for the period from a positive screen until 12 months past the positive and the diagnosis was not conclusively malignant.

Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.

- **No malignancy and no diagnostic/staging procedures performed:** The participant reports that he/she had a follow-up visit with his/her health care provider who determined that there was no malignancy. No further diagnostic/staging pro-

cedures were performed. This information is not documented in the medical record and cannot be validated by the participant's health care provider. Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.

- **Colorectal malignancy confirmed histologically (exclude carcinoma in situ):** The record indicates that the participant was diagnosed with primary colorectal cancer, confirmed by histologic examination (study of tissue). Histologic information can be found on the pathology report, sometimes called the histopathology report. Neoplasm of uncertain behavior of the colorectum (excluding villous adenoma), carcinoid of the colorectum, extranodal lymphoma arising in the colorectum and sarcoma of the colorectum should be recorded here. A diagnosis of carcinoma in situ of the colorectum, also known as an advanced adenoma that meets the following criteria: greater than or equal to 1 cm, villous elements in histology and/or severe high-grade dysplasia, should not be recorded here. Darken the circle and go to Part C, Primary Colorectal Cancer Diagnosis Information.
  - This includes a diagnosis of adenocarcinoma of the appendix.
  - This includes the case where the diagnosis is based on tissue obtained from a metastatic site such as liver or a lymph node.
- **Colorectal malignancy confirmed cytologically (exclude carcinoma insitu):** The diagnosis of primary colorectal cancer was confirmed by cytologic examination (study of cells). Cytologic information can be found on the cytology report, sometimes called a cytopathology report. Neoplasm of uncertain behavior of the colorectum (excluding villous adenoma), carcinoid of the colorectum, extranodal lymphoma arising in the colorectum and sarcoma of the colorectum should be recorded here. A diagnosis of carcinoma in situ of the colorectum, also known as an advanced adenoma that meets the criteria defined above, should not be recorded here (see also Item A.4a.). Darken the circle and go to Part C: Primary Colorectal Cancer Diagnosis Information.

**NOTE:** *If the colorectal malignancy was confirmed by both histologic and cytologic examination, A.7 should be recorded "Colorectal Malignancy confirmed histologically". The histopathology report is more definitive, and therefore, every attempt should be made to verify if one exists before utilizing cytologic confirmation. If the colorectal malignancy was confirmed by cytologic examination alone, then cancer diagnosis information should be taken from the cytopathology report.*

- **Colorectal malignancy diagnosed by clinical examination only:** The record indicates that the participant was diagnosed with primary colorectal cancer by clinical examination and not confirmed by histologic examination (study of tissue) or cytologic examination (study of cells). It is an extremely rare event, however, for a malignancy to be confirmed only by clinical examination and not histologically or cytologically. Darken the circle and go to Part C, Primary Colorectal Cancer Diagnosis Information.

In these cases there will be a 12-month "holding period" to be sure that no pathologic confirmation followed. The following guidelines should be used to determine if the diagnosed "clinically" code is appropriate:

- If the initial response is "clinically" and within the 12-month period there is pathologic confirmation, the diagnosis should be changed to "histologically" or "cytologically" and the diagnosis date should be updated.

- If the initial response is "clinically" and non-surgical treatment (other than neoadjuvant) is given right away, the "clinically" code becomes validated and should remain.
- If the initial response is "clinically" but after 12 months there is no follow-up or treatment, the diagnosis is questionable and should be changed to "no malignancy."
- If the initial response is "clinically," but the lack of treatment is due to other reasons, such as advanced stage of disease, participant refusal, etc., the clinically diagnosed result should remain on the DE form.
- **Other malignancy confirmed histologically or cytologically:** The diagnosis of a malignancy *other* than primary colorectal cancer was confirmed by histologic examination (study of tissue) and or cytologic examination (study of cells). Histologic information can be found on the pathology report, sometimes called the histopathology report, and cytologic information can be found on the cytology report, sometimes called a cytopathology report. Darken the circle and go to Part B: Diagnosis Information For Cancers Other Than Colorectal Cancer.

This answer category should also be coded if the diagnostic evaluation for primary colorectal cancer reveals a malignancy (including a colorectal malignancy) that is a metastasis from a primary cancer site other than the colon. In this situation, the primary cancer site should be recorded in Part B: Diagnosis Information For Cancers Other Than Colorectal Cancer.

**NOTE:**

- *If the participant was diagnosed with another PLCO malignancy (prostate, lung, or ovarian) as the result of the diagnostic evaluation for colorectal cancer, the appropriate Diagnostic Evaluation form (DEP, DEL, or DEO) must also be completed, unless previously confirmed.*
- *If the participant was diagnosed with a malignancy other than one of the PLCO cancers, an Other Cancer Form (OCF) must also be completed, unless previously confirmed.*

- **No information available:** There is equivocal or no information available in the record regarding the result of the diagnostic evaluation for colorectal cancer. "No information available" should also be coded in the situation when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a colorectal or other malignancy.

Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.

**Part B: Diagnosis Information for Cancers Other Than Colorectal Cancer:**

This section is to document other cancer diagnoses, which resulted from the diagnostic evaluation. Other cancer diagnoses may include neoplasms of uncertain behavior), carcinoids, sarcomas, lymphomas and other malignancies that have an origin other than the colorectum.

8. **Other Cancer Diagnosis:** This item is concerned with cancer diagnoses other than the colorectum. Other cancer diagnoses may also include neoplasms of uncertain behavior), carcinoids, sarcomas, lymphomas, and other malignancies that have an origin other than the colorectum. Lung carcinoma in situ is an other cancer diagnosis, but do not include carcinoma in situ of the prostate and colon as other cancer diag-

noses. These diagnoses must be classified according to ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification). ICD-9-CM coding for the PLCO Screening Trial must be consistent with the National ICD-9-CM coding standards and should not be influenced by specific institutional coding philosophies.

Darken the circle corresponding to an other cancer diagnosis as follows:

**No:** The record clearly states or indicates that no other cancers were determined as a result of diagnostic or staging procedures. Also mark this item if there is no information for physician diagnosis or if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to Part D.

**Yes:** The record states or indicates that one or more other cancer diagnoses were determined as a result of diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for Item B.8 as follows:

- **ICD-9-CM Classification:** These items must be completed by a nosologist (a trained medical coder). The nosologist should code the five digit ICD-9-CM classification in the space provided and darken the circles corresponding to each number or letter. When coding ICD-9-CM, always left justify the code and ignore the decimal place. If the ICD-9-CM code is a three or four digit code, record "X" for the remaining blank box(es). The following examples illustrate how the ICD-9-CM code boxes should be coded:
  - The ICD-9-CM code for Hodgkin's disease, unspecified site is 201.90. This should be coded as "20190."
  - The ICD-9-CM code for malignant neoplasm of the bladder is 188.9 This should be coded as "1889X."
  - The ICD-9-CM code for malignant neoplasm of the thyroid gland is 193. This should be coded as "193XX."

**NOTE:** *If the diagnostic evaluation results in an extranodal lymphoma of the prostate, lung, or ovary, assign the appropriate ICD-9-CM code for the type of lymphoma with "0" as the 5th digit denoting "extranodal." An "OCF" will be triggered. Complete an "MDF" for the OCF and manually set the expectation for the appropriate DE form. Complete the DEP, DEL or DEO for the prostate, lung or ovarian lymphoma.*

- **Date of Other Cancer Diagnosis:** Record the month, day and year that the other cancer diagnosis was determined. If the day of the other cancer diagnosis is not clear in the record, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.
- **More Than Two "Other" Cancer Diagnoses:**  
Record codes for more than two other cancer diagnoses in Item E.21, Comments, as shown in the following example:

Item E.21, Comments:

Item #	Comments
B.8	3; ICD-9-CM Classification = ____; Date of Other Cancer Diagnosis = mm/dd/yyyy

Be sure to set an expectation in the SMS for any additional "other" cancers.

If Part B is completed, skip Part C and go to Part E.

### **Part C: Primary Colorectal Cancer Diagnosis Information:**

In this section we are interested in obtaining all relevant information pertaining to a primary colorectal cancer diagnosis, which includes cancers of the appendix, neoplasms of uncertain behavior of the colorectum (excluding villous adenomas), extra nodal lymphoma of the colorectum, sarcoma of the colorectum and/or a carcinoid of the colorectum. A villous adenoma is classified as a neoplasm of uncertain behavior of the colorectum and should be recorded in Part A.4, Adenomas on Sigmoidoscopy or Colonoscopy. Do not record a villous adenoma in this section. This section is to be completed only by a CTR or CTR-eligible individual. Every attempt should be made to complete this form in a timely manner. For participants who have a positive PLCO screening result, the Medical Record Abstract-DEC Form should be completed within six months of the positive screening result. If specific items cannot be completed within the six-month time frame (i.e., awaiting access to photocopy a form or awaiting TNM staging by the Tumor or Cancer Registrar), those items should be left blank and the information completed within nine to eleven months.

If the participant was diagnosed with more than one primary colorectal cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For all subsequent primaries use another DEC form. If more than one primary was diagnosed on the first date of diagnosis, record information about the most advanced cancer diagnosed on that day in Part C, and use additional DEC forms for any other cancers diagnosed on that day.

Use the following guidelines, to determine the number of primary cancers that were diagnosed.

- Simultaneous multiple lesions of the same histologic type within the same site will be considered a single primary.
- Multiple lesions of the same histologic type occurring in different sites are considered to be separate primaries unless stated to be metastatic.
- Multiple lesions of different histologic types within a single site are considered separate primaries whether occurring simultaneously or at different times.
- Multiple lesions of different histologic types occurring in different sites are considered separate primaries whether occurring simultaneously or at different times.

Reference: SEER Program Code Manual, Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute. 1998, pp.12-13.

9. **Description of Carcinoma:** This item refers to any carcinoma identified as a result of sigmoidoscopy, colonoscopy, polypectomy, resection, or some other procedure. Information on location and gross morphology is to be recorded for the highest grade

of carcinoma identified. If an abnormality was diagnosed as benign but subsequently the same abnormality was diagnosed as a carcinoma, it should be recorded only once on the DEC form, in this item (C.9).

This information can be found in the procedure reports (sigmoidoscopy report, colonoscopy report, etc.). If more than one procedure identified this carcinoma, the report from the procedure that collected the most tissue should be used.

Use column 1 only of the table to record the information on the carcinoma. If more than one colorectal primary is diagnosed, record each one on a separate DEC. See page 26 (second paragraph in Part C) and page 3 (second bullet) for general instructions. Leave columns 2 and 3 blank.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any carcinomas. Darken the circle for "No" and go to Item C.10.

**Yes:** The record states or indicates that the participant had one or more carcinomas. Darken the circle for "Yes" and complete the table for Item C.9. For each tumor complete the following items:

- **Procedure:** (Mark all that apply) Darken the circle corresponding to the type of procedure performed that provided the histological or cytological confirmation of the primary colorectal cancer. The procedure types are defined as follows:
  - 1 = Sigmoidoscopy:** Visual examination of the sigmoid colon with either a flexible or rigid endoscope.
  - 2 = Colonoscopy:** Visual examination of the entire colon with a flexible endoscope.
  - 3 = Polypectomy:** Surgical removal of a polyp.
  - 4 = Surgical resection:** Surgical excision of a portion of an organ or other structure.
  - 5 = Local transanal or other resection:** Polypectomy or excision of a lesion through an anoscope.
  - 8 = Endoscopy (NOS):** The abbreviation "NOS" represents "not otherwise specified." The record does not specify, or it is questionable, whether the endoscopy performed was a sigmoidoscopy or a colonoscopy.
- **Location:** Information about the anatomic location and/or the distance in centimeters where the tumor(s) were located, should be available in the record. Complete both Parts a and b.
  - a. **Anatomic:** Darken the circle(s) corresponding to the anatomic location of the tumor. Mark all that apply.
    - If the anatomic location given is "rectosigmoid" or "sigmoid descending," record "07" for "Sigmoid colon."
    - If the anatomic location given is "right colon," record "02 = Ascending colon".
    - If the anatomic location given is "left colon," record "06 = Descending colon."

- If the procedure is a sigmoidoscopy, the following anatomic location codes are not acceptable: 01, 02, 03 and 04.
  - If the anatomic location is not given or is unknown, record "99."
  - If the information is unclear or questionable, consult the SC Lead Abstractor, SC Coordinator and/or Principal Investigator for a resolution prior to contacting the CC MRA Coordinator.
- b. **Distance in cm:** Record the distance in centimeters where the tumor was located. If necessary, round to the nearest centimeter using the rounding rules in Appendix K of the MOOP. Darken the circles corresponding to the numbers recorded.
- If the distance in centimeters for the location is not given or is unknown, record "99."
  - If the information is unclear or questionable, consult the SC Lead Abstractor, SC Coordinator and/or Principal Investigator for a resolution prior to contacting the CC MRA Coordinator.
- **Gross Morphology:** Darken the circle corresponding to the gross morphologic characteristic of the carcinoma. Gross morphology should be taken from the pathology report but this information should be clarified by reviewing the endoscopy and operative reports as well as any clinical notes of the case. The gross morphologic characteristics are defined as follows:
- 1 = Exophytic:** The record indicates that the carcinoma was growing within the lumen of the colon. Typical location: Right side of colon; Synonyms: Fungating, either pedunculated or sessile; polypoid, or bulky.
  - 2 = Endophytic:** The record indicates that the carcinoma was growing predominantly within the wall of the colon. Synonyms: Ulcerative.
  - 3 = Annular:** The record indicates that the carcinoma was growing around the colon, constricting it. Typical location: Transverse and descending colon. Synonyms: Napkin-ring, apple-core, constricting, stenosing, circumferential, or ulcerating.
  - 4 = Diffusely infiltrative:** Linitis plastica. The record indicates that the carcinoma was full thickness bowel wall involvement converting the colon into a rigid tube with a thickened wall.
  - 9 = Not available:** The gross morphology of the carcinoma is not available or is stated as unknown in the record.

If more than one of the descriptions are mentioned, the dominant morphologic appearance should be coded using the following hierarchy: diffusely infiltrative; annular; exophytic; endophytic. For example, if one report describes the cancer as diffusely infiltrative and another notes an exophytic appearance, the worst case should be coded – diffusely infiltrative.

**Unknown:** If the Description of Colorectal Carcinoma is unknown or not mentioned in the record. Darken the circle for "Unknown" and go to Item C.10.

10. **Date of Primary Colorectal Cancer Diagnosis:** Record the month, day and year of the primary colorectal cancer diagnosis that was confirmed by histopathology or cytopathology if histopathology is not available. This is the date on the report that the actual procedure (biopsy, surgery, aspiration of cells, etc.) was performed that confirmed this primary colorectal cancer diagnosis. Operative reports are generally more

accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report. For example, the date on the pathology report may be the date that the slides were read or the date that the diagnosis was determined or reported, rather than the date of the operative procedure.

If there are multiple reports that confirmed this primary cancer, record the earliest date available that has an adequate tissue specimen. If histopathology is not available, record the earliest date with cytopathologic confirmation of the malignancy. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. In the rare situation in which colorectal cancer was diagnosed by clinical examination only and not histologically or cytologically, the date of first colorectal cancer diagnosis is the date of the clinical examination, which diagnosed the cancer.

Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year. Month and year of colorectal cancer diagnosis must be known. However, if day is unknown, record "99."

**11. Verbatim Description of Primary Colorectal Cancer Diagnosis:** This item is concerned with the actual physician diagnosis of the primary colorectal cancer. This item is optional except in the following situations:

- The diagnosis is based on clinical examination and not pathology (Item A.7 = Colorectal malignancy diagnosed by clinical examination only); or
- The SC is unable to obtain a copy of the pathology or cytology report that corresponds to the ICD-O-2 code in Item C.12 (Item C.13 = Not available).

Record the verbatim description of the colorectal cancer diagnosis from the pathology/histopathology report (or cytology/cytopathology report if a pathology report is not available). The verbatim description should come from the diagnosis section of the earliest (chronological) pathology report (or cytology report if the pathology report is not available), that had an adequate specimen and which confirms the cancer diagnosis.

- Occasionally, the diagnosis section will say "see above" or "see microscopic." In this situation record verbatim all of the information from the appropriate section of the report which pertains to the cancer diagnosis.
- Do not record any information about metastases or recurrent cancer.
- Do not record any information about benign conditions listed in the diagnosis section of the pathology or cytology report.

**12. ICD-O-2 Cancer Classification:** This item is for classifying the physician diagnosis of the colorectal cancer according to ICD-O-2 (*International Classification of Diseases for Oncology*, Second edition, 1990). The CTR should code the ten digit ICD-O-2 classification in the space provided. Darken the circles corresponding to the letter and each number.

- The ICD-O-2 code should reflect the diagnosis from the earliest (chronological) histopathology report, that has an adequate specimen, (or cytology report if tissue is not available) which confirms the cancer diagnosis. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. This should be the same report that was used as a source for the date of diagnosis in Item C.10.
- When the diagnosis of colorectal cancer is based upon tissue obtained from a metastatic site such as a lymph node or the liver, the grade in the ICD-O-7 code should be recorded as 9 (unknown).

- A neoplasm of uncertain behavior of the colorectum is considered to be a cancer by NCI and should be recorded in this section (excluding villous adenoma which will be recorded in Item A.4). Use the following guidelines for ICD-O-2 coding of neoplasm of uncertain behavior of the colorectum:
  - Assign the topography and morphology codes for this neoplasm according to ICD-O-2.
  - The behavior code for neoplasms of uncertain behavior is "1." Under "Behavior" enter "1" in the box and darken the circle for "1" printed on the form.
  - Grade will be coded "9" for neoplasms of uncertain behavior. Under "Grade," enter a "9" in the box and darken the circle for "9" printed on the form.

If the medical record contains information about this neoplasm that would result in a behavior code other than "1" or a grade code other than "9," contact the CC MRA Coordinator.

Use the following guidelines to determine how to record an extranodal diagnosis of lymphoma of the colorectum. Refer to Appendix K-17-2 of the MOOP for explanation of Nodal vs. Extra-Nodal Lymphomas:

- If an extranodal lymphoma of the colorectum is designated as the primary, record this lymphoma on the corresponding DEC3 form and assign the ICD-O-2 topography code corresponding to the site. Be sure this is the primary site of origin and not just a site where the biopsy was taken. The TIC2 form is required for each DEC3 form, as it is for any colorectal primary.
- If the site of origin is determined to be the lymph nodes of the colorectum lymphoma on the OCF and assign the ICD-O-2 topography code for lymph nodes (C77.\_\_). If diagnosed as part of the evaluation for colorectal cancer, this would be entered in Part B of the DEC3 form, Other Cancer Diagnosis.
- If a lymphoma is diagnosed in both a nodal and an extranodal colorectal site, consult the SC principal investigator to determine where the lymphoma originated and code the primary to that site.
- If an extranodal lymphoma arising in the colorectum is reported on an ASU, the SC will need to use the three-digit PLCO code for the colon, rather than the three-digit code for lymphoma in order to trigger the appropriate DE form. Complete the DEC3 for the extranodal lymphoma arising in the Colorectum. Complete the TIC2 also.
- If an extranodal lymphoma arising in the colorectum is reported on a death certificate, an OCF will be triggered. The SC will complete an MDF (for the OCF) and manually set the expectation for a DEC3 form. Complete the DEC3 for the extranodal lymphoma arising in the colorectum. Complete the TIC2 form also.
- If an extranodal lymphoma arising in a PLCO organ is reported on an ASU, the SC will need to use the three-digit PLCO code for the organ, rather than the three-digit code for lymphoma in order to trigger the appropriate DE form. Complete the DE for the extranodal lymphoma arising in the PLCO organ. Complete the TI also.
- If an extranodal lymphoma arising in an organ other than PLCO, or a lymphoma of the lymph nodes is reported on the ASU, use the three-digit code for lymphoma and complete the OCF.

- If an extranodal lymphoma arising in a PLCO organ is reported on a death certificate, an OCF will be triggered. The SC will complete an MDF (for the OCF) and manually set the expectation for the appropriate DE. Complete the DE for the extranodal lymphoma arising in the PLCO organ. Complete the TI also.
- Extranodal lymphomas arising in the colorectum may require the T-cell, B-cell, or NK cell designation. If so, enter the appropriate code from ICD-O-2 in the "Grade" space. The T-cell, B-cell or NK cell designation has priority over the grade when both are provided. NK cell designation = "8." A bubble for "8" does not exist on the form. Darken the space for "8" under "Grade" for NK cell if this applies.
- Do not code the descriptions "high grade," "low grade," or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.
- If the record clearly indicates that colorectal cancer was confirmed by a pathology or cytology report, but the report is not available, code the diagnosis from other available documents, (i.e. physician's notes, progress reports, etc.) that reference the earliest procedure from an adequate specimen. Place an asterisk by Item C.12, and indicate in the Comments section the source of the diagnosis. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.21, Comments:

Item #	Comments
C.12	Pathology/cytology report not available. Source of diagnosis is....

- If the colorectal cancer is diagnosed by clinical examination only, code the diagnosis using the report from the clinical examination form, which diagnosed the cancer.
  - The ICD-O-2 cancer classification should be coded by the CTR regardless of whether ICD-O-2 code is available in the medical record.
- 13. Photocopy of Report Confirming Primary Colorectal Cancer:** The purpose of this item is to document that the histopathology report (or cytopathology report if a histopathology report is not available) that confirmed the colorectal cancer has been photocopied and attached to the Medical Record Abstract-DEC Form.
- If there are multiple pathology reports confirming this primary colorectal cancer, the photocopy should be of the histopathology or cytology report, which was the source for recording the date of colorectal cancer diagnosis recorded in Item C.10, and the ICD-O-2 code recorded in Item C.12. If the Date of Colorectal Cancer Diagnosis and the ICD-O-2 Cancer Classification came from different reports, attach copies of both reports used to code Items C.10 and C.12.
  - A situation may arise in which an institution does not allow the photocopying of records. Every reasonable attempt should be made to obtain permission to photocopy the histopathology or cytology report since the cancer diagnosis is a critical end-point of the screening trial. If special permission or approval is required, the abstractor should work with the SC Coordinator/Principal Investigator to obtain the necessary approval. If this item cannot be completed in a timely manner, leave it blank and obtain the information at a later date via data retrieval.

Darken the circle to indicate whether a photocopy of the pathology or cytology report is available as follows:

- **Pathology/Histopathology:** The histopathology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEC Form. The photocopy should be labeled with the item number followed by the participant's ID number, study year, multiple primary number (if applicable), titled "Medical Record Abstract-DEC/Pathology Report," and inserted into the participant's folder.
- **Cytology/Cytopathology:** The cytology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEC Form. The photocopy should be labeled with the item number followed by the participant's ID number, study year, multiple primary number (if applicable), titled "Medical Record Abstract-DEC/Cytology Report," and inserted into the participant's folder.
- **Not available:** The histopathology or cytology report exists in the medical record, but a photocopy cannot be obtained or there is no report in the medical record. Place an asterisk by Item C.13, and provide a detailed explanation in the Comments section of why the pathology or cytology report cannot be obtained. (In this situation, Item C.11 (Verbatim Description of Colorectal Cancer Diagnosis) must be completed.) Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.21, Comments:

Item #	Comments
C.13	Pathology or cytology report cannot be obtained because...

**14. Histopathologic Type for Primary Colorectal Cancer:** This item is to document the histopathologic type of the primary colorectal cancer. This refers to the type of cell comprising the tumor, usually determined by the pathologist from a tissue specimen. This information can be obtained from the histopathology report that confirmed the colorectal cancer and collected the most tissue. If a pathology report is not available, this information may be found in the discharge summary, operative report, or in a cytology report. If the histopathologic type is obtained from a source other than the pathology report, place an asterisk by Item C.14, and record the source of the information in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.21, Comments:

Item #	Comments
C.14	Source of histopathologic type of lesion is...

- If the cancer has two different histopathologic types, the diagnosis is usually based on the predominant type. This should be stated in the pathology report. In this situation, record the predominant histopathologic type. If the pathology report does not indicate a predominant type record both types in Other (SPECIFY) for Item C.14 as follows: "Histopathologic type is \_\_\_\_\_ and \_\_\_\_\_."
- The abstractor should select the general category into which the result fits rather than using Other-specify to list a more detailed result. For example, "Adenocarci-

noma in tubulovillous adenoma, "papillary adenocarcinoma," and "superficial spreading adenocarcinoma" should be included in the "Adenocarcinoma" category.

- **Neoplasm of uncertain behavior of the colorectum:** Histopathologic Type for neoplasm of uncertain behavior of the colorectum will be designated as "Other." Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- **Extranodal lymphoma arising in the colorectum:** Histopathologic Type for extranodal lymphoma arising in the colorectum will be designated as "Other". Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- **Primary sarcoma of the colorectum:** Histopathologic Type for primary sarcoma of the colorectum will be designated as "Other." Darken the circle for "Other" and record the specific histopathologic type on the line provided.

Darken the circle corresponding to the histopathologic type of the colorectal cancer. If the histopathologic type is other than those listed, darken the circle for "Other" and specify the histopathologic type. If the histopathologic type is unknown or not available in the record, darken the circle for "Unknown."

15. **Histopathologic Grade of Primary Colorectal Cancer:** This item is to document the histopathologic grade of the primary colorectal cancer. Grade refers to a system of classifying certain characteristics of the cell. This information can be obtained directly from the pathology report, which collected the most tissue, a cytology report, a TNM form, a staging classification form, the discharge summary, or from doctor's notes.

- If the medical record states two different histopathologic grades, or a range of grades, record the most severe type. For example, "well differentiated" is the least severe type and "undifferentiated" is the most severe type. The most severe grade should be recorded from the primary site. Do not record the most severe grade from the metastatic site.
- **Neoplasm of uncertain behavior of the colorectum:** Neoplasm of uncertain behavior of the colorectum usually does not have a grade designation; therefore, "Grade cannot be assessed (GX)" should be recorded. If the medical record contains information about this neoplasm that would result in a specific grade, contact the CC MRA Coordinator.
- **Extranodal lymphoma arising in the colorectum:** If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown". Do not code the descriptions "high grade," "low grade," or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.
- **Primary sarcoma of the colorectum:** If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown."

Darken the circle corresponding to the histopathologic grade of the colorectal cancer. Darken the circle for "Unknown" when there is no indication in the record of the histopathologic grade or if the basis for the diagnosis is from tissue from a metastatic site such as a lymph node or the liver.

16. **TNM Staging for Primary Colorectal Cancer:** This item refers to the TNM or AJCC (American Joint Committee on Cancer) staging system. The AJCC Manual for Staging of Cancer provides the minimum requirements for clinical and pathologic staging. A

list of relevant documentation, based on those requirements can be found below. If TNM staging was performed, darken the circle corresponding to the edition of the AJCC Cancer Staging Manual used, the 4th Edition or the 5th Edition.

**Note:** The 5th Edition of the AJCC manual was published in January 1998. This latest edition should be used to stage all cancers diagnosed on or after January 1, 1998. For all previous cases the 4th Edition should be used.

TNM staging describes the anatomic extent of disease based on three components:

- (1) the extent of the primary tumor (T),
- (2) the absence or presence and extent of regional lymph node metastases (N), and
- (3) the absence or presence of distant metastases (M).

The addition of numbers to these three components indicates the extent of the malignant disease, thus showing progressive increase in tumor size or involvement.

If the TNM staging is available in the medical record, the abstractor may record it directly from the record. This staging is often performed by a Tumor Registrar (also known as a Cancer Registrar) and, if not available in the medical record, it may be available in the tumor registry. If the TNM staging is not available in the tumor registry, the abstractor should attempt to have the stage classified by the Tumor Registrar or a physician at a later date. The Tumor Registrar must be a CTR or CTR-eligible. If the TNM staging is not in the records or if the abstractor disagrees with the staging, the CTR may assign the TNM code when all relevant documentation from the patient's medical record is available to him/her. If an institution does not have a Tumor Registrar, then a physician can assign the TNM stage as long as all relevant patient documentation is available to the physician. The nosologist or abstractor should not assign the TNM staging, unless s/he is also a CTR (or CTR-eligible) and all relevant documentation is available.

If a participant receives neoadjuvant therapy prior to surgical resection, NCI would like the abstractors to do Clinical Staging of the Primary Cancer. Then record the TNM Pathologic Staging, using surgical pathology. In this situation TNM Pathologic Staging should be recorded as follows:

- Complete the item for TNM Pathologic Staging using the surgical pathology report.
- Place an asterisk next to the item number and go to the Comments section in Part E.
- Record the item number in the left margin of the Comments section and begin with the phrase, "ypT\_N\_M", including the appropriate numerical stage of the carcinoma which was recorded in Part C, TNM Pathologic Staging. "y" is a TNM descriptor that indicates that staging was performed during or following multi-modal therapy and the "p" indicates pathologic staging. After the appropriate information has been included in the "ypTNM" format, briefly state what treatment was received prior to surgery.

Item E.21, Comments

Item #	Comments:
C.16.b	ypT_N_M_; Treatment received prior to surgery was...

**General Guidelines for NX vs. NO and MX vs. MO:**

The X category should be used when involvement of regional lymph nodes or distant metastatic sites was not evaluated or could not be evaluated. It is not sufficient to assume that an evaluation would have been negative (or positive). If there is a statement in the record documenting the physician's assessment of regional lymph nodes and/or metastatic sites as negative or not involved, without physical examination, imaging or other diagnostic procedures, this may be used to assign 0 rather than X. The use of category 0, as in NO or MO, means that no involvement was found after some type of evaluation including appropriate workup and/or the physician's clinical impression.

**NOTE:** SCs should photocopy any documents from medical records that are used for TNM staging, and keep these with the participant's file.

**a. TNM Clinical Staging**

If both the clinical and pathological staging are available, both should be recorded. Clinical staging is based on the assessment of the anatomic extent of disease before instituting definitive therapy. All information available prior to the first definitive treatment of the primary colorectal cancer may be used for TNM clinical staging. Relevant documentation that is suggested to assign clinical staging includes:

- Medical history;
- Physical examination;
- Routine and special roentgenograms, including barium enema;
- Sigmoidoscopy and colonoscopy with biopsy; and
- Special examinations used to demonstrate the presence of extracolonic metastasis, including chest films, liver function tests, and liver scans.

Darken the circle to indicate whether the TNM clinical staging is available as follows:

**Yes:** If the TNM clinical staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available.

**No:** If no part of the TNM clinical staging is available, then darken the circle for "No" and skip to Item C.16b, TNM Pathologic Staging. Other situations in which TNM staging does not apply, and "No" should be darkened include:

- Neoplasm of uncertain behavior of the colorectum
- Extranodal lymphoma arising in the colorectum
- Primary sarcoma of the colorectum

**b. TNM Pathologic Staging**

Colorectal cancers are usually staged pathologically because it is necessary to establish the depth of tumor invasion through the bowel. Relevant documentation necessary to assign pathologic staging includes:

- Any data for clinical staging;
- Pathologic report of the resected specimen; and
- Surgical exploration of the abdomen.

Darken the circle to indicate whether the TNM pathologic staging is available as follows:

**Yes:** If the TNM pathologic staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available.

**No:** If no part of the TNM pathologic staging is available, then darken the circle for "No" and skip to Item C.17, Record Stage. Other situations in which TMN staging does not apply, and "No" should be darkened include:

- Neoplasm of uncertain behavior of the colorectum
- Extranodal Lymphoma arising in the colorectum
- Primary sarcoma of the colorectum

**17. Record Stage:** If TNM Pathologic Staging is complete, this item must be skipped. If any part of the TNM Pathologic Staging is not available or is incomplete (i.e., "Tx", "Nx", or "Mx"), this item must be completed. This item is to document the stage of disease (other than TNM staging) for primary colorectal cancer. Staging of colorectal cancer is always based on pathologic staging procedures. There are four stage classifications provided for colorectal cancer: "Stage Only," "Dukes," "Modified Dukes (Astler-Coller) Staging," and "Summary Staging."

- If information about one or more of the stage classifications is not available in the medical record, it is not necessary to try to obtain it from another source.
- If a stage classification other than those provided on the form is available in the record and all or part of TNM Pathologic Staging is not available, place an asterisk beside Item C.17, and record in the comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.21, Comments

Item #      Comments

C.17      Other Stage Classification is \_\_\_\_ Stage = \_\_\_\_.

- If stage is available for an extranodal lymphoma arising in the colorectum, for a primary sarcoma of the colorectum, or for any other type of primary colorectal malignancy which cannot be staged using TNM, record the stage in Item C.17.

Darken the circle to indicate whether stage of disease is available as follows:

**Yes:** If "Stage Only," "Dukes," "Modified Dukes (Astler-Coller)," and/or "Summary Staging" is available in the record, darken the circle for "Yes" and then darken the circles corresponding to the code for each. If stage of disease is not available for any particular classification, darken the circle next to "Not available" in the appropriate column.

**No:** If none of the stage classifications, "Stage Only," "Dukes," "Modified Dukes (Astler-Coller) Staging," or "Summary Staging" is available in the record, darken the circle for "No" and skip to Part E: Physician/Hospital Location Information.

- **Neoplasm of uncertain behavior of the colorectum:** Darken the circle for "No." Typically, a neoplasm of uncertain behavior is not staged. If the medical record contains staging information about this neoplasm, contact the CC MRA Coordinator.
- If no stage of disease information is available, it is not necessary for the abstractor to obtain it from another source. Also, the abstractor should not attempt to code stage of disease unless s/he is a Certified Tumor Registrar (CTR) or CTR eligible. If the abstractor is a CTR, or is CTR eligible, and has all of the necessary documentation for determining the stage of disease, then s/he may code stage of disease and record it following the guidelines above.

#### **Part D: Date of Diagnostic Evaluation Determination:**

18. Complete this item by recording the month, day and year of the diagnostic evaluation determination if one of the following conditions is satisfied:

- Item A.7 = No malignancy or
- Item A.7 = No malignancy and no diagnostic procedures were performed or
- Item A.7 = No information available

Darken the circle corresponding to each number. If the exact day of diagnostic evaluation determination cannot be determined from the record, year and month can usually be assessed. In this situation, record the exact month and year. Record the day as "99." Zero fill month and day, and record four digits for year.

#### **Part E: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant underwent diagnostic evaluation for colorectal cancer, other than what was reported prior to abstracting. Items E.19 and E.20 are not required but it is recommended that these items be completed to facilitate collection of additional medical record data, including pathology reports and slides. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

19. **Physician for Diagnostic Evaluation:** Record the name, address, and telephone number of the primary physician who provided care during the participant's diagnostic evaluation for colorectal cancer and/or the physician who performed the diagnostic evaluation procedures. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.

20. **Hospital or Clinic for Diagnostic Evaluation:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent one or more diagnostic procedures for colorectal cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.

21. **Comments:** Use this section to record any overflow information. Discrepant information should no longer be recorded in Comments. If an item being abstracted has con-

flicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or the Principal Investigator should review the discrepant information for the appropriate coding decision prior to calling the CC MRA Coordinator.

*Do not darken the "Yes" or "No" circles at the top of pages 11-12 if Comments continues on these pages. Leave the circles blank. Comments "Yes" "No" circles should only be darkened on page 10 of the form.*

*Darken Comments Continuation circle at the bottom right of page 12 if a Comments Continuation Form (CCF) is required. Do not darken Comments Continuation circles on pages 10-11.*

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as in the following example when a 7th medical complication should be collected:

Item #	Comments
A.6	7; Type = ____; Date = ____

- First enter the item number indicating the item to which the comments are related, and record the comments in the space provided to the right of the item number.
- Throughout these specifications, standard phrases are given to preface comments so they will be easier to locate during analysis. Please use these phrases at the beginning of the comments, if applicable.
- Place an asterisk next to the item number being referenced in the main body of the DEC form.

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM TREATMENT INFORMATION - COLORECTUM (TIC2/TCQ2)

**1. Date Abstracted:**

MO.	DAY	YEAR
		20
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

**2. Abstractor ID #:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**3. CTR ID#:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**4. Study Year T0-T13:**

T	0	0
	1	1
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	

**5. Purpose of Abstract:**

Initial abstract  
 Re-abstract for QA

### FOR OFFICE USE ONLY

**6. Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)**

**Data Entry of Non-Scannable Items:**      **Data Retrieval:**

Form Received into SMS       Completed       None Required       Attempted       None Required

Manual Review Completed

**Disposition:**

Interim Complete (ICM)       Final Complete (FCM)       Final Incomplete (FIC)

PLEASE DO NOT WRITE IN THIS AREA



007799

**PART A: INITIAL TREATMENT INFORMATION**

**1. SURGICAL TREATMENT FOR COLORECTAL CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

PROCEDURE #	1	2	3	4																																																																																																																																				
<b>TYPE OF SURGICAL PROCEDURE</b>  (SEE SURGICAL PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 03 04 06 07 08 09 10 88  _____ SPECIFY	01 03 04 06 07 08 09 10 88  _____ SPECIFY	01 03 04 06 07 08 09 10 88  _____ SPECIFY	01 03 04 06 07 08 09 10 88  _____ SPECIFY																																																																																																																																				
<b>DATE OF SURGERY</b>  (MO. - DAY - YEAR)	<table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						

**SURGICAL PROCEDURE CODES**

- |  |   |
|--|---|
| 01 = Local excision (includes local transanal excision)<br>03 = Surgical resection with reanastomosis<br>04 = Surgical resection with colostomy<br>06 = Bypass surgery or palliative resection<br>07 = Cryosurgery | 08 = Lymphadenectomy/Lymph node sampling<br>09 = Appendectomy (for appendiceal primaries only)<br>10 = Laser ablation<br>88 = Other (SPECIFY) |
|--|---|

**2. RADIATION TREATMENT FOR COLORECTAL CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2																																																																		
<b>DATE RADIATION TREATMENT BEGAN</b>  (MO. - DAY - YEAR)	<table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="font-size: 8px; border-collapse: collapse;"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		

**PART A CONTINUED . . .**

**3. CHEMOTHERAPEUTIC TREATMENT FOR COLORECTAL CANCER:**

- No                     
  Yes (COMPLETE TABLE BELOW)                     
  Unknown

TREATMENT #	1	2																																																																																																																																																																								
DATE CHEMOTHERAPEUTIC TREATMENT BEGAN  (MO. - DAY - YEAR)	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="3">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR										0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3	3	3	3	3	3	3	4	4	4	4	4	4	4	5	5	5	5	5	5	5	6	6	6	6	6	6	6	7	7	7	7	7	7	7	8	8	8	8	8	8	8	9	9	9	9	9	9	9	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="3">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR										0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3	3	3	3	3	3	3	4	4	4	4	4	4	4	5	5	5	5	5	5	5	6	6	6	6	6	6	6	7	7	7	7	7	7	7	8	8	8	8	8	8	8	9	9	9	9	9	9	9
MO.		DAY		YEAR																																																																																																																																																																						
0	0	0	0	0	0	0																																																																																																																																																																				
1	1	1	1	1	1	1																																																																																																																																																																				
2	2	2	2	2	2	2																																																																																																																																																																				
3	3	3	3	3	3	3																																																																																																																																																																				
4	4	4	4	4	4	4																																																																																																																																																																				
5	5	5	5	5	5	5																																																																																																																																																																				
6	6	6	6	6	6	6																																																																																																																																																																				
7	7	7	7	7	7	7																																																																																																																																																																				
8	8	8	8	8	8	8																																																																																																																																																																				
9	9	9	9	9	9	9																																																																																																																																																																				
MO.		DAY		YEAR																																																																																																																																																																						
0	0	0	0	0	0	0																																																																																																																																																																				
1	1	1	1	1	1	1																																																																																																																																																																				
2	2	2	2	2	2	2																																																																																																																																																																				
3	3	3	3	3	3	3																																																																																																																																																																				
4	4	4	4	4	4	4																																																																																																																																																																				
5	5	5	5	5	5	5																																																																																																																																																																				
6	6	6	6	6	6	6																																																																																																																																																																				
7	7	7	7	7	7	7																																																																																																																																																																				
8	8	8	8	8	8	8																																																																																																																																																																				
9	9	9	9	9	9	9																																																																																																																																																																				

**4. OTHER TYPE OF TREATMENT FOR COLORECTAL CANCER:**

- No                     
  Yes (COMPLETE TABLE BELOW)                     
  Unknown

TREATMENT #	1	2																																																																																																																																																																								
DATE OTHER TREATMENT BEGAN  (MO. - DAY - YEAR)	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="3">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR										0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3	3	3	3	3	3	3	4	4	4	4	4	4	4	5	5	5	5	5	5	5	6	6	6	6	6	6	6	7	7	7	7	7	7	7	8	8	8	8	8	8	8	9	9	9	9	9	9	9	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="3">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR										0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3	3	3	3	3	3	3	4	4	4	4	4	4	4	5	5	5	5	5	5	5	6	6	6	6	6	6	6	7	7	7	7	7	7	7	8	8	8	8	8	8	8	9	9	9	9	9	9	9
MO.		DAY		YEAR																																																																																																																																																																						
0	0	0	0	0	0	0																																																																																																																																																																				
1	1	1	1	1	1	1																																																																																																																																																																				
2	2	2	2	2	2	2																																																																																																																																																																				
3	3	3	3	3	3	3																																																																																																																																																																				
4	4	4	4	4	4	4																																																																																																																																																																				
5	5	5	5	5	5	5																																																																																																																																																																				
6	6	6	6	6	6	6																																																																																																																																																																				
7	7	7	7	7	7	7																																																																																																																																																																				
8	8	8	8	8	8	8																																																																																																																																																																				
9	9	9	9	9	9	9																																																																																																																																																																				
MO.		DAY		YEAR																																																																																																																																																																						
0	0	0	0	0	0	0																																																																																																																																																																				
1	1	1	1	1	1	1																																																																																																																																																																				
2	2	2	2	2	2	2																																																																																																																																																																				
3	3	3	3	3	3	3																																																																																																																																																																				
4	4	4	4	4	4	4																																																																																																																																																																				
5	5	5	5	5	5	5																																																																																																																																																																				
6	6	6	6	6	6	6																																																																																																																																																																				
7	7	7	7	7	7	7																																																																																																																																																																				
8	8	8	8	8	8	8																																																																																																																																																																				
9	9	9	9	9	9	9																																																																																																																																																																				

**5. ANY LOCAL OR REGIONAL RESIDUAL DISEASE LEFT AFTER SURGERY:**

- No                                     
  Not applicable  
 Yes - Microscopic                     
  Unknown  
 Yes - Gross Tumor



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**TREATMENT INFORMATION – COLORECTUM VERSION 2 (TIC2/TCQ2)**

This form is to be completed by the Medical Record Abstractor and the CTR or CTR-eligible individual. Specifically, the CTR will be required to complete Item A.5 (Any Local or Regional Residual Disease Left After Surgery).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- When abstracting date information for items with multiple treatments, record the dates in the order in which they are found in the medical record.
- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that the information must be obtained from a physician, hospital or tumor registry. If the treatment is considered to be a non-traditional therapy that would not usually be mentioned in a medical record, it is acceptable to take the participant's self-report. In all other cases, a therapy that is not mentioned in the medical record should not be recorded.
- Information about treatment procedures should be collected for the first planned course of treatment (usually within 6 months of the cancer diagnosis). The maximum time period for which medical records could be collected for treatment information is about 1 year from the date of a cancer diagnosis.
- This form includes items, which require that data be entered verbatim, such as recording "other (specify)," and recording comments. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If additional space is needed to record treatment information, use the Comments section. Record the same type of data as requested in the treatment table.
- If any item has unclear, discrepant, or conflicting information, review this information with the SC Lead Abstractor, SC Coordinator or the Principal Investigator prior to contacting the CC MRA Coordinator.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy black marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
  - Mark only one response for each question, unless the instructions tell you otherwise.
  - Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.
- 

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled in. Darken the circle corresponding to each remaining number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized, erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the T1. If more than one abstractor completes the T1, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form—this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.
3. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item A.5 (Any Local or Regional Residual Disease Left After Surgery). Darken the circle corresponding to the four digits.
4. **Study Year:** Darken the circles corresponding to the study year, from T0 to T13. Zero-fill the number for T0 - T9 (e.g., T00, T01, T02, etc.).
5. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:

- **Initial abstract:** Medical record information is being abstracted for the “first” time to confirm the treatment of colorectal cancer.
  - **Re-abstract for QA:** Medical record information that has already been abstracted to confirm the treatment of colorectal cancer is being re-abstracted for the purpose of quality assurance. Not yet implemented.
6. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except “Disposition” are optional. “Disposition” is required and may be marked on the form or entered directly into DEES. Dispositions of “Final Complete” (FCM) may also be set automatically in DEES when the form is edited (See DEES User’s Guide).
- **Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 for instructions on receipting forms.)
  - **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)
  - **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to “Completed.” If no data entry of non-scannable items is required, darken the circle next to “None Required.”
  - **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to “Attempted.” If no data retrieval was required, darken the circle next to “None Required.”
  - **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
    - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data are abstracted, remove the ICM so that the appropriate disposition is assigned.
    - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are “UNLIKELY” errors that have been investigated by the SC, or errors on the optional form processing items.
    - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;

- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

**Part A: Initial Treatment Information:**

In this section, record all treatments that make up the first course of treatment the participant received for colorectal cancer.

- If the treatment is intended as initial management, it should be recorded regardless of the timeframe or treatment site.
- If the first course of treatment is directed toward a metastatic site, it is appropriate to code this treatment.
- Combination Treatments: If multiple treatments are given in combination, enter the date treatment began for the combination treatments. If another treatment is added to this combination (or one is removed), the new combination should be listed as a new treatment entry with a new start date.
- Time period Rules for First Course of Treatment (in order of precedence):
  1. If there is a documented, planned first course of treatment, first course ends at the completion of this treatment plan, regardless of the duration of the treatment plan.
  2. If the patient is treated according to a facility's standards of practice, first course ends at the completion of the treatment.
  3. If there is no documentation of a planned first course of treatment or standard of practice, first course of treatment includes all treatment received before disease progression or treatment failure. If it is undocumented whether there is disease progression/treatment failure and the treatment in question begins more than one year after diagnosis, assume that the treatment is not part of the first course.
  4. If a patient refuses all treatment modalities and does not change his/her mind within a reasonable time frame, or if the physician opts not to treat the patient, record that there was no treatment in the first course.
- If treatment is given for symptoms/disease progression after a period of "watchful waiting," this treatment is not considered part of the first course. For example, if a physician and patient choose a "wait and watch" approach to colorectal cancer and the patient become symptomatic, consider the symptoms to be an indication that the disease has progressed and that any further treatment is not part of the first course.
- All modalities of treatment are included regardless of sequence or the degree of completion of any component method.

Reference: SEER Program Code Manual, Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute; 1998, p.119.

- If there is a significant treatment that is not in the first course of treatment and the abstractor and SC Principal Investigator feel it should be recorded, this will need to be sent to the CC MRA Coordinator. The relevant medical records should be copied (identifiers deleted) and sent to the CC MRA Coordinator with a memo describing the issue.
1. **Surgical Treatment for Colorectal Cancer:** This item is concerned with the surgical treatment that the participant received for colorectal cancer. Complete this item as follows:

**No:** The record clearly states that the participant did not receive surgical treatment, *or* there is no mention of surgical treatment (planned or given) in the records. Darken the circle for “No” and go to Item 2.

**Yes:** The record indicates that the participant received surgical treatment. Darken the circle for “Yes” and complete the table for Item 1. For each surgical procedure performed, complete the following items:

- **Type of Surgical Procedure:** Darken the circle corresponding to the type of surgical procedure performed. Refer to the Surgical Procedure Codes for the list of common surgical procedures for colorectal cancer. If the participant had a surgical procedure other than those listed, darken the circle for “Other (SPECIFY)” and record the surgical procedure performed on the line provided. The definitions for the surgical procedures are as follows:

**01 = Local excision (includes Local Transanal excision):** Surgical removal of a polyp or tumor without an accompanying bowel resection.

**03 = Surgical resection with reanastomosis:** Surgical excision of an adequate amount of normal colon proximal and distal to the tumor with *reanastomosis*. Use the code when there is a surgical resection with reanastomosis and when there is a temporary diverting colostomy. Even if the surgical resection is done as a separate procedure from the reanastomosis (two stages), the surgical treatment should be recorded only once as code 03.

**04 = Surgical resection with colostomy:** Radical surgery performed by a transabdominal/perineal procedure. Surgery is extensive with removal of anus and a permanent colostomy is placed.

**06 = Bypass surgery or palliative resection:** A palliative procedure is performed only to relieve symptoms, not to cure disease.

**07 = Cryosurgery:** In colon cancer, this procedure is performed for removal/resection of hepatic lesions. Use this code for Fulguration.

**08 = Lymphadenectomy/Lymph node sampling:** Removal of the lymph nodes or a sample of lymph node tissue for diagnostic purposes.

**09 = Appendectomy:** Removal of the appendix. Use this code only when the diagnosis is a primary cancer of the appendix.

**10 = Laser ablation:** Destruction or removal of cancerous tissue through the use of a laser.

**88 = Other (SPECIFY):** The participant had some other type of surgery to treat cancer. Use the specify line to describe the surgery.

**Note:** Lymph node removal accompanying surgical resection should be coded as two separate procedures. Code the resection with the appropriate code and the lymph node removal under 08 = Lymphadenectomy/Lymph node sampling.

- **Date of Surgery:** Record the month, day and year that the surgical procedure was performed. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as “99”. Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional surgical procedures, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional surgical treatment in Comments would be the fifth surgical treatment recorded:

Item B.8, Comments:

Item #	Comments
A.1	5; Type = ____; Date = ____

**Unknown:** The record states that surgical treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 2.

2. **Radiation Treatment for Colorectal Cancer:** This item is concerned with the radiation treatment the participant received. Radiation treatment most commonly consists of either external photon beam therapy or brachytherapy (endocavitary implant). More rarely, radiation treatment may consist of either neutron or proton external beam therapy. Note that this item is concerned with radiation treatment and not diagnostic x-rays such as a CT scan.

External photon beam therapy is delivered by a machine, which generates x-rays or contains a large amount of a radioactive isotope (cobalt), or delivered by a linear accelerator. External beam treatments are given in one or more "series" or "courses." Each course of radiation is administered over a period of days or weeks in small daily doses.

Brachytherapy is a method of radiotherapy in which radioactive sources are applied on the external surface of the patient, implanted in tissue, or inserted into body cavities. Brachytherapy procedures usually are performed in an operating room since they require anesthesia. Although the brachytherapy treatment may be performed in a surgical suite and recorded in surgical notes, it is radiotherapy and should be recorded as such for purposes of describing the participant's treatment.

Some institutions may have the capability to deliver neutron beam therapy, via a hospital based high-energy cyclotron, or proton beam therapy, via a hospital-based synchrotron. Treatment via these modalities is usually administered in "courses" or "series" over a period of time. Most institutions, however, find these machines impractical for a hospital setting due to their cost and size.

Darken the circle corresponding to whether the participant received radiation treatment as follows:

**No:** The record clearly states that the participant did not receive radiation treatment, or there is no mention of radiation treatment (planned or given) in the records. Darken the circle for "No" and go to Item 3.

**Yes:** The record indicates that the participant received radiation treatment. Darken the circle for "Yes" and complete the table for Item 2. Record information for each course of radiation treatment received in a separate column. For each radiation treatment received, complete the following:

- **Date Radiation Treatment Began:** Record the month, day and year that the radiation treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be

determined. In this situation, record the exact month and year. Record the day as "99". Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional radiation treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional radiation treatment in Comments would be the third radiation treatment recorded:

Item B.8, Comments:

Item #	Comments
A.2	3; Date = ____

**Unknown:** The record states that radiation treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 3.

3. **Chemotherapeutic Treatment for Colorectal Cancer:** This item is concerned with any chemotherapeutic treatment the participant received. Chemotherapeutic treatment is the use of drugs given as treatment for cancer. Chemotherapeutic treatment may be the primary treatment, prescribed in cases of advanced cancer, or may be an adjuvant treatment, given in addition to surgery and/or radiation.

The participant's medical record may or may not contain chemotherapeutic treatment data. Unlike surgery and radiation treatments, which must be performed at a hospital or clinic, chemotherapeutic treatment may be administered at a physician's office or self-administered under the guidance and supervision of a physician. It is, therefore, especially important that the abstractor carefully review the record and, if necessary, contact the physician for information on chemotherapeutic treatment.

Darken the circle corresponding to whether the participant received chemotherapeutic treatment as follows:

**No:** The record clearly states that the participant did not receive chemotherapeutic treatment, or there is no mention of chemotherapeutic treatment (planned or given) in the records. Darken the circle for "No" and go to Item 4.

**Yes:** The record indicates that the participant received chemotherapeutic treatment. Darken the circle for "Yes" and complete the table for Item 3. For each protocol of chemotherapeutic treatment received, complete the following:

- Date Chemotherapeutic Treatment Began: Record the month, day and year that the chemotherapeutic treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional chemotherapeutic treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional chemotherapeutic treatment in Comments would be the third chemotherapeutic treatment recorded:

Item B.8, Comments:

Item #	Comments
A.3	3; Date = _____

**Unknown:** The record states that chemotherapeutic treatment is planned but then there is no mention of whether or not it was given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 4.

4. **Other Type of Treatment for Colorectal Cancer:** This item is concerned with any treatment other than surgery, radiation and chemotherapeutic treatment that the participant received for colorectal cancer, such as electrofulguration, electrocoagulation, biologic therapy, or alternative treatments.

Darken the circle corresponding to whether the participant received some other type of treatment as follows:

**No:** The record clearly states that the participant did not receive any other type of treatment, or there is no mention of other treatments (planned or given) in the records. Darken the circle for "No" and go to Item 5.

**Yes:** The record indicates that the participant received some other type of treatment. Darken the circle for "Yes" and complete the table for Item 4. For each type of treatment received, complete the following:

- **Date Other Treatment Began:** Record the month, day and year that the other type of treatment began. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record other type of treatments for colorectal cancer, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional other type of treatment for colorectal cancer in Comments would be the third other type of treatment for colorectal cancer recorded:

Item B.8, Comments:

Item #	Comments
A.4	3; Date = _____

**Unknown:** The record states that an "other" treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 5.

5. **Any Local or Regional Residual Disease Left After Surgery:** This item is to be completed only by a CTR or a CTR-eligible individual. This item documents whether the participant had any local or regional residual disease left after surgery. Record information for this item for any attempted surgical procedure even if the procedure was not completed. Surgery is defined as any of the surgical procedures listed in Item

1. If there are multiple surgeries, use the last surgery in the first course of treatment. Regional residual disease is defined as a cancer that remains after surgery and is related to the original site by direct extension. This regional disease refers to the site of the surgery (not necessarily the site of the primary cancer). It does not apply to metastases. Information should be taken from the pathology report since this is the most definitive source for determining residual disease and the operative report may be used for further clarification. If neither pathology nor operative reports are available, a discharge summary or doctor's note with treatment plan may be used to record this item. "Perineural or vascular invasion" noted on a surgical pathology report, does not infer that regional or residual disease is left after surgery. The pathology report refers only to the specimen or tissue removed during surgery, not to tumor that remains following surgery. Darken the circle corresponding to whether the participant had any local or regional residual disease left after surgery as follows:

**No:** The record indicates that the participant had no local or regional residual disease left after surgery. Darken the circle for "No" and go to Item 6.

**Yes - Microscopic:** The local or regional residual disease remaining is microscopic (of minute size). The pathology report may state "tumor to surgical margin." Darken the circle for "Yes – Microscopic" and go to Item 6.

**Yes - Gross Tumor:** A tumor remaining in the colorectum or the nearby region after surgery. The pathology report may state "gross residual disease remaining with nearby structural invasion." Darken the circle for "Yes – Gross Tumor" and go to Item 6.

The highest order of evidence should be coded. For example, if the operative report notes that gross disease remains, then "gross" should be coded. But if the report notes that there were positive surgical margins without gross evidence of disease, the "microscopic" response should be used.

**Not applicable:** The participant did not receive any surgical treatment for colorectal cancer or Item A.1, Surgical Treatment for Colorectal Cancer, is "No" or "Unknown". Darken the circle for "Not applicable" and go to Item 6.

**Unknown:** The record does not mention if the participant had local or regional residual disease left after surgery, or the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 6.

### **Part B: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant received treatment for colorectal cancer. Items B.6 and B.7 are not required, but it is recommended that they be completed to facilitate collection of additional medical record data. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

6. **Physician for Treatment:** Record the name, address, and telephone number of the primary physician who provided care during the participant's treatment for colorectal cancer and/or the physician who provided or administered the treatment. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.
7. **Hospital or Clinic for Treatment:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent treatment for colorec-

tal cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.

8. **Comments:** Use this section to record notes, comments and any overflow information while abstracting from the participant's medical record. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should review the discrepant information for the appropriate coding decision prior to contacting the CC MRA Coordinator.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as follows. First enter the item number indicating the item to which the comments are related, record the comments in the space provided to the right of the item number as in the following example when a fifth surgical procedure for colorectal cancer should be collected:

Item #	Comments:
A.1	5; Type = ____; Date = ____

Place an asterisk next to the item number being referenced in the main body of the TIC form. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

## **A-8-4**

**A-8-4: Ovarian Cancer Medical Record Abstract  
Forms (DEO3, TIO2)  
[Diagnostic Evaluation and Treatment Information**

**Specifications for the Ovarian Cancer Medical  
Record Abstract Forms**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM DIAGNOSTIC EVALUATION - OVARY (DEO3/DOQ3)

<b>1.</b>	Date Abstracted: MO. DAY YEAR	<b>2.</b>	Abstractor ID #:	<b>3.</b>	Nosologist ID #:	<b>4.</b>	CTR ID#:	<b>5.</b>	Study Year To-T13:	<b>6.</b>	Purpose of Abstract:																																																																																																																																																																																																											
	20							T		<input type="radio"/> Initial abstract <input type="radio"/> Re-abstract for QA																																																																																																																																																																																																												
	<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	8	8	8	8	8	8	9	9	9	9	9	9	<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="width: 100%; text-align: center; font-size: small;"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<b>7. Multiple Primary Cancer #:</b>  <table style="text-align: center; font-size: small;"> <tr><td>2</td><td>3</td><td>4</td><td>5</td></tr> <tr><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table> (GO TO A.6)	2	3	4	5	6	7	8	9
0	0	0	0	0	0																																																																																																																																																																																																																	
1	1	1	1	1	1																																																																																																																																																																																																																	
2	2	2	2	2	2																																																																																																																																																																																																																	
3	3	3	3	3	3																																																																																																																																																																																																																	
4	4	4	4	4	4																																																																																																																																																																																																																	
5	5	5	5	5	5																																																																																																																																																																																																																	
6	6	6	6	6	6																																																																																																																																																																																																																	
7	7	7	7	7	7																																																																																																																																																																																																																	
8	8	8	8	8	8																																																																																																																																																																																																																	
9	9	9	9	9	9																																																																																																																																																																																																																	
0	0	0	0																																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																																			
0	0	0	0																																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																																			
0	0	0	0																																																																																																																																																																																																																			
1	1	1	1																																																																																																																																																																																																																			
2	2	2	2																																																																																																																																																																																																																			
3	3	3	3																																																																																																																																																																																																																			
4	4	4	4																																																																																																																																																																																																																			
5	5	5	5																																																																																																																																																																																																																			
6	6	6	6																																																																																																																																																																																																																			
7	7	7	7																																																																																																																																																																																																																			
8	8	8	8																																																																																																																																																																																																																			
9	9	9	9																																																																																																																																																																																																																			
0	0																																																																																																																																																																																																																					
1	1																																																																																																																																																																																																																					
2	2																																																																																																																																																																																																																					
3	3																																																																																																																																																																																																																					
4	4																																																																																																																																																																																																																					
5	5																																																																																																																																																																																																																					
6	6																																																																																																																																																																																																																					
7	7																																																																																																																																																																																																																					
8	8																																																																																																																																																																																																																					
9	9																																																																																																																																																																																																																					
2	3	4	5																																																																																																																																																																																																																			
6	7	8	9																																																																																																																																																																																																																			

### FOR OFFICE USE ONLY

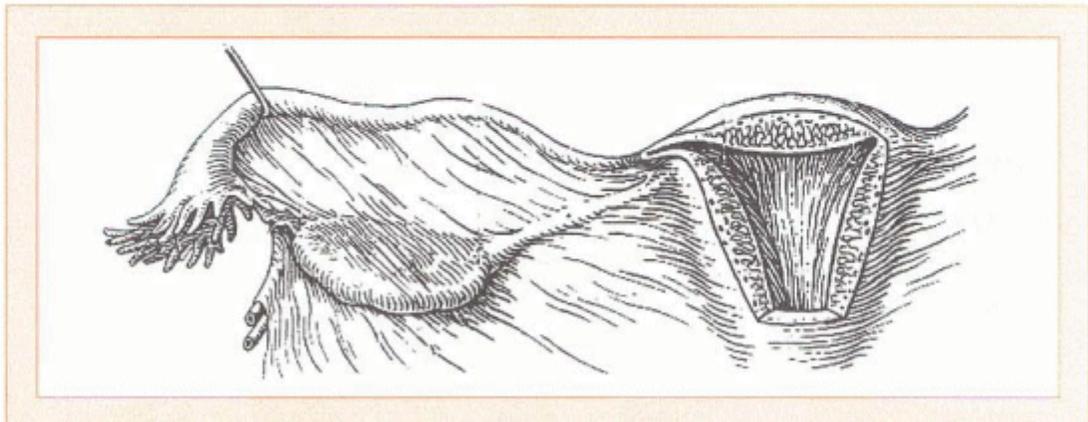
**8.**

#### Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)

<b>Data Entry of Non-Scannable Items:</b>	<b>Data Retrieval:</b>
Form Received into SMS <input type="radio"/> Manual Review Completed <input type="radio"/>	Completed <input type="radio"/> None Required <input type="radio"/> Attempted <input type="radio"/> None Required <input type="radio"/>
<b>Disposition:</b>	
Interim Complete (ICM) <input type="radio"/> Final Complete (FCM) <input type="radio"/> Final Incomplete (FIC) <input type="radio"/>	

### PART A: DIAGNOSTIC EVALUATION AND STAGING

<b>1. Diagnostic Procedures Performed:</b>  <input type="radio"/> Yes <input type="radio"/> No, Physician report <input type="radio"/> No, Participant self-report } (GO TO A.6)	<b>2. Reason for Initial Visit for Clinical Assessment:</b> (MARK ALL THAT APPLY) <input type="radio"/> Symptomatic <input type="radio"/> Follow-up of positive PLCO screen <input type="radio"/> Other (SPECIFY) _____ _____
--	--



DesignExpert™ by NCS    Printed in U.S.A.    Mark Reflex® EW-21966-4-654321    HC05

PLEASE DO NOT WRITE IN THIS AREA



022824

**PART A CONTINUED . . .**

**3. CA-125 Blood Test: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

CA-125 BLOOD TEST	1	2	3																																																																																																																																																																					
<b>CA-125 LEVEL</b> (units/ml)	<table border="1"> <tr><td></td><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1"> <tr><td></td><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1"> <tr><td></td><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9																																	
0	0	0	0																																																																																																																																																																					
1	1	1	1																																																																																																																																																																					
2	2	2	2																																																																																																																																																																					
3	3	3	3																																																																																																																																																																					
4	4	4	4																																																																																																																																																																					
5	5	5	5																																																																																																																																																																					
6	6	6	6																																																																																																																																																																					
7	7	7	7																																																																																																																																																																					
8	8	8	8																																																																																																																																																																					
9	9	9	9																																																																																																																																																																					
0	0	0	0																																																																																																																																																																					
1	1	1	1																																																																																																																																																																					
2	2	2	2																																																																																																																																																																					
3	3	3	3																																																																																																																																																																					
4	4	4	4																																																																																																																																																																					
5	5	5	5																																																																																																																																																																					
6	6	6	6																																																																																																																																																																					
7	7	7	7																																																																																																																																																																					
8	8	8	8																																																																																																																																																																					
9	9	9	9																																																																																																																																																																					
0	0	0	0																																																																																																																																																																					
1	1	1	1																																																																																																																																																																					
2	2	2	2																																																																																																																																																																					
3	3	3	3																																																																																																																																																																					
4	4	4	4																																																																																																																																																																					
5	5	5	5																																																																																																																																																																					
6	6	6	6																																																																																																																																																																					
7	7	7	7																																																																																																																																																																					
8	8	8	8																																																																																																																																																																					
9	9	9	9																																																																																																																																																																					
<b>CA-125 ASSAY BRAND</b>  1 = Centacor 2 = Abbott 8 = Other (SPECIFY) 9 = Not available	(1)(2)(8)(9)  _____ SPECIFY	(1)(2)(8)(9)  _____ SPECIFY	(1)(2)(8)(9)  _____ SPECIFY																																																																																																																																																																					
<b>LAB RANGE</b> (units/ml)	<table border="1"> <tr><td></td><td></td><td>to</td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td></td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td></td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td></td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td></td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td></td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td></td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td></td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td></td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td></td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td></td><td>9</td><td>9</td></tr> </table>			to			0	0		0	0	1	1		1	1	2	2		2	2	3	3		3	3	4	4		4	4	5	5		5	5	6	6		6	6	7	7		7	7	8	8		8	8	9	9		9	9	<table border="1"> <tr><td></td><td></td><td>to</td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td></td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td></td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td></td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td></td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td></td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td></td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td></td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td></td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td></td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td></td><td>9</td><td>9</td></tr> </table>			to			0	0		0	0	1	1		1	1	2	2		2	2	3	3		3	3	4	4		4	4	5	5		5	5	6	6		6	6	7	7		7	7	8	8		8	8	9	9		9	9	<table border="1"> <tr><td></td><td></td><td>to</td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td></td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td></td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td></td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td></td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td></td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td></td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td></td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td></td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td></td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td></td><td>9</td><td>9</td></tr> </table>			to			0	0		0	0	1	1		1	1	2	2		2	2	3	3		3	3	4	4		4	4	5	5		5	5	6	6		6	6	7	7		7	7	8	8		8	8	9	9		9	9
		to																																																																																																																																																																						
0	0		0	0																																																																																																																																																																				
1	1		1	1																																																																																																																																																																				
2	2		2	2																																																																																																																																																																				
3	3		3	3																																																																																																																																																																				
4	4		4	4																																																																																																																																																																				
5	5		5	5																																																																																																																																																																				
6	6		6	6																																																																																																																																																																				
7	7		7	7																																																																																																																																																																				
8	8		8	8																																																																																																																																																																				
9	9		9	9																																																																																																																																																																				
		to																																																																																																																																																																						
0	0		0	0																																																																																																																																																																				
1	1		1	1																																																																																																																																																																				
2	2		2	2																																																																																																																																																																				
3	3		3	3																																																																																																																																																																				
4	4		4	4																																																																																																																																																																				
5	5		5	5																																																																																																																																																																				
6	6		6	6																																																																																																																																																																				
7	7		7	7																																																																																																																																																																				
8	8		8	8																																																																																																																																																																				
9	9		9	9																																																																																																																																																																				
		to																																																																																																																																																																						
0	0		0	0																																																																																																																																																																				
1	1		1	1																																																																																																																																																																				
2	2		2	2																																																																																																																																																																				
3	3		3	3																																																																																																																																																																				
4	4		4	4																																																																																																																																																																				
5	5		5	5																																																																																																																																																																				
6	6		6	6																																																																																																																																																																				
7	7		7	7																																																																																																																																																																				
8	8		8	8																																																																																																																																																																				
9	9		9	9																																																																																																																																																																				
<b>DATE OF TEST</b> (MO. - DAY - YEAR)	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> <tr><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </table>	MO.	DAY	YEAR				0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9																																																									
MO.	DAY	YEAR																																																																																																																																																																						
0	0	0																																																																																																																																																																						
1	1	1																																																																																																																																																																						
2	2	2																																																																																																																																																																						
3	3	3																																																																																																																																																																						
4	4	4																																																																																																																																																																						
5	5	5																																																																																																																																																																						
6	6	6																																																																																																																																																																						
7	7	7																																																																																																																																																																						
8	8	8																																																																																																																																																																						
9	9	9																																																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																																																						
0	0	0																																																																																																																																																																						
1	1	1																																																																																																																																																																						
2	2	2																																																																																																																																																																						
3	3	3																																																																																																																																																																						
4	4	4																																																																																																																																																																						
5	5	5																																																																																																																																																																						
6	6	6																																																																																																																																																																						
7	7	7																																																																																																																																																																						
8	8	8																																																																																																																																																																						
9	9	9																																																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																																																						
0	0	0																																																																																																																																																																						
1	1	1																																																																																																																																																																						
2	2	2																																																																																																																																																																						
3	3	3																																																																																																																																																																						
4	4	4																																																																																																																																																																						
5	5	5																																																																																																																																																																						
6	6	6																																																																																																																																																																						
7	7	7																																																																																																																																																																						
8	8	8																																																																																																																																																																						
9	9	9																																																																																																																																																																						

**PART A CONTINUED . . .**

**4. Other Diagnostic/Staging Procedures: (DO NOT RECORD RESULTS OF PLCO SCREENING EXAMINATIONS)**

No       Yes (COMPLETE TABLE BELOW)       Unknown

PROCEDURE #	1	2	3																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
PROCEDURE #	4	5	6																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 13 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**PROCEDURE CODES**

- |   |  |   |
|---|--|---|
| 01 = Barium enema<br>02 = Biopsy (SPECIFY)<br>03 = Chest radiograph<br>04 = Color doppler<br>05 = CT scan - abdominal<br>06 = CT scan - other (SPECIFY)<br>07 = CT scan - pelvic<br>08 = Culdocentesis<br>09 = Intra-abdominal washings (peritoneal or pelvic)<br>10 = Intravenous pyelography (IVP)/excretory urography<br>11 = Laparotomy<br>12 = Lymphangiogram<br>13 = MRI scan - abdominal | 14 = MRI scan - other (SPECIFY)<br>15 = MRI scan - pelvic<br>16 = Needle aspiration<br>17 = Paracentesis<br>21 = Transabdominal/pelvic ultrasound or sonogram<br>22 = Transvaginal ultrasound<br>23 = Oophorectomy/Salpingoophorectomy<br>24 = Abdominal/vaginal hysterectomy<br>25 = Clinical evaluation<br>26 = CT scan - abdomen and pelvis combined<br>27 = CT scan - chest<br>28 = Hysteroscopy<br>29 = Laparoscopy | 30 = Lymphadenectomy/Lymph node sampling<br>31 = Omentectomy, complete/NOS<br>32 = Omentectomy, partial<br>33 = Radiograph, other (SPECIFY)<br>34 = Record review<br>35 = Resection (SPECIFY)<br>36 = Sigmoidoscopy/Colonoscopy<br>37 = Thoracentesis<br>38 = Transabdominal/pelvic and transvaginal ultrasounds combined<br>39 = Ultrasound, other (SPECIFY)<br>88 = Other (SPECIFY) |
|---|--|---|

**PART A CONTINUED . . .**

PROCEDURE #	7	8	9																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88 <hr/> SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; text-align: center; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; text-align: center; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; text-align: center; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
PROCEDURE #	10	11	12																																																																																																			
<b>TYPE OF PROCEDURE</b> (SEE PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88 <hr/> SPECIFY	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 88 <hr/> SPECIFY																																																																																																			
<b>DATE OF PROCEDURE</b> (MO. - DAY - YEAR)	<table border="1" style="width:100%; text-align: center; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; text-align: center; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; text-align: center; border-collapse: collapse;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**4b.** DIAGNOSTIC/STAGING PROCEDURES SUPPLEMENT FORM COMPLETED

**PROCEDURE CODES**

- |   |  |   |
|---|--|---|
| 01 = Barium enema<br>02 = Biopsy (SPECIFY)<br>03 = Chest radiograph<br>04 = Color doppler<br>05 = CT scan - abdominal<br>06 = CT scan - other (SPECIFY)<br>07 = CT scan - pelvic<br>08 = Culdocentesis<br>09 = Intra-abdominal washings (peritoneal or pelvic)<br>10 = Intravenous pyelography (IVP)/excretory urography<br>11 = Laparotomy<br>12 = Lymphangiogram<br>13 = MRI scan - abdominal | 14 = MRI scan - other (SPECIFY)<br>15 = MRI scan - pelvic<br>16 = Needle aspiration<br>17 = Paracentesis<br>21 = Transabdominal/pelvic ultrasound or sonogram<br>22 = Transvaginal ultrasound<br>23 = Oophorectomy/Salpingoophorectomy<br>24 = Abdominal/vaginal hysterectomy<br>25 = Clinical evaluation<br>26 = CT scan - abdomen and pelvis combined<br>27 = CT scan - chest<br>28 = Hysteroscopy<br>29 = Laparoscopy | 30 = Lymphadenectomy/Lymph node sampling<br>31 = Omentectomy, complete/NOS<br>32 = Omentectomy, partial<br>33 = Radiograph, other (SPECIFY)<br>34 = Record review<br>35 = Resection (SPECIFY)<br>36 = Sigmoidoscopy/Colonoscopy<br>37 = Thoracentesis<br>38 = Transabdominal/pelvic and transvaginal ultrasounds combined<br>39 = Ultrasound, other (SPECIFY)<br>88 = Other (SPECIFY) |
|---|--|---|

PLEASE DO NOT WRITE IN THIS AREA



022824

**PART A CONTINUED . . .**

**5. Medical Complications of Diagnostic Evaluation and Staging:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

COMPLICATION #	1	2	3																																																																																																			
<b>TYPE OF COMPLICATION</b>  (SEE COMPLICATION CODES BELOW)	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 400 401 402 403 408 409 412 413 414 415	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 400 401 402 403 408 409 412 413 414 415	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 400 401 402 403 408 409 412 413 414 415																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
<b>DATE OF COMPLICATION</b>  (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse; font-size: 8px;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; font-size: 8px;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; font-size: 8px;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
COMPLICATION #	4	5	6																																																																																																			
<b>TYPE OF COMPLICATION</b>  (SEE COMPLICATION CODES BELOW)	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 400 401 402 403 408 409 412 413 414 415	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 400 401 402 403 408 409 412 413 414 415	1 2 20 21 22 23 24 25 26 27 28 29 30 31 32 33 400 401 402 403 408 409 412 413 414 415																																																																																																			
	SPECIFY	SPECIFY	SPECIFY																																																																																																			
<b>DATE OF COMPLICATION</b>  (MO. - DAY - YEAR)	<table border="1" style="width:100%; border-collapse: collapse; font-size: 8px;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; font-size: 8px;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width:100%; border-collapse: collapse; font-size: 8px;"> <thead> <tr><th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**MEDICAL COMPLICATION CODES**

- |  |   |                                     |
|--|---|-------------------------------------|
| 1 = Infection (SPECIFY)                      | 27 = Blood loss requiring transfusion             | 402 = Ileus                         |
| 2 = Fever requiring antibiotics              | 28 = Deep venous thrombosis (DVT)                 | 407 = Blood in stool                |
| 20 = Cardiac arrest                          | 29 = Acute/chronic respiratory failure            | 408 = Bowel injury                  |
| 21 = Respiratory arrest                      | 30 = Hypotension                                  | 409 = Adhesions                     |
| 22 = Hospitalization                         | 31 = Congestive heart failure (CHF)               | 412 = Peritonitis                   |
| 23 = Pulmonary embolus/emboli                | 32 = Wound dehiscence                             | 413 = Pneumonia                     |
| 24 = Myocardial infarction                   | 33 = Hypokalemia                                  | 414 = Urinary tract infection (UTI) |
| 25 = Cardiac arrhythmia                      | 400 = Diarrhea                                    | 415 = Wound infection               |
| 26 = Cerebral vascular accident (CVA)/Stroke | 401 = Small bowel obstruction/partial or complete |                                     |

PLEASE DO NOT WRITE IN THIS AREA



022824

**PART A CONTINUED . . .**

**6. Result of Diagnostic Evaluation for Ovarian Cancer:**

- No malignancy (GO TO PART B)
- No malignancy and no diagnostic/staging procedures performed (GO TO PART D)
- Ovarian malignancy confirmed histologically (GO TO PART C)
- Ovarian malignancy confirmed cytologically (GO TO PART C)
- Ovarian malignancy diagnosed by clinical examination only (GO TO PART C)
- Other malignancy confirmed histologically or cytologically (GO TO PART B)
- No information available (GO TO PART D)

**PART B: DIAGNOSIS INFORMATION FOR SPECIFIC CONDITIONS OTHER THAN OVARIAN CANCER**

**7. Specific Ovarian Diagnosis:**

- No
- Yes (COMPLETE TABLE BELOW)

DIAGNOSIS #	1	2	3																																																																																																			
<b>DIAGNOSIS</b> 1 = Cyst 2 = Polycystic ovary 3 = Teratoma 4 = Benign neoplasm	① ② ③ ④	① ② ③ ④	① ② ③ ④																																																																																																			
<b>DATE OF DIAGNOSIS</b> (MO. - DAY - YEAR)	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				
MO.	DAY	YEAR																																																																																																				
0	0	0																																																																																																				
1	1	1																																																																																																				
2	2	2																																																																																																				
3	3	3																																																																																																				
4	4	4																																																																																																				
5	5	5																																																																																																				
6	6	6																																																																																																				
7	7	7																																																																																																				
8	8	8																																																																																																				
9	9	9																																																																																																				

**8. Other Cancer Diagnosis:**

- No
- Yes (COMPLETE TABLE BELOW)

OTHER CANCER DIAGNOSIS 1				OTHER CANCER DIAGNOSIS 2																																																																																																																																																																	
ICD-9-CM CLASSIFICATION	DATE OF OTHER CANCER DIAGNOSIS	ICD-9-CM CLASSIFICATION	DATE OF OTHER CANCER DIAGNOSIS	ICD-9-CM CLASSIFICATION	DATE OF OTHER CANCER DIAGNOSIS	ICD-9-CM CLASSIFICATION	DATE OF OTHER CANCER DIAGNOSIS																																																																																																																																																														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td>X</td><td>X</td></tr> </tbody> </table>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	X	X	X	X	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> <tr><td>X</td><td>X</td><td>X</td><td>X</td></tr> </tbody> </table>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	X	X	X	X	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
0	0	0	0																																																																																																																																																																		
1	1	1	1																																																																																																																																																																		
2	2	2	2																																																																																																																																																																		
3	3	3	3																																																																																																																																																																		
4	4	4	4																																																																																																																																																																		
5	5	5	5																																																																																																																																																																		
6	6	6	6																																																																																																																																																																		
7	7	7	7																																																																																																																																																																		
8	8	8	8																																																																																																																																																																		
9	9	9	9																																																																																																																																																																		
X	X	X	X																																																																																																																																																																		
MO.	DAY	YEAR																																																																																																																																																																			
0	0	0																																																																																																																																																																			
1	1	1																																																																																																																																																																			
2	2	2																																																																																																																																																																			
3	3	3																																																																																																																																																																			
4	4	4																																																																																																																																																																			
5	5	5																																																																																																																																																																			
6	6	6																																																																																																																																																																			
7	7	7																																																																																																																																																																			
8	8	8																																																																																																																																																																			
9	9	9																																																																																																																																																																			
0	0	0	0																																																																																																																																																																		
1	1	1	1																																																																																																																																																																		
2	2	2	2																																																																																																																																																																		
3	3	3	3																																																																																																																																																																		
4	4	4	4																																																																																																																																																																		
5	5	5	5																																																																																																																																																																		
6	6	6	6																																																																																																																																																																		
7	7	7	7																																																																																																																																																																		
8	8	8	8																																																																																																																																																																		
9	9	9	9																																																																																																																																																																		
X	X	X	X																																																																																																																																																																		
MO.	DAY	YEAR																																																																																																																																																																			
0	0	0																																																																																																																																																																			
1	1	1																																																																																																																																																																			
2	2	2																																																																																																																																																																			
3	3	3																																																																																																																																																																			
4	4	4																																																																																																																																																																			
5	5	5																																																																																																																																																																			
6	6	6																																																																																																																																																																			
7	7	7																																																																																																																																																																			
8	8	8																																																																																																																																																																			
9	9	9																																																																																																																																																																			

**PART C: PRIMARY OVARIAN CANCER DIAGNOSIS INFORMATION**

**9. Date of Primary Ovarian Cancer Diagnosis:**

MO.		DAY		YEAR		
0	0	0	0	0	0	0
1	1	1	1	1	1	1
2	2	2	2	2	2	2
3	3	3		3	3	
4		4		4	4	
5		5		5	5	
6		6		6	6	
7		7		7	7	
8		8		8	8	
9	9	9		9	9	9

**10. Verbatim Description of Primary Ovarian Cancer Diagnosis:**

---

---

---

---

---

---

---

---

---

---

**11. ICD-O-2 Cancer Classification:**

Topography				Morphology				Behavior		Grade	
C	0	0	0	0	0	0	0				
1	1	1		1	1	1	1	1		1	
2	2	2		2	2	2	2			2	
3	3	3		3	3	3	3	3		3	
4	4	4		4	4	4	4			4	
5	5	5		5	5	5	5			5	
6	6	6		6	6	6	6			6	
7	7	7		7	7	7	7			7	
8	8	8		8	8	8	8			8	
9	9	9		9	9	9	9	9		9	

**12. Photocopy of Report Confirming Primary Ovarian Cancer: (MARK ONE)**

- Pathology/Histopathology (ATTACH COPY)
- Cytology/Cytopathology (ATTACH COPY)
- Not available

**13. Histopathologic Type for Primary Ovarian Cancer:**

- Serous cystadenoma (low potential/borderline malignancy)
- Serous cystadenocarcinoma
- Mucinous cystadenoma (low potential/borderline malignancy)
- Mucinous cystadenocarcinoma
- Endometrioid tumor (low potential/borderline malignancy)
- Endometrioid adenocarcinoma
- Clear cell tumor (low potential/borderline malignancy)
- Clear cell cystadenocarcinoma
- Undifferentiated carcinoma
- Other (SPECIFY) \_\_\_\_\_
- Unknown

**14. Histopathologic Grade for Primary Ovarian Cancer:**

- Grade cannot be assessed (GX)
- Borderline malignancy (GB)
- Well differentiated (G1)
- Moderately differentiated (G2)
- Poorly differentiated or undifferentiated (G3-4)
- Unknown

**PART C CONTINUED . . .**

**15. TNM Staging for Primary Ovarian Cancer:**

If TNM Staging performed, what AJCC Cancer Staging Manual did you use?  4th Edition  5th Edition

**a. TNM Clinical Staging:**

Yes (COMPLETE 15.a.1, 15.a.2, 15.a.3)  No (GO TO C.15.b)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
<p>(T) Codes</p> <p><input type="radio"/> Tx <input type="radio"/> T2a  <input type="radio"/> T0 <input type="radio"/> T2b  <input type="radio"/> T1 <input type="radio"/> T2c  <input type="radio"/> T1a <input type="radio"/> T3  <input type="radio"/> T1b <input type="radio"/> T3a  <input type="radio"/> T1c <input type="radio"/> T3b  <input type="radio"/> T2 <input type="radio"/> T3c</p> <p><input type="radio"/> Not available</p>	<p>(N) Codes</p> <p><input type="radio"/> Nx  <input type="radio"/> N0  <input type="radio"/> N1</p> <p><input type="radio"/> Not available</p>	<p>(M) Codes</p> <p><input type="radio"/> Mx  <input type="radio"/> M0  <input type="radio"/> M1</p> <p><input type="radio"/> Not available</p>

**b. TNM Pathologic Staging:**

Yes (COMPLETE 15.b.1, 15.b.2, 15.b.3)  No (GO TO C.16)

1. PRIMARY TUMOR (T)	2. NODAL INVOLVEMENT (N)	3. DISTANT METASTASES (M)
<p>(T) Codes</p> <p><input type="radio"/> Tx <input type="radio"/> T2a  <input type="radio"/> T0 <input type="radio"/> T2b  <input type="radio"/> T1 <input type="radio"/> T2c  <input type="radio"/> T1a <input type="radio"/> T3  <input type="radio"/> T1b <input type="radio"/> T3a  <input type="radio"/> T1c <input type="radio"/> T3b  <input type="radio"/> T2 <input type="radio"/> T3c</p> <p><input type="radio"/> Not available</p>	<p>(N) Codes</p> <p><input type="radio"/> Nx  <input type="radio"/> N0  <input type="radio"/> N1</p> <p><input type="radio"/> Not available</p>	<p>(M) Codes</p> <p><input type="radio"/> Mx  <input type="radio"/> M0  <input type="radio"/> M1</p> <p><input type="radio"/> Not available</p>

**16. Record Stage: (COMPLETE IF 15.b.1, 15.b.2, OR 15.b.3 IS NOT AVAILABLE, OTHERWISE SKIP)**

Yes (RECORD STAGING BELOW)  No (GO TO PART E)

**FIGO**

- I  II  III  IV  
 IA  IIA  IIIA  
 IB  IIB  IIIB  
 IC  IIC  IIIC

**GO TO PART E**

PLEASE DO NOT WRITE IN THIS AREA



022824

**PART D: DATE OF DIAGNOSTIC EVALUATION DETERMINATION**

17.

Complete this item if:

- Item A.6 = No malignancy and Item B.7 and Item B.8 = No OR
- Item A.6 = No malignancy and no diagnostic procedures performed OR
- Item A.6 = No information available

MO.		DAY		YEAR		
0	0	0	0	0	0	0
1	1	1	1	1	1	1
2	2	2	2	2	2	2
3	3	3		3	3	
4		4		4	4	
5		5		5	5	
6		6		6	6	
7		7		7	7	
8		8		8	8	
9	9	9	9	9	9	9

**PART E: PHYSICIAN/HOSPITAL LOCATION INFORMATION**

18.

Physician for Diagnostic Evaluation:

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

19.

Hospital or Clinic for Diagnostic Evaluation:

a. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

b. Name: \_\_\_\_\_

Address: \_\_\_\_\_

City State ZIP Code

Telephone: (\_\_\_\_) \_\_\_\_\_ Medical Record/Chart # \_\_\_\_\_

20.

Comments:

- No  Yes (SPECIFY)

Item #	Comments

(  CONTINUED )

PLEASE DO NOT WRITE IN THIS AREA



022824







## PLCO Cancer Screening Trial

### **SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT FORM: DIAGNOSTIC EVALUATION - OVARY VERSION 3 (DEO3/DOQ3)**

This form is to be completed by the Medical Record Abstractor, a nosologist (trained medical coder), and a Tumor (or Cancer) Registrar who is also a Certified Tumor Registrar (CTR) or CTR-eligible. Items, which are to be completed by a nosologist or a CTR, are specified. The abstractor should complete all other items. Specifically, the nosologist will be required to complete Item B.8 (Other Cancer Diagnosis). The CTR will be required to complete Part C: Items C.9 (Date of Primary Ovarian Cancer Diagnosis), C.10 (Verbatim Description of Primary Ovarian Cancer Diagnosis), C.11 (ICD-O-2 Cancer Classification), C.12 (Photocopy of Report Confirming Primary Ovarian Cancer), C.13 (Histopathologic Type for Primary Ovarian Cancer), C.14 (Histopathologic Grade for Primary Ovarian Cancer), C.15 (TNM Staging for Ovarian Cancer), and C.16 (Record Stage).

Refer to the General Abstracting Techniques (Appendix K of the MOOP) for guidelines on general abstracting techniques. Some key guidelines are presented below:

- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry; it should not be obtained from the participant, except in Item A.1, Diagnostic Procedures Performed, in which the information recorded may be based on participant self-report. Written documentation from the physician or the medical record, for example, is preferable to obtaining information verbally.
- Information about diagnostic procedures could possibly be collected up to 12 months after the date of a positive screen (if a conclusive diagnosis or the next screening exam does not come first). In addition, information about complications of diagnostic procedures should be collected up to 12 months from the time diagnostic procedures began. In the event of a cancer diagnosis, medical complications should be collected for an additional 6 months after the diagnosis.
- Before beginning abstraction, the medical record documents should be placed in chronological order and the diagnostic/staging procedures should be abstracted chronologically. If, however, a diagnostic or staging procedure is identified and added after the form has been completed, it is not necessary to shift all of the data to maintain the chronological order; the new procedure may be added at the end of the appropriate item.
- This form includes items, which require that data be entered verbatim, such as recording diagnoses, recording "Other (specify)," and recording comments. Verbatim comments should be succinct and accurate. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If the medical record contains unclear, discrepant, or conflicting information for any item, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should first be consulted for a resolution and for making an appropriate coding decision, prior to contacting the CC MRA Coordinator.
- When recording information in the Comments section, be sure to identify the item to which the comment refers. Appropriate identification will aid in the analysis of

Comments data. Throughout the specifications, examples have been given for recording information in Comments.

Below are some guidelines for the collection of diagnostic evaluation information:

- Information regarding diagnostic procedures that occurred prior to the participant's randomization date should not be recorded.
- Procedures that occurred prior to the date of the initial visit for clinical assessment (i.e., the first visit to a doctor for clinical assessment), should not be recorded, with the exception of procedures that are part of the diagnostic evaluation for a suspected cancer. If a screening test is positive or a participant experiences symptoms and a diagnostic procedure is performed before the participant actually visits the doctor, this diagnostic procedure should be recorded on the DE form (even though it took place prior to the initial visit for clinical assessment).

For example, in the case of a positive PLCO screen with a biopsy performed, the screen is the event that led to the initiation of diagnostic follow-up and should not be recorded, but the biopsy is the first procedure in the diagnostic follow-up process, and should be recorded.

- Following a positive screening exam, the SC should collect diagnostic evaluation information until:
  - a conclusive diagnosis (either malignant or non-malignant) is made, OR
  - 12 months after the date of the positive screen, OR
  - the next screening exam,

*whichever comes first.*

At the end of the 12 months or on the date of the next screen, if the diagnostic evaluation is not conclusively malignant, record the result of the diagnostic evaluation in Item A.6 as "No malignancy."

- An exception to the above is when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had an ovarian or other malignancy. In this situation it is not appropriate to record a conclusive diagnosis, but rather to record "No information available." If a Lead Abstractor cannot conclusively determine the result of a diagnostic evaluation from the medical record, contact the CC MRA Coordinator.

It is the SC's responsibility to encourage timely follow-up of positive screens. If, despite SC efforts, the participant does not initiate follow-up of a positive screen until late in the year, 10 months after the positive screen for example, the SC should still collect only the diagnostic evaluation data until 12 months after the positive screen or the next screen, whichever comes first. In the example given, this would mean two months of diagnostic evaluation data.

- All staging information related to the initial diagnosis of primary ovarian cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEO form). Staging information on ovarian cancer recurrence should not be collected.
- If multiple primary ovarian cancers are diagnosed at the same time (i.e., as part of the same diagnostic evaluation process and prior to the first definitive treatment), it is necessary to complete portions of a separate DEO for each multiple primary. Item 7 (Multiple Primary Cancer #) allows the abstractor to indicate whether the DEO is being used for abstracting information about a multiple pri-

mary ovarian cancer. If there are multiple primary cancers, each cancer should be recorded on a separate DEO3 form.

- If a cancer is not confirmed or staged until the first treatment is performed, information regarding the first treatment should be abstracted onto both the Diagnostic Evaluation Form and the Treatment Information Form because the treatment is also part of diagnosis and staging.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy black marks that fill the circle completely.**



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted, this is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for "2" and "0" have been filled. Darken the circle corresponding to each remaining number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized ("Final Complete" or "Final Incomplete"), erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the DE. If more than one abstractor completes the DE, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form -- this abstractor's ID number should be recorded here. Darken the circles corresponding to the four digits.

3. **Nosologist ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item B.8 (ICD-9-CM Classification of Other Cancer Diagnoses). Darken the circles corresponding to the four digits.
4. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting specific items related to ICD-O-2 Classification and cancer diagnosis/staging in Part C. Darken the circles corresponding to the four digits.
5. **Study Year:** Record the study year, T0 to T13. This is the study year in which the SC was notified of a suspicion of ovarian cancer. For example, if the cancer was reported on a T1 ASU, the study year for the DEO is T1. Darken the corresponding circles. Remember to right justify and zero-fill the number for study years T0 - T9 (e.g., T00, T01, T02, etc.).
6. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the “first” time to confirm a suspicion of ovarian cancer. This includes an initial abstract for a multiple primary cancer (see Item 7).
  - **Re-abstract for QA:** Medical record information, that has already been abstracted to confirm a suspicion of ovarian cancer, is being re-abstracted for the purpose of quality assurance. This includes a re-abstract for a multiple primary cancer (see Item 7). Not yet implemented.
7. **Multiple Primary Cancer #:** The purpose of this item is to indicate whether this form is being used to abstract information about an additional primary ovarian cancer that was diagnosed at the same time as the first primary ovarian cancer (i.e., as part of the same diagnostic evaluation and staging process, and before the first definitive treatment). If this primary cancer is the second primary diagnosed (in chronological date order), darken the circle for “2.” If it is the third, darken the circle for “3,” etc. If only one primary cancer was diagnosed, this item should be skipped.
 

If the participant was diagnosed with more than one primary ovarian cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For the first primary, the DEO must be completed in full (all parts). For all subsequent primaries, use another DEO form and complete the administrative section, Item A.6 (Result of Diagnostic Evaluation for Ovarian Cancer), and Part C only. If more than one primary was diagnosed on the first date of diagnosis, designate the most advanced cancer diagnosed on that day as the “first primary” and complete the entire DEO form. Use additional DEO forms for any other cancers diagnosed on that day.
8. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except “Disposition” are optional. “Disposition” is required and may be marked on the form or entered directly into DEES. Dispositions of “Final Complete” (FCM) may also be set automatically in DEES when the form is edited (See DEES User’s Guide).
  - **Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)
  - **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible, and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)

- **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 of the MOOP for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
- **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
- **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
  - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data is abstracted, remove the ICM so that the appropriate disposition is assigned.
  - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report, or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
  - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A: Diagnostic Evaluation and Staging:**

This section refers to the diagnostic evaluation and staging for ovarian cancer. Abstracting this data will require careful review of the participant's medical records at one or more hospitals, clinics, or physicians' offices.

When abstracting information onto this form, do not include information from any physician/hospital visits or procedures that took place prior to the participant's date of randomization, even if these visits or procedures are related to a diagnosis which was made after the participant was enrolled in the trial.

1. **Diagnostic Procedures Performed:** The purpose of this item is to document whether or not a physician recommended and performed diagnostic procedures as part of the follow-up to a positive PLCO screening examination (CA-125II blood test, ovarian palpation exam (OVR), and/or transvaginal ultrasound (TVU)). If the DEO is being completed in response to ovarian cancer being reported via an ASU, for example, if the participant was in fact diagnosed with cancer, it is assumed that diagnostic procedures were performed and this item should be coded "Yes." Darken the circle corresponding to the most appropriate response as follows:

**Yes:** The record indicates that diagnostic procedures were recommended by a physician and were performed. This includes situations when diagnostic procedures were performed to follow-up a positive PLCO screening exam or when ovarian cancer was reported to the SC via an ASU.

**No, Physician Report:** The record indicated or the physician reported to the SC that based on review of the PLCO screening exam results, and possibly any medical history prior to the screening exam, no additional follow-up was deemed necessary. Complete Item A.6 (Result of Diagnostic Evaluation for Ovarian Cancer) and Parts B, D, and E of the form.

**No, Participant Self-Report:** The participant reported that the physician reviewed the PLCO screening exam results, and possibly other medical history prior to the screening exam, and deemed no additional follow-up was necessary. Complete Item A.6 (Result of Diagnostic Evaluation for Ovarian Cancer) and Parts D and E of the form.

- *Before accepting a participant self-report the SC should first attempt to obtain written documentation from the participant's physician. If written documentation cannot be obtained from the physician, the SC should then attempt to obtain verbal confirmation from the physician's office that the physician did not recommend additional follow-up of the positive PLCO screening exam. In cases where only the participant's report of the physician's recommendation can be obtained, this circle should be darkened.*

2. **Reason for Initial Visit for Clinical Assessment:** The purpose of this item is to identify the participant's motivation for seeking clinical evaluation. Because motivation is sometimes not clearly stated in the record, NCI assumes that if a participant seeks medical care within 12 months of a positive screen, it is for the purpose of follow-up of that positive screen. If medical care is sought more than 12 months after a positive screen, NCI assumes that it is not for follow-up to a positive screen. Darken the circles corresponding to all the reasons that apply as follows:

- **Symptomatic:** The record indicates that symptoms prompted the participant to go for a clinical evaluation.
- **Follow-up of positive PLCO screen:** The record indicates that the participant went for an initial clinical evaluation to follow up a positive PLCO screen, within 12 months of the positive screen.
- **Other (SPECIFY):** If the record indicates that the participant went for a clinical evaluation for a reason other than those listed, specify the reason in the space provided. Include here the asymptomatic participant whose cancer suspicion was from a non-PLCO health screening test result such as a non-PLCO TVU or CA-125. Please specify the test that prompted the evaluation for cancer along with the result on the line provided.

3. **CA-125 Blood Test:** This item refers to whether the participant had a CA-125 blood test for ovarian cancer, and, if so, the result and date of the blood test.

- Do not record any CA-125 blood test performed during the PLCO screening examinations.
- Do not record any non-PLCO screening CA-125 blood tests.
- Do not record any CA-125 blood test unless it is part of the diagnostic evaluation for a suspected ovarian cancer.
- Do not record any CA-125 blood tests after a diagnosis of ovarian cancer is confirmed.

- If a participant has several CA-125 tests within the 12 month period following a positive screen, NCI assumes that a conclusive diagnosis is not made until the results of the last CA-125 test are reported, regardless of whether the participant saw a physician during the time that the follow-up lab tests were performed.

Complete this item as follows:

**No:** The record states or indicates that the participant did not have any CA-125 blood tests. Darken the circle for "No" and go to Item A.4.

**Yes:** The record states or indicates that the participant had one or more CA-125 blood tests performed. Darken the circle for "Yes" and complete the table for Item A.3. If space is needed to record additional CA-125 result data, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example:

Item E.20, Comments:

Item#:	Comments:
A.3	4; Level =___; Assay brand =___; Lab range =__ to __; Date =__

**Unknown:** If there is no indication in the record whether CA-125 blood tests were or were not performed, darken the circle for "Unknown" and go to Item A.4.

For each CA-125 blood test performed, complete the following items:

- **CA-125 Level:** Record the CA-125 level (units/ml) for each blood test obtained as part of the diagnostic evaluation and staging and then darken the circle corresponding to each number.
- **CA-125 Assay Brand:** Darken the circle corresponding to the CA-125 assay brand name used by the lab. This information can be found on the lab report for the test.

**Centacour, Abbott:** These are the most common CA-125 assay brands.

**Other (SPECIFY):** If the CA-125 assay brand is other than those listed, darken the circle for "Other (SPECIFY)" and record the assay brand name on the line provided.

**Not available:** If the CA-125 assay brand name is not available, darken the circle for "Not available." *It is not necessary to attempt to obtain this information if it is not available in the record.*

- **Lab Range:** Record the reference range (units/ml) used by the lab for the particular test. This information can be found on the lab report for the test. Darken the circles corresponding to the numbers. If lab range is not available in the medical record, record "99" in each of the spaces provided, i.e., "99" to "99." If the lab range uses operators such as > and <, report the range in a way that reflects the operator. For example, if the range is stated as "< 40" record the range as "00 to 39."
- **Date of Test:** Record the month, day and year corresponding to each CA-125 blood test obtained. Month and day should be zero filled and four digits recorded for the year (e.g., 03/08/1994). If it is not clear from the record the day that the blood test was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record

the exact month and year. Record the day as "99." Darken the circle corresponding to each number.

4. **Other Diagnostic/Staging Procedures:** This item is concerned with any diagnostic/staging procedures that the participant underwent during the evaluation for ovarian cancer, other than CA-125 blood tests.

Darken the circle corresponding to whether the participant underwent diagnostic/staging procedures as follows:

**No:** The record clearly states or indicates that the participant did not undergo any other diagnostic/staging procedures. Darken the circle for "No" and go to Item A.5.

**Yes:** The record states or indicates that the participant underwent one or more of the diagnostic/staging procedures for ovarian cancer other than CA-125 blood tests. Darken the circle for "Yes" and complete the table for Item A.4. If space is needed to record more than twelve diagnostic/staging procedures, use the Diagnostic/Staging Procedures Supplement (DSS) form (refer to Item A.4.b). All diagnostic and staging procedures should be recorded individually.

**Unknown:** If there is no indication in the record whether or not diagnostic/staging procedures were or were not performed, darken the circle for "Unknown" and go to Item A.5.

The following are general guidelines for identifying diagnostic and staging procedures in the medical record:

- Both surgical approaches and the surgical procedure should be recorded. For example, if a participant has a laporotomy and a BSO performed, both procedures would be recorded seperately.
- Operative reports are generally more accurate for the date of the procedure than surgical pathology reports, so in the case of a discrepancy, record the date of the procedure from the operative report.
- Following a positive PLCO screening exam (CA-125 and TVU), the SC should collect information on diagnostic procedures until a conclusive diagnosis is made, or until 12 months from the date of the positive screen, or until the next screen, whichever comes first.
- All staging information related to the initial diagnosis of a primary ovarian cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DEO form.) Surgical resection of the primary organ, lymph nodes and other organs should be included. Staging procedures performed after the start of the first definitive treatment should not be collected. Staging information on ovarian cancer recurrence should not be collected.

For each diagnostic/staging procedure performed, complete the following items:

- **Type of Procedure:** Darken the circle corresponding to the type of diagnostic/staging procedure performed. Refer to the Procedure Codes for the list of diagnostic/staging procedures for ovarian cancer. When the procedure on the Procedure Code list indicates, "SPECIFY," describe the body site or the actual procedure, as appropriate. Refer to Appendix K-17-2 of the MOOP for an alphabetical listing of definitions and synonyms for the diagnostic/staging procedures listed on the DE forms. The following are guidelines for coding type of procedure:

- **Biopsy:**

02 = Biopsy (SPECIFY): Specify the site of the biopsy on the line. Record both incisional and excisional biopsies. Do not record biopsies under 88 = Other (SPECIFY).

- A peritoneal biopsy should be recorded as 02 = Biopsy, not as 16 = Needle aspiration. Enter "peritoneal" on the specify line.
- Do not record endometrial biopsies as a Diagnostic/Staging Procedure. Generally, they are not used to stage ovarian cancer.

- **Clinical Evaluation and Record Review:**

25 = Clinical evaluation: A clinical evaluation is defined as a visit to a health care provider for medical care and should include a history and physical exam related to the organ of interest. If a history includes information about the PLCO Screen only, this is to be considered a clinical evaluation. It does not include a telephone conversation to a health care provider. The following examples show how the form should be completed to document a clinical evaluation.

- If a visit to a health care provider includes a history as well as a bimanual exam, this is considered a clinical evaluation. Use code 25 = Clinical Evaluation.
- If a visit to a health care provider includes a history without a pelvic exam, this is also considered a clinical evaluation. Use code 25 = Clinical Evaluation.

**Note:** A clinical evaluation that only serves to repeat or confirm previous findings should not be recorded.

34 = Record review: This procedure should only be recorded when a review of the medical record is performed for the purpose of a second opinion of diagnosis, and a record review contributes to the diagnosis or staging of the cancer in question.

- **CT Scans:**

05 = CT scan – abdominal

06 = CT scan – other (SPECIFY)

07 = CT scan – pelvic

26 = CT scan – abdomen and pelvis combined: If CT abdominal and CT pelvic procedures appear in the record as a combined procedure, they should be recorded as a single procedure under 26 = CT scan - abdomen and pelvis combined with one date. If they are performed on the same date, and appear in the record as separate procedures, the abstractor should record them separately using codes 05 and code 07 respectively.

27 = CT scan - chest

- If a CT scan is performed as part of a diagnostic procedure, as in the case of a "CT guided biopsy," the CT scan should not be recorded as a separate procedure. In this case, the CT scan is the approach or means to perform the biopsy.

- **Endoscopic/Surgical Evaluation Procedures:**

- 11 = Laparotomy
- 28 = Hysteroscopy
- 29 = Laparoscopy
- 36 = Sigmoidoscopy/Colonoscopy

- **Fluid – Removing Procedures:**

- 08 = Culdocentesis
- 09 = Intra-abdominal washings (peritoneal or pelvic): This code should be used when, during a surgical procedure, fluid is introduced into the peritoneum or pelvis as a means of creating “washings,” for collection of cytological specimens for diagnosis or staging.
  - Ascites: Procedure Code 88=Other (SPECIFY) should be used when, during an intraoperative procedure, fluid (ascites) is discovered in the peritoneum, and is collected for cytological diagnosis or staging. Specify procedure as “ascites removal” on the specify line. Do not record “ascites” as a procedure if there was not cytological diagnosis or staging of the fluid.
- 16 = Needle aspiration
- 17 = Paracentesis
- 37 = Thoracentesis

- **Laboratory Tests: Record only CA-125 tests in Item A.3. Do not record any other laboratory tests in Item A.4.**

*Hormone Receptors:* “Hormone receptors” is not considered a diagnostic evaluation or staging procedure. It is usually used to determine appropriate treatment. Do not code “hormone receptors” on the DEO.

*PAP Smear and D&C:* Do not record Papanicolaou smear (PAP smear) or Dilation and Curettage (D&C) as diagnostic/staging procedures for ovarian cancer.

- **MRI Scans:**

- 13 = MRI scan – abdominal
- 14 = MRI scan – other (SPECIFY)
- 15 = MRI scan - pelvic

- **Other (SPECIFY):** Use code 88 = Other (SPECIFY) to record procedures that cannot be listed using one of the other codes on the form.

- **Radiographic Procedures:**

- 01 = Barium enema
- 03 = Chest radiograph: The first (chronological) chest radiograph found in the record should be recorded. Additional chest radiographs should not be recorded unless they reveal a new abnormality that is diagnostic of cancer, which was not noted on the previous film.
- 10 = Intravenous pyelography (IVP)/excretory urography
- 12 = Lymphangiogram
- 33 = Radiograph, other (SPECIFY)

- **Surgical Procedures:**

23 = Oophorectomy/Salpingoophorectomy

- Salpingoophorectomy should be recorded using procedure code as 23 = Oophorectomy/ Salpingoophorectomy.
- When a participant has a bilateral oophorectomy, the procedure should be recorded as one procedure, rather than recording the removal of each ovary as a separate procedure.
- If either normal or pathologic ovaries are removed following a positive PLCO screen, record the type of procedure as 23 = Oophorectomy

24 = Abdominal/vaginal hysterectomy:

- Record a hysterectomy as a diagnostic/staging procedure for both cancer and non-cancer ovarian cases.

30 = Lymphadenectomy/lymph node sampling:

- If lymph node sampling and lymph node dissection are both performed, this should be considered as one procedure and recorded only once using procedure code = 30.
- Lymph node removal accompanying surgical resection, such as an oophorectomy, should be coded as two separate procedures. Code both procedures separately using the appropriate code for the resection (23 for oophorectomy) and using procedure code = 30 for the lymph node removal.

31 = Omentectomy, complete/NOS

32 = Omentectomy, partial

35 = Resection (SPECIFY)

- Include appendectomy and/or gall bladder here only if on pathological review, a post-removal tumor involvement is identified. (Do not record the incidental appendectomy or cholecystectomy that are part of the abdominal surgery if no cancer is found there.)

**Tumor Debulking:** Record tumor debulking as a Diagnostic/ Staging procedure using "88 = Other (SPECIFY)".

Note: The surgical approach, laparotomy or laparoscopy, to a surgical procedure should be recorded.

**Lysis and Adhesions:** Record Lysis of Adhesions (LOA) as a Diagnostic Staging procedure using "88=Other (Specify) if some of the tissue is sent for pathologic review. Otherwise, do not record.

- **Ultrasound:**

04 = Color doppler: Record as a separate procedure if performed during a transvaginal ultrasound.

21 = Transabdominal/pelvic ultrasound or sonogram

22 = Transvaginal ultrasound

38 = Transabdominal/pelvic and transvaginal ultrasound combined:

- If a pelvic transabdominal ultrasound and a pelvic transvaginal ultrasound appear in the record as a combined procedure, they should be recorded as a single procedure with one date using code 38. If they are performed on the same date and not done sequentially, so not immediately following each other, and appear in the record as separate procedures, record them separately using codes 21 and 22 respectively.

39 = Ultrasound, other (SPECIFY)

Please refer to Section A-8-6 of the MOOP, Diagnostic/Staging Procedures Supplement (DSS), for an additional listing of Diagnostic/Staging Procedures.

- **Date of Procedure:** Record the month, day and year that the diagnostic/staging procedure was performed. If it is not clear from the record the day that the diagnostic/staging procedure was performed, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

**4b. Diagnostic/Staging Procedures Supplement Form Completed:** If space is needed for recording more than 12 diagnostic/staging procedures, darken the circle and go to the Diagnostic/Staging Procedures Supplement (DSS) form. Otherwise, do not darken the circle and go to Item A.5.

The DSS form provides eleven additional spaces for recording diagnostic/staging procedures, numbered 13 through 23. If there are more than 23 diagnostic/staging procedures, place an asterisk beside Item 4 (Diagnostic/Staging Procedures) on the DSS, and use the Comments section of the DEO to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example:

Item E.20, Comments:

Item#:	Comments:
A.4	24; Type = ____; Date = ____

Refer to the specifications for the DSS for additional information on completing the DSS.

- 5. Medical Complications of Diagnostic Evaluation and Staging:** General guidelines for identifying selected medical complications in the medical record are given below:
  - Only selected medical complications that were a result of the diagnostic evaluation or staging procedures *and that required medical intervention should be recorded.*
  - Information on medical complications can usually be found in the discharge summary, or the doctor's or nurse's notes within the medical record.
  - Medical complications should be collected up to 12 months from the time diagnostic procedures were initiated. In the event of a cancer diagnosis, medical complications should be collected through 6 months after the date of the cancer diagnosis.

- If more than one medical complication occurred during a particular event, record each selected medical complication, even if they occurred on the same date. Hospitalization, code 22, should be recorded only if the reason for hospitalization is not another selected medical complication. For example, in the case of fever requiring antibiotics and hospitalization, only record fever requiring antibiotics.

Darken the circle corresponding to medical complications as follows:

**No:** The record clearly states or indicates that none of the selected medical complications resulted from a diagnostic or staging procedure. Also mark this item if no diagnostic/staging procedures were performed as part of the evaluation. Darken the circle for "No" and go to Item A.6.

**Yes:** The record states or indicates that one or more of the selected medical complications resulted from a diagnostic or staging procedure. If a participant had more than six medical complications, place an asterisk beside Item A.5, and use the Comments section to record the same data as requested in the table. In Comments, record the item numbers and labels followed by the data. Be certain to record the number associated with the complication next to "Type," rather than the text, which describes the complication. For example, fever requiring antibiotics was the seventh medical complication mentioned in the record:

Item E.20, Comments:

Item #	Comments
A.5	7; Type = 2; Date = mm/dd/yyyy

**Unknown:** Only use this code when you may not have all of the medical record and you cannot reliably determine complications. Darken the circle for "Unknown" and go to Item A.6.

Darken the circle for "Yes" and complete the table for Item A.5 as follows:

- **Type of Medical Complication:** Darken the circle corresponding to the type of medical complication that occurred. Refer to the Medical Complication Codes for the list of selected medical complications that required medical intervention for ovarian cancer. Refer to Appendix K-17-2 of the MOOP for definitions and synonyms for the medical complications listed on the DE forms. The following are guidelines for recording medical complications of Diagnostic Evaluation and Staging.
  - 1 = Infection (SPECIFY):** Specify the site or source of the infection on the line provided.
  - 22 = Hospitalization:** Use only if the reason for the hospitalization is not another selected medical complication.
  - 27 = Blood loss requiring transfusion:** Only record transfusion of blood if it involves giving red blood cells from a stored source, usually described as a unit of red blood cells. There can be a number of words that would apply - whole, packed, washed, irradiated, etc. The transfusion of red blood cells implies that the blood loss was significant enough to require a replacement of the red blood cells. Other types of fluids or blood products that do not include red blood cells, such as D5, saline (NaCl), platelets, albumin, or fresh frozen plasma should not be considered when recording blood loss requiring transfusion. The intra-operative recycling of blood lost, filtered,

and returned immediately to participant will also not be considered equivalent to blood loss requiring transfusion and should not be recorded as a medical complication.

*The Lead Abstractor should consult with the CC MRA Coordinator if it cannot be determined if a medical complication should be recorded.*

- **Date of Complication:** Record the month, day and year that the medical complication began. If it is not clear from the record the day the complication began, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

6. **Result of Diagnostic Evaluation for Ovarian Cancer:** The purpose of this item is to record the overall results of the diagnostic evaluation for ovarian cancer. This information should be found in the impression or conclusion sections of the various diagnostic and staging reports. This information may also be found in a physician's note.

Record the result of the diagnostic evaluation for ovarian cancer as follows:

- **No malignancy:** The record indicates that no malignancy was found as a result of the diagnostic and staging procedures. A result of "No malignancy" should be coded in the following situations:
  - When a conclusive diagnosis is made following a positive screen and the diagnosis is not ovarian or any other cancer. Include Cyst, Polycystic ovary, Teratoma, and Benign neoplasm.
  - When no diagnostic procedures are performed following a positive PLCO screening exam—that is, when the physician recommends against any diagnostic evaluation Item A.1, Diagnostic Procedures Performed, is coded "No, physician report." No malignancy is presumed. This decision by the physician must be documented.
  - When diagnostic follow-up data have been abstracted for the period from a positive screen until 12 months past the positive screen or until the next screen (whichever came first) and the diagnosis was not conclusively malignant.
  - When the only diagnostic procedures performed during the 12 month follow-up were CA-125 test (s) and there is not cancer diagnosis.

Darken the circle and go to Part B: Diagnosis Information For Specific Conditions Other Than Ovarian Cancer.

- **No malignancy and no diagnostic/staging procedures performed:** The participant reports that he/she had a follow up visit with his/her physician who determined that there was no malignancy. No further diagnostic/staging procedures were performed. This information is not documented in the medical record and cannot be validated by the participant's health care provider. Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination.
- **Ovarian malignancy confirmed histologically:** The record indicates that the participant has been diagnosed with primary ovarian cancer, confirmed by histologic examination (study of tissue). This includes the case when the basis of the diagnosis is from tissue from a metastatic site. Histologic information can be found on the pathology report, sometimes called the histopathology report. Neoplasm of uncertain behavior of the ovary, carcinoid of the ovary, extranodal lymphoma arising in the ovary, and sarcoma of the ovary should be recorded here if con-

firmed histologically. Darken the circle and go to Part C: Primary Ovarian Cancer Diagnosis Information.

- **Ovarian malignancy confirmed cytologically:** The diagnosis of primary ovarian cancer was confirmed by cytologic examination (study of cells). Cytologic information can be found on the cytology report, sometimes called a cytopathology report. Neoplasm of uncertain behavior of the ovary, carcinoid of the ovary, extranodal lymphoma arising in the ovary and sarcoma of the ovary should be recorded here if confirmed cytologically. Darken the circle and go to Part C: Primary Ovarian Cancer Diagnosis Information.

**NOTE:** If the ovarian malignancy was confirmed by both histologic and cytologic examination, the response to A.6 should be "Ovarian malignancy confirmed histologically" even if the cytology is earlier. The histopathology report is more definitive, and therefore, every attempt should be made to verify if one exists before utilizing cytologic confirmation for the ovarian malignancy.

- **Ovarian malignancy diagnosed by clinical examination only:** The record indicates that the participant was diagnosed with primary ovarian cancer by clinical examination and not confirmed by histologic examination (study of tissue) or cytologic examination (study of cells). It is an extremely rare event, however, for a malignancy to be confirmed only by clinical examination and not histologically or cytologically. Darken the circle and go to Part C, Primary Ovarian Cancer Diagnosis Information.

In these cases, there will be a 12-month "holding period" to be sure that no pathologic confirmation followed. The following guidelines should be used to determine if the diagnosed "clinically" code is appropriate:

- If the initial response is "clinically" and within the 12-month period there is pathologic confirmation, the diagnosis should be changed to "histologically" or "cytologically" and the diagnosis date should be updated.
  - If the initial response is "clinically" and treatment is given right away, the "clinically" code becomes validated and should remain.
  - If the initial response is "clinically" but after 12 months there is no follow-up or treatment, the diagnosis is questionable and the code should be changed to "no malignancy".
  - If the initial response is "clinically," but the lack of treatment is due to other reasons, such as advanced stage of disease, participant refusal, etc., the clinically diagnosed result should remain on the DE form.
- **Other malignancy confirmed histologically or cytologically:** The diagnosis of a malignancy *other* than primary ovarian cancer was confirmed by histologic examination (study of tissue) and or cytologic examination (study of cells). Histologic information can be found on the pathology report, sometimes called the histopathology report, and cytologic information can be found on the cytology report, sometimes called a cytopathology report. Darken the circle and go to Part B: Diagnosis Information For Specific Conditions Other Than Ovarian Cancer.

This answer category should also be coded if the diagnostic evaluation for primary ovarian cancer reveals a malignancy (including an ovarian malignancy) that is a metastasis from a primary cancer site other than the ovary. In this situation, the

primary cancer site should be recorded in Part B: Diagnosis Information For Specific Conditions Other Than Ovarian Cancer, Other Cancer Diagnosis.

*NOTE:*

- *If the participant was diagnosed with another PLCO malignancy (prostate, lung, or colorectal) as the result of the diagnostic evaluation for the ovarian cancer, the appropriate Diagnostic Evaluation form (DEP, DEL, or DEC) must also be completed, unless previously confirmed.*
- *If the participant was diagnosed with a malignancy other than one of the PLCO cancers, an Other Cancer Form (OCF) must also be completed, unless previously confirmed.*
- **No information available:** There is equivocal or no information available in the record regarding the result of the diagnostic evaluation for ovarian cancer. Darken the circle and go to Part D: Date of Diagnostic Evaluation Determination. Information. "No information available" should also be coded in the situation when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had an ovarian or other malignancy.

**Part B: Diagnosis Information for Specific Conditions Other Than Ovarian Cancer:**

This section is to document Specific Ovarian Diagnosis and/or Other Cancer Diagnosis, which resulted from the diagnostic evaluation. Other cancer diagnoses may include neoplasms of uncertain behavior, carcinoids, sarcomas, lymphomas, and other malignancies that have an origin other than the ovary. Specific ovarian diagnoses include cyst, polycystic ovary, teratoma and benign neoplasm. This information will most likely be obtained directly from the participant's physician when the SC contacts the physician during follow-up of a positive PLCO screening exam. Depending on the extent of the information available and the physician's preference, the requested information may be obtained either verbally by phone or via written documentation. The diagnosis should be recorded from documents in the medical record that are prefaced with "Diagnosis/Impression/Conclusion/Assessment." The physician diagnosis can be from a source other than the original diagnosing physician as long as the source states the physician's original diagnosis. One example is a progress note written by a follow-up physician. A pathology report documenting a benign condition is also an appropriate source. Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.

7. **Specific Ovarian Diagnosis:** This item is concerned with benign conditions of the ovary. These include cyst, polycystic ovary, teratoma, and benign neoplasm.

Darken the circle corresponding to the specific ovarian diagnosis as follows:

**No:** The record clearly states or indicates that no specific ovarian diagnosis was determined as a result of diagnostic or staging procedures. Use "No" if result of diagnostic evaluation is another conclusive non-cancer ovarian diagnosis that is not listed on the form. Also mark this item if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to item B.8.

**Yes:** The record states or indicates that one or more specific ovarian diagnoses were determined as a result of the diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for item B.7 as follows:

- **Diagnosis:** Darken the circle corresponding to the type of specific ovarian diagnosis that was found. The types of specific ovarian diagnoses, determined as a result of diagnostic/staging procedures for ovarian cancer, are defined below:

- 1 = **Cyst:** The record indicates that the participant had a benign cyst(s) of the ovary, which can be of varied origins and types.
- 2 = **Polycystic Ovary:** The record indicates that the participant had polycystic ovarian syndrome (PCOS) which is part of a syndrome with enlarged cystic ovaries and endocrinologic abnormalities.
- 3 = **Teratoma:** The record indicates that the participant had a teratoma, which is a growth/tumor with multiple tissues, including tissues not normally associated with the ovary. These are usually benign, and form dermoid cysts.
- 4 = **Benign neoplasm:** The record indicates that the participant had a benign neoplasm of the ovary, which is a non-malignant tumor growing on the ovary. Synonyms: benign adenofibroma (endometrioid, mucinous, papillary, serous), benign cystadenoma (endometrioid, mucinous, papillary, serous), benign endometrioid adenoma, benign serous surface papilloma, benign Brenner tumor

- **Date of Diagnosis:** Record the month, day, and year that the specific ovary diagnosis was made. If the exact day of the diagnosis cannot be determined from the record, year and month can usually be assessed. In this situation, record for the exact month and year. Record the day as "99." Zero fill month and day, and record four digits for the year.

**Note:** When there is no ovarian cancer diagnosis and the clinician continues to order additional diagnostic tests, a conclusive diagnosis has not been made. The date of diagnosis of a specific ovarian diagnosis should reflect the date of completion of the diagnostic evaluation following possible screening exam.

- 8. **Other Cancer Diagnosis:** This item is concerned with cancer diagnoses other than ovarian cancer. Other cancer diagnoses may also include neoplasms of uncertain behavior, carcinoids, sarcomas, lymphomas, and other malignancies that have an origin other than the ovary. Lung carcinoma in situ is also an other cancer, but do not include carcinoma in situ of the colon. These diagnoses must be classified according to ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification). ICD-9-CM coding for the PLCO Screening Trial must be consistent with the national ICD-9-CM coding standards and should not be influenced by specific institutional coding philosophies.

Darken the circle corresponding to an other cancer diagnosis as follows:

**No:** The record clearly states or indicates that no other cancers were diagnosed as a result of diagnostic/staging procedures. Also mark this item if there is no information for physician diagnosis or if there is no information because the participant discontinued the diagnostic evaluation process. Darken the circle for "No" and go to Part D.

**Yes:** The record states or indicates that one or more other cancer diagnoses were determined as a result of diagnostic or staging procedures.

Darken the circle for "Yes" and complete the table for Item B.8 as follows:

- **ICD-9-CM Classification:** These items must be completed by a nosologist (a trained medical coder). The nosologist should code the five digit ICD-9-CM

classification in the space provided and darken the circles corresponding to each number or letter. When coding ICD-9-CM, always left justify the code and ignore the decimal place. If the ICD-9-CM code is a three or four digit code, record "X" for the remaining blank box(es). The following examples illustrate how the ICD-9-CM code boxes should be coded:

- The ICD-9-CM code for Hodgkin's disease, unspecified site is 201.90. This should be recorded as "20190."
- The ICD-9-CM code for malignant neoplasm of the female breast is 174.9. This should be recorded as "1749X."
- The ICD-9-CM code for malignant neoplasm of the thyroid gland is 193. This should be recorded as "193XX."

**Note:** If the diagnostic evaluation results in an extranodal lymphoma of the lung or colorectum, assign the appropriate ICD-9-CM code for the type of lymphoma with "0" as the 5th digit denoting "extranodal." An "OCF" will be triggered. Complete an "MDF" for the OCF and manually set the expectation for the appropriate DE form. Complete the DEL, DEC or DEO for the lung, colorectal or ovarian lymphoma.

- **Date of Other Cancer Diagnosis:** Record the month, day, and year that the other cancer diagnosis was determined. If the day of the other cancer diagnosis is not clear in the record, then year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for the year.
- **More Than Two "Other" Cancer Diagnoses:**  
Record codes for more than two "other" cancer diagnoses in Item E.20, Comments, as shown in the following example:

Item E.20, Comments:

Item #	Comments
B.8	3; ICD-9CM Classification = ____; Date of Other Cancer Diagnosis = mm/dd/yyyy

Be sure to set an expectation in the SMS for any additional "other" cancers.

If Part B is completed, skip Part C and go to Part D.

**Part C: Primary Ovarian Cancer Diagnosis Information:**

In this section we are interested in obtaining all relevant information pertaining to a primary ovarian cancer diagnosis, including lymphoma arising in the ovary, sarcoma, neoplasm of uncertain behavior of the ovary, and/or a carcinoid of the ovary. This section is to be completed only by a CTR or CTR-eligible individual. Every attempt should be made to complete this form in a timely manner. For participants who have a positive PLCO screening result, the Medical Record Abstract-DEO Form should be completed within six months of the positive screening result. If specific items cannot be completed within the six - month time frame (i.e., awaiting access to photocopy a form or awaiting TNM staging by the Tumor or Cancer Registrar), those items should be left blank and the information completed within nine to eleven months.

If the participant was diagnosed with more than one primary ovarian cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For all subsequent primaries, use another DEO form. If more than one primary was diagnosed on the first date of diagnosis, record information about the most advanced cancer diagnosed on that day in Part C, and use additional DEO forms for any other cancers diagnosed on that day.

9. **Date of Primary Ovarian Cancer Diagnosis:** Record the month, day and year of the primary ovarian cancer diagnosis that was confirmed by histopathology or by cytopathology if histopathology is not available. This is the date on the report that the actual procedure (biopsy, surgery, aspiration of cells, etc.) was performed that confirmed this primary ovarian cancer diagnosis. Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report. For example, the date on the pathology report may be the date that the slides were read or the date that the diagnosis was determined or reported, rather than the date of the operative procedure.

If there are multiple reports that confirmed this primary cancer, record the earliest date available that has an adequate tissue specimen. If histopathology is not available, record the earliest date that has an adequate cytopathology specimen. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. In the rare situation in which ovarian cancer was diagnosed by clinical examination only and not histologically or cytologically, the date of first ovarian cancer diagnosis is the date of the clinical examination, which diagnosed the cancer.

Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year. Month and year of ovarian cancer diagnosis must be known, however, if day is unknown, record "99."

10. **Verbatim Description of Primary Ovarian Cancer Diagnosis:** This item is concerned with the actual physician diagnosis of ovarian cancer. *This item is optional except in the following situations:*

- The diagnosis is based on clinical examination and not pathology (Item A.6 = Ovarian malignancy diagnosed by clinical examination only); or
- The SC is unable to obtain a copy of the pathology or cytology report that corresponds to the ICD-O-2 code in Item C.11 (Item C.12 = Not available).

Record the verbatim description of the primary ovarian cancer diagnosis from the histopathology report (or cytopathology report if a histopathology report is not available). The verbatim description should come from the diagnosis section of the earliest (chronological) histopathology report (or cytology report if the pathology report is not available) that had an adequate specimen and which confirms the cancer diagnosis.

- Occasionally, the diagnosis section will say "see above" or "see microscopic." In this situation record verbatim all of the information from the appropriate section of the report which pertains to the cancer diagnosis.
- Do not record any information about metastases or recurrent cancer.
- Do not record any information about benign conditions listed in the diagnosis section of the histopathology or cytology report.

11. **ICD-O-2 Cancer Classification:** This item is for classifying the physician diagnosis of the primary ovarian cancer according to ICD-O-2 (International Classification of Diseases for Oncology, Second edition, 1990). The CTR should code the ten digit ICD-

O-2 classification in the space provided. Darken the circles corresponding to the letter and each number.

- The ICD-O-2 code should reflect the diagnosis from the earliest (chronological) pathology report, that has tissue, (or cytology report if the histopathology report is not available) which confirms the cancer diagnosis. NCI wants to code the earliest definitive procedure that diagnosed the cancer, even if it is not the most complete picture of the cancer. This should be the same report that was used as a source for the date of diagnosis in Item C.9. Do not record any information about benign conditions listed in the diagnosis section of the histopathology or cytology report. If the basis for the ovarian cancer diagnosis is based from tissue from a metastatic site, then the grade in the ICD-O-2 code should be recorded as 9 ("unknown").
- A borderline malignancy should have 9 recorded as the grade. This is also called a low malignant potential cancer.
- A neoplasm of uncertain behavior of the ovary is considered to be a cancer by NCI and should be recorded in this section. Use the following guidelines for ICD-O-2 coding of neoplasms of uncertain behavior of the ovary:
  - Assign the topography and morphology codes for this neoplasm according to ICD-O-2.
  - The behavior code for neoplasms of uncertain behavior is "1." Under "Behavior," enter "1" in the box and darken the circle for "1" printed on the form.
  - Grade will be coded "9" for neoplasms of uncertain behavior. Under "Grade," enter a "9" in the box and darken the circle for "9" printed on the form.

*If the medical record contains information about this neoplasm that would result in a behavior code other than "1" or a grade code other than "9," contact the CC MRA Coordinator.*
- If the record clearly indicates that ovarian cancer was confirmed by a histology or cytology report, but the report is not available, code the diagnosis from other available documents, (i.e. physician's notes, progress reports, etc.) that reference the earliest procedure from an adequate specimen. Place an asterisk by Item C.11, and indicate in the Comments section the source of the diagnosis. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments:

Item #	Comments
C.11	Pathology/cytology report not available. Source of diagnosis is...

- If the ovarian cancer was diagnosed by clinical examination only, record the verbatim description as reported on the clinical examination form, which diagnosed the cancer.
 

The ICD-O-2 cancer classification should be coded by the CTR regardless of whether ICD-O-2 code is available in the medical record.
- Use the following guidelines to determine how to record a diagnosis of lymphoma for PLCO. Refer to Appendix K-17-2 of the MOOP for explanation of Nodal vs. Extra-Nodal Lymphomas:

- If an extranodal lymphoma of the ovary is designated as the primary, record this lymphoma on the DEO3 form and assign the ICD-O-2 topography code corresponding to the ovary. Be sure this is the primary site of origin and not just a site where a biopsy was taken. The TIO2 form is required for each DEO3 form, as it is for any PLCO primary.
- If a lymphoma is diagnosed in both a nodal and an extranodal lymphoma of the ovary, consult the SC principal investigator to determine where the lymphoma originated and code the primary to that site.
- If no primary site is stated or the primary site cannot be determined, record this lymphoma on an OCF and assign the ICD-O-2 topography code for lymph nodes (C77.\_). For lymphomas, a mass specified only as "retroperitoneal" or "peritoneal," "inguinal," "mediastinal," or "mesentery" (with no specific information as to tissue involved), is to be coded as a nodal primary and recorded on the OCF, rather than to an extranodal primary site.
- If an extranodal lymphoma arising in a PLCO site is discovered during the diagnostic evaluation of another PLCO site, the ICD-9-CM code for lymphoma will be entered in Part B of the DE form. This code will trigger an OCF. The SC will complete an MDF (for the OCF) and manually set the expectation for the appropriate DE. For example, an extranodal lymphoma of the colon is discovered as a result of the diagnostic evaluation of a positive ovarian screen. The ICD-9-CM code for the type of lymphoma will be entered in part B of the DEO, with "0" as the 5th digit denoting "extranodal." An OCF will be triggered. Complete an MDF (for the OCF) and manually set the expectation for a DEC. Complete the DEC for the extranodal lymphoma arising in the colon. Complete the TIC also.
- If an extranodal lymphoma arising in the ovary is reported on an ASU, the SC will need to use the three-digit PLCO code for the ovary, rather than the three-digit code for lymphoma in order to trigger the DEO3 form. Complete the DEO3 for the extranodal lymphoma arising in the ovary. Complete the TIO2 form also.
- Extranodal lymphomas arising in the ovary may require the T-cell, B-cell, or NK cell designation. If so, enter the appropriate code from ICD-O-2 in the "Grade" space. The T-cell, B-cell or NK cell designation has priority over the grade when both are provided. NK cell designation = "8." A bubble for "8" does not exist on the form. Darken the space for "8" under "Grade" for NK cell if this applies.
- Do not code the descriptions "high grade," "low grade," or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.

**12. Photocopy of Report Confirming Primary Ovarian Cancer:** The purpose of this item is to document that the pathology/histopathology report (or cytology/cytopathology report if a pathology report is not available) that confirmed the primary ovarian cancer has been photocopied and attached to the Medical Record Abstract-DEO Form.

- If there are multiple pathology reports confirming this primary ovarian cancer, the photocopy should be of the pathology or cytology report which was the source for recording the date of ovarian cancer diagnosis recorded in Item C.9, and the ICD-O-2 code recorded in Item C.11. If the Date of Ovarian Cancer Diagnosis and the ICD-O-2 Cancer Classification came from different reports, attach copies of both reports used to code Items C.9 and C.11.

- A situation may arise in which an institution does not allow the photocopying of records. Every reasonable attempt should be made to obtain permission to photocopy the pathology or cytology report since it is a critical end-point of the screening trial. If special permission or approval is required, the abstractor should work with the SC Coordinator/Principal Investigator to obtain the necessary approval. If this item cannot be completed in a timely manner, leave it blank and attempt to obtain the information at a later date via data retrieval.

Darken the circle to indicate whether a photocopy of the pathology or cytology report is available as follows:

- **Pathology/Histopathology**: The pathology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEO Form. The photocopy should be labeled with the participant's ID number, the study year, titled "Medical Record Abstract-DEO/Pathology Report," and inserted into the participant's folder.
- **Cytology/Cytopathology**: The cytology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DEO Form. The photocopy should be labeled with the participant's ID number, the study year, titled "Medical Record Abstract-DEO/Cytology Report," and inserted into the participant's folder.
- **Not available**: The pathology or cytology report exists in the medical record, but a photocopy cannot be obtained or there is no report in the medical record. Place an asterisk by Item C.12, and provide a detailed explanation in the Comments section of why the pathology or cytology report cannot be obtained. (In this situation, Item C.10 (Verbatim Description of Primary Ovarian Cancer Diagnosis) must be completed.) Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments:

Item #	Comments
C.12	Pathology or cytology report cannot be obtained because...

13. **Histopathologic Type for Primary Ovarian Cancer**: This item is to document the histopathologic type of the primary ovarian cancer. This refers to the type of cell comprising the tumor, usually determined by the pathologist from a tissue specimen. This information can be obtained from the pathology report that confirmed the ovarian cancer and collected the most tissue. If a pathology report is not available, this information may be found in the discharge summary, operative report, or in a cytology report. If the histopathologic type is obtained from a source other than the pathology report, place an asterisk by Item C.13, and record the source of the information in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments

Item #	Comments:
C.13	Source of histopathologic type of lesion is...

- If a cancer has two different histopathologic types, the diagnosis is usually based on the predominant type. This should be stated in the pathology report. If the pathology report does not indicate a predominant type record both types in Other (SPECIFY) for Item C.13 as follows: "Histopathologic type is \_\_\_\_\_ and \_\_\_\_\_."
- The abstractor should select the general category into which the result fits rather than using Other-specify to list a more detailed result. For example, "Serous adenocarcinoma" should be included in the "Serous cystadenocarcinoma" category.
- Borderline/low malignant potential neoplasms indicated by morphology in the ICD-0-2 code need to match with the description in this question—for example, cystadenoma or endometrioid tumor.
- Neoplasm of uncertain behavior of the ovary: Histopathologic Type for Neoplasm of uncertain behavior of the ovary will be designated as "Other." Darken the circle for "Other" and record the histopathologic type on the line provided.
- Extranodal lymphoma arising in the ovary: Histopathologic Type for Extranodal lymphoma arising in the ovary will be designated as "Other." Darken the circle for "Other" and record the specific histopathologic type on the line provided.
- Primary sarcoma of the ovary: Histopathologic Type for Primary sarcoma of the ovary will be designated as "Other". Darken the circle for "Other" and record the specific histopathologic type on the line provided.

Darken the circle corresponding to the histopathologic type of the ovarian cancer. If the histopathologic type is other than those listed, darken the circle for "Other" and specify the histopathologic type. If the histopathologic type is unknown or not available in the record, darken the circle for "Unknown."

**14. Histopathologic Grade for Primary Ovarian Cancer:** This item documents the histopathologic grade of the ovarian cancer diagnosis. Grade refers to a system of classifying certain characteristics of the cell. This information can be obtained directly from the pathology report, which collected the most tissue, cytology report, a TNM form, a staging classification form, the discharge summary, or from doctor's notes.

- If the medical record states two different of histopathologic grades, or a range of grades, record the most severe type. For example, "well differentiated" is the least severe type and "poorly differentiated or undifferentiated" is the most severe type. The most severe grade should be recorded from the primary site. Do not record the most severe grade from the metastatic site.
- Neoplasm of uncertain behavior of the ovary: Neoplasm of uncertain behavior of the ovary usually does not have a grade designation; therefore, "Grade cannot be assessed (GX)" should be recorded. If the medical record contains information about this neoplasm that would result in a specific grade, contact the CC MRA Coordinator.
- Extranodal lymphoma arising in the ovary: If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown." Do not code the descriptions "high grade," "low grade," or "intermediate grade" for lymphomas. These terms refer to categories in the Working Formulation of lymphoma diagnoses and not to histologic grade.
- Primary sarcoma of the ovary: If the grade is specified, darken the corresponding circle. If it is not mentioned or unknown, darken the circle for "Unknown."
- Borderline or low malignant potential tumors must be coded (GB) "borderline malignancy"

Darken the circle corresponding to the histopathologic grade of the ovarian cancer. Darken the circle for "Unknown" when there is no indication in the record of the histopathologic grade or if the diagnosis of ovarian cancer is based on tissue from a metastatic site.

15. **TNM Staging for Ovarian Cancer:** This item refers to the TNM or AJCC (American Joint Committee on Cancer) staging system. The AJCC Manual for Staging of Cancer provides the minimum requirements for clinical and pathologic staging. A list of relevant documentation, based on those requirements can be found below. If TNM staging was performed, darken the circle corresponding to the edition of the AJCC Cancer Staging Manual used, the 4th Edition or the 5th Edition.

**Note:** The 5th Edition of the AJCC manual was published in January 1998. This latest edition should be used to stage all cancers diagnosed on or after January 1, 1998. For all previous cases the 4th Edition should be used.

TNM staging describes the anatomic extent of disease based on three components:

- (1) The extent of the primary tumor (T),
- (2) The absence or presence and extent of regional lymph node metastases (N), and
- (3) The absence or presence of distant metastases (M).

The addition of numbers to these three components indicates the extent of the malignant disease, thus showing progressive increase in tumor size or involvement.

If the TNM staging is available in the medical record, the abstractor may record it directly from the record. This staging is often performed by a Tumor Registrar (also known as a Cancer Registrar) and, if not available in the medical record, it may be available in the tumor registry. If the TNM staging is not available in the tumor registry, the abstractor should attempt to have the stage classified by the Tumor Registrar or a physician at a later date. The Tumor Registrar must be a CTR or CTR eligible. If the TNM staging is not in the records or if the abstractor disagrees with the staging, the CTR may assign the TNM stage when all relevant documentation from the patient's medical record is available to him/her. If an institution does not have a Tumor Registrar, then a physician can assign the TNM stage as long as all relevant patient documentation is available to the physician. *The nosologist or abstractor should not assign the TNM staging, unless s/he is also a CTR (or CTR-eligible) and all relevant documentation is available.*

If a participant receives neoadjuvant therapy prior to surgical resection, NCI would like the abstractors to do Clinical Staging of the Primary Cancer. Then record the TNM Pathologic Staging, using surgical pathology. In this situation TNM Pathologic Staging should be recorded as follows:

- Complete the item for TNM Pathologic Staging using the surgical pathology report.
- Place an asterisk next to the item number and go to the Comments section in Part E.
- Record the item number in the left margin of the Comments section and begin with the phrase, "ypT\_N\_M," including the appropriate numerical stage of the carcinoma which was recorded in Part C, TNM Pathologic Staging. "y" is a TNM descriptor that indicates that staging was performed during or following multi-modal therapy and the "p" indicates pathologic staging. After the appropriate information has been included in the "ypTNM" format, briefly state what treatment was received prior to surgery.

Item E.20, Comments

Item #	Comments:
C.15.b	ypT_N_M_; Treatment received prior to surgery was...

**General Guidelines for NX vs. NO and MX vs. MO:**

The X category should be used when involvement of regional lymph nodes or distant metastatic sites was not evaluated or could not be evaluated. It is not sufficient to assume that an evaluation would have been negative (or positive). If there is a statement in the record documenting the physician's assessment of regional lymph nodes and/or metastatic sites as negative or not involved, without physical examination, imaging or other diagnostic procedures, this may be used to assign 0 rather than X. The use of category 0, as in NO or MO, means that no involvement was found after some type of evaluation including appropriate work-up and/or the physician's clinical impression.

**NOTE:** SCs should photocopy any documents from medical records that are used for TNM staging, and keep these with the participant's file.

**a. TNM Clinical Staging**

If both the clinical and pathological staging are available, both should be recorded. (Generally ovarian cancer involves only pathological staging.) All information available prior to the first definitive treatment of primary ovarian cancer may be used for TNM clinical staging. Relevant documentation, which is suggested to assign clinical staging, includes:

- Laparotomy;
- Chest radiography; and
- Imaging studies, including computed tomography, may be helpful.

**Guidelines for Clinical Staging of the Ovary:**

Although uncommon, ovarian cancer can be clinically staged. However, evaluation of the primary tumor must be done surgically. The clinical T (cT) category cannot be determined on the basis of imaging alone; there must be surgery and there should be histologic confirmation of the disease. A laparotomy is the most widely accepted procedure. Laparoscopy is also acceptable. Clinical studies may include physical examination and history, palpation of abdomen, routine radiography of chest and abdomen, CT, liver studies and hemograms. The clinical staging period includes all information obtained prior to definitive treatment. (*Sources: AJCC manual, 4th and 5th editions, Registrar's Key*)

Darken the circle to indicate whether the TNM clinical staging is available as follows:

**Yes:** If the TNM clinical staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available..

**No:** If no part of the TNM clinical staging is available, then darken the circle for "No" and skip to C.15b, TNM Pathologic Staging.

- Extranodal lymphoma arising in the ovary: Darken the circle for "No." TNM clinical staging does not apply to extranodal lymphoma arising in the ovary.

- Primary sarcoma of the ovary: Darken the circle for "No." TNM clinical staging does not apply to primary sarcoma of the ovary.

**b. TNM Pathologic Staging**

Relevant documentation necessary to assign pathologic staging includes:

- Any data for clinical staging;
- Laparotomy;
- Resection of ovarian masses;
- Hysterectomy; and
- Biopsies of suspicious sites required, for example, omentum, mesentery, liver, diaphragm, and lymph nodes.

Darken the circle to indicate whether the TNM pathologic staging is available as follows:

**Yes:** If the TNM pathologic staging is available, or at least some part of it is available, darken the circle for "Yes" and then darken the circles corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, darken the circle next to "Not available" in the column(s) for which the code is not available.

**No:** If no part of the TNM pathologic staging is available, then darken the circle for "No" and skip to Item C.16, Record Stage.

- Extranodal lymphoma arising in the ovary: Darken the circle for "No." TNM pathologic staging does not apply to extranodal lymphoma arising in the ovary.
- Primary sarcoma of the ovary: Darken the circle for "No." TNM pathologic staging does not apply to primary sarcoma of the ovary.

**16. Record Stage:** *If TNM Pathologic Staging is complete, this item must be skipped. If any part of the TNM Pathologic Staging is not available or is incomplete (i.e., "Tx", "Nx", or "Mx"), this item must be completed.* This item is to document the stage of disease (other than TNM staging) for primary ovarian cancer. There is one stage classification provided for ovarian cancer: "FIGO" (Federation Internationale de Gynecologie et d'Obstetrique).

- If information about stage of disease is not available in the medical record, it is not necessary to try to obtain it from another source.
- If a stage classification other than FIGO is available in the record, and all or part of the TNM Pathologic Staging is not available, place an asterisk beside Item C.16, and record in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

Item E.20, Comments

Item #	Comments
C.16	Other Stage Classification is_____. Stage = ____

- If the stage is available for an extra nodal lymphoma arising in the ovary, for a primary sarcoma of the ovary, or for any other type of primary ovarian malignancy that cannot be staged using TNM, complete Item C.16.

Darken the circle to indicate whether stage of disease is available as follows:

**Yes:** If stage of disease (FIGO staging) is available, darken the circle for "Yes" and record the information in the space provided.

**No:** If no stage of disease is available, darken the circle for "No" and skip to Part E, Physician/Hospital Location Information.

- If no stage of disease information is available, it is not necessary for the abstractor to obtain it from another source. Also, the abstractor should not attempt to code stage of disease unless s/he is a Certified Tumor Registrar (CTR) or is CTR eligible. If the abstractor is a CTR, or is CTR eligible, and has all of the necessary documentation for determining the stage of disease, then s/he may code stage of disease and record it following the guidelines above.

#### **Part D: Date of Diagnostic Evaluation Determination:**

17. Complete this item by recording the month, day and year of the diagnostic evaluation determination if one of the following conditions is satisfied:

- Item A.6 = No malignancy and Items B.7 and B.8 = No or
- Item A.6 = No malignancy and no diagnostic procedures were performed or
- Item A.6 = No information available

Darken the circle corresponding to each number. If the exact day of diagnostic evaluation determination cannot be determined from the record, year and month can usually be assessed. In this situation, record the exact month and year. Record the day as "99". Zero fill month and day, and record four digits for year.

#### **Part E: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant underwent diagnostic evaluation for ovarian cancer, other than what was reported prior to abstracting. Items E.18 and E.19 are not required, but it is recommended that these items be completed to facilitate collection of additional medical record data, including pathology reports and slides. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

18. **Physician for Diagnostic Evaluation:** Record the name, address, and telephone number of the primary physician who provided care during the participant's diagnostic evaluation for ovarian cancer and/or the physician who performed the diagnostic evaluation procedures. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.

19. **Hospital or Clinic for Diagnostic Evaluation:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent one or more diagnostic procedures for ovarian cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.

20. **Comments:** Use this section to record any overflow information. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or the

Principal Investigator should review the discrepant information for the appropriate coding decision prior to calling the CC MRA Coordinator.

*Do not darken the "Yes" or "No" circles at the top of pages 10-12 if Comments continues on these pages. Leave the circles blank. Comments "Yes" "No" circles should only be darkened on page 10 of the form.*

*Darken Comments Continuation circle at the bottom right of page 12 if a Comments Continuation Form (CCF) is required. Do not darken Comments Continuation circles on pages 9-11.*

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as in the following example when a seventh medical complication should be collected:

Item #	Comments
A.4	7; Type = ____; Date = ____

- First enter the item number indicating the item to which the comments are related, and record the comments in the space provided to the right of the item number.
- Throughout these specifications, standard phrases are given to preface comments so they will be easier to locate during analysis. Please use these phrases at the beginning of the comments, if applicable.
- Place an asterisk next to the item number being referenced in the main body of the DEO form.

## ATTACHMENT 1

### A CONCEPTUAL APPROACH TO ABSTRACTING OVARIAN CASES FROM THE PLCO OVARIAN SUBCOMMITTEE-DRAFT

**A. Statement of Problem:** Modifications and revisions in the practice of reporting diagnostic and staging "procedures" on the DEO3 form but not the "approach" has made it difficult to determine the number of various types of surgical procedures performed. This in turn has an impact on the ability to evaluate accurately the cost and health impact of evaluating positive screens. For example, the magnitude of expense and health risk for laparotomy is different from that of laparoscopy. The ovarian subcommittee would like to provide guidance for completing the DEO as described below. The procedures and their codes are unchanged.

#### B. Types of procedures recorded on DEO-3:

1. Radiographic evaluation:

03CXR

21 transabdominal/pelvic ultrasound

22 transvaginal ultrasound

30 transabdominal/pelvic and transvaginal ultrasound combined

04 color doppler

39 ultrasound, other (specify)

01 barium enema

10 IVP

12 lymphangiogram

05 CT abdomen

07 CT pelvis

26 CT abdomen/pelvis combined

27 CT chest

06 CT, other (specify)

13 MRI abdomen

15 MRI pelvis

14 MRI, other (specify)

2. Other evaluation:

25 clinical evaluation

34 record review

36 sigmoidoscopy/colonoscopy

28 hysteroscopy

88 other, specify

3. Pathologic evaluation:

**a. Non-surgical**

08 culdocentesis

- 17 paracentesis
- 37 thoracentesis
- 16 needle aspiration
- 02 biopsy, specify

**b. Surgical**

- 24 abdominal/vaginal hysterectomy
- 29 laparoscopy
- 11 laparotomy

**C. Notes**

1. If a diagnosis of ovarian cancer has been made, the patient will virtually always have had pathological verification of cancer by one or more of the procedures listed under 3a and/or 3b. In rare instances, the diagnosis may have been made clinically, without pathologic confirmation, and procedures may not have been performed. In other circumstances procedures may have been performed but pathology was negative. If ovarian cancer is diagnosed, however, the participant would be expected to have had one or more of the procedures listed in 3a and/or 3b recorded on the Diagnostic Evaluation (DE) form.
2. A diagnosis can be made "non-surgically" in three ways:
  - a. Free fluid obtained from a body cavity via needle: culdocentesis (08), paracentesis (17), or thoracentesis (37).
  - b. Needle aspiration (code 16): This refers to obtaining cells from a solid or solid/cystic mass,
  - c. Biopsy: It is recognized that a biopsy may be obtained surgically and that during surgery, multiple biopsies may be obtained. Code 02 (biopsy, specify) in a patient who does not have a surgical code implies the diagnosis was made without abdominal/pelvic surgery. This will be uncommon, but could include percutaneous needle biopsy of the liver, inguinal lymph node biopsy, etc.
3. A diagnosis of ovarian cancer can be made "surgically" using one of three approaches:
  - a. Abdominal/vaginal hysterectomy (24): An abdominal hysterectomy has to be performed via laparoscopy or laparotomy; therefore, procedure code 24 in the absence of laparoscopy (code 29) or laparotomy (code 11) will imply vaginal hysterectomy. Procedure code 24 in combination with code 29 or code 11 will generally (but not exclusively) be an abdominal hysterectomy,
  - b. Laparoscopy (29).
  - c. Laparotomy (11).
4. Oophorectomy/salpingo-oophorectomy (23), intra-abdominal washings (09), lymphadenectomy/lymph node sampling (30), omentectomy (31 or 32) and resection, specify (35) are performed intraoperatively and should only be used in subjects who have had a laparoscopy (29) or laparotomy (11). Rarely, some of these procedures may have been done through a vaginal approach (24).
5. In some cases, a biopsy (02) may be performed intra-operatively to make a diagnosis in the absence of other procedures such as an oophorectomy.

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM TREATMENT INFORMATION - OVARY (TIO2/TOQ2)

**1. Date Abstracted:**

MO.	DAY	YEAR
		20
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

**2. Abstractor ID #:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**3. CTR ID#:**

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**4. Study Year T0-T13:**

T	0	0
	1	1
	2	2
	3	3
	4	4
	5	5
	6	6
	7	7
	8	8
	9	9

**5. Purpose of Abstract:**

Initial abstract

Re-abstract for QA

### FOR OFFICE USE ONLY

**6.**

#### Form Processing (MARK RESPONSES AS STEPS ARE COMPLETED)

Form Received into SMS   
Manual Review Completed

**Data Entry of Non-Scannable Items:**

Completed  None Required

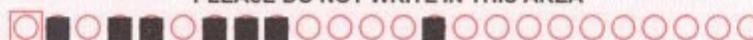
**Data Retrieval:**

Attempted  None Required

**Disposition:**

Interim Complete (ICM)  Final Complete (FCM)  Final Incomplete (FIC)

PLEASE DO NOT WRITE IN THIS AREA



008666

**PART A: INITIAL TREATMENT INFORMATION**

**1. SURGICAL TREATMENT FOR OVARIAN CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

PROCEDURE #	1	2	3	4																																																																																																																																				
<b>TYPE OF SURGICAL PROCEDURE</b> (SEE SURGICAL PROCEDURE CODES BELOW. IF OTHER, SPECIFY)	05 06 08 09 10 11 12 13 14 15 16 88	05 06 08 09 10 11 12 13 14 15 16 88	05 06 08 09 10 11 12 13 14 15 16 88	05 06 08 09 10 11 12 13 14 15 16 88																																																																																																																																				
	SPECIFY	SPECIFY	SPECIFY	SPECIFY																																																																																																																																				
<b>DATE OF SURGERY</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						
MO.	DAY	YEAR																																																																																																																																						
0	0	0																																																																																																																																						
1	1	1																																																																																																																																						
2	2	2																																																																																																																																						
3	3	3																																																																																																																																						
4	4	4																																																																																																																																						
5	5	5																																																																																																																																						
6	6	6																																																																																																																																						
7	7	7																																																																																																																																						
8	8	8																																																																																																																																						
9	9	9																																																																																																																																						

**SURGICAL PROCEDURE CODES**

- |  |  |  |
|--|--|--|
| 05 = Bilateral salpingoophorectomy         | 10 = Adhesiolysis                        | 14 = Omentectomy, partial                    |
| 06 = Unilateral salpingoophorectomy        | 11 = Bowel resection                     | 15 = Resection (SPECIFY)                     |
| 08 = Pelvic exenteration, partial or total | 12 = Lymphadenectomy/Lymph node sampling | 16 = Tumor debulking (Cytoreductive surgery) |
| 09 = Abdominal/vaginal hysterectomy        | 13 = Omentectomy, complete/NOS           | 88 = Other (SPECIFY)                         |

**2. RADIATION TREATMENT FOR OVARIAN CANCER:**

No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2																																																																		
<b>DATE RADIATION TREATMENT BEGAN</b> (MO. - DAY - YEAR)	<table border="1"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th><th>DAY</th><th>YEAR</th></tr> </thead> <tbody> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR	0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		
MO.	DAY	YEAR																																																																		
0	0	0																																																																		
1	1	1																																																																		
2	2	2																																																																		
3	3	3																																																																		
4	4	4																																																																		
5	5	5																																																																		
6	6	6																																																																		
7	7	7																																																																		
8	8	8																																																																		
9	9	9																																																																		

**PART A CONTINUED . . .**

**3. CHEMOTHERAPEUTIC TREATMENT FOR OVARIAN CANCER:**

- No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2																																																																																																																																																
<p>DATE CHEMOTHERAPEUTIC TREATMENT BEGAN</p> <p>(MO. - DAY - YEAR)</p>	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td> </td><td>3</td><td>3</td></tr> <tr><td>4</td><td> </td><td>4</td><td> </td><td>4</td><td>4</td></tr> <tr><td>5</td><td> </td><td>5</td><td> </td><td>5</td><td>5</td></tr> <tr><td>6</td><td> </td><td>6</td><td> </td><td>6</td><td>6</td></tr> <tr><td>7</td><td> </td><td>7</td><td> </td><td>7</td><td>7</td></tr> <tr><td>8</td><td> </td><td>8</td><td> </td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR								0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3		3	3	4		4		4	4	5		5		5	5	6		6		6	6	7		7		7	7	8		8		8	8	9	9	9	9	9	9	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td> </td><td>3</td><td>3</td></tr> <tr><td>4</td><td> </td><td>4</td><td> </td><td>4</td><td>4</td></tr> <tr><td>5</td><td> </td><td>5</td><td> </td><td>5</td><td>5</td></tr> <tr><td>6</td><td> </td><td>6</td><td> </td><td>6</td><td>6</td></tr> <tr><td>7</td><td> </td><td>7</td><td> </td><td>7</td><td>7</td></tr> <tr><td>8</td><td> </td><td>8</td><td> </td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR								0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3		3	3	4		4		4	4	5		5		5	5	6		6		6	6	7		7		7	7	8		8		8	8	9	9	9	9	9	9
MO.		DAY		YEAR																																																																																																																																														
0	0	0	0	0	0																																																																																																																																													
1	1	1	1	1	1																																																																																																																																													
2	2	2	2	2	2																																																																																																																																													
3	3	3		3	3																																																																																																																																													
4		4		4	4																																																																																																																																													
5		5		5	5																																																																																																																																													
6		6		6	6																																																																																																																																													
7		7		7	7																																																																																																																																													
8		8		8	8																																																																																																																																													
9	9	9	9	9	9																																																																																																																																													
MO.		DAY		YEAR																																																																																																																																														
0	0	0	0	0	0																																																																																																																																													
1	1	1	1	1	1																																																																																																																																													
2	2	2	2	2	2																																																																																																																																													
3	3	3		3	3																																																																																																																																													
4		4		4	4																																																																																																																																													
5		5		5	5																																																																																																																																													
6		6		6	6																																																																																																																																													
7		7		7	7																																																																																																																																													
8		8		8	8																																																																																																																																													
9	9	9	9	9	9																																																																																																																																													

**4. OTHER TYPE OF TREATMENT FOR OVARIAN CANCER:**

- No                       Yes (COMPLETE TABLE BELOW)                       Unknown

TREATMENT #	1	2																																																																																																																																																
<p>DATE OTHER TREATMENT BEGAN</p> <p>(MO. - DAY - YEAR)</p>	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td> </td><td>3</td><td>3</td></tr> <tr><td>4</td><td> </td><td>4</td><td> </td><td>4</td><td>4</td></tr> <tr><td>5</td><td> </td><td>5</td><td> </td><td>5</td><td>5</td></tr> <tr><td>6</td><td> </td><td>6</td><td> </td><td>6</td><td>6</td></tr> <tr><td>7</td><td> </td><td>7</td><td> </td><td>7</td><td>7</td></tr> <tr><td>8</td><td> </td><td>8</td><td> </td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR								0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3		3	3	4		4		4	4	5		5		5	5	6		6		6	6	7		7		7	7	8		8		8	8	9	9	9	9	9	9	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td> </td><td>3</td><td>3</td></tr> <tr><td>4</td><td> </td><td>4</td><td> </td><td>4</td><td>4</td></tr> <tr><td>5</td><td> </td><td>5</td><td> </td><td>5</td><td>5</td></tr> <tr><td>6</td><td> </td><td>6</td><td> </td><td>6</td><td>6</td></tr> <tr><td>7</td><td> </td><td>7</td><td> </td><td>7</td><td>7</td></tr> <tr><td>8</td><td> </td><td>8</td><td> </td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.		DAY		YEAR								0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3		3	3	4		4		4	4	5		5		5	5	6		6		6	6	7		7		7	7	8		8		8	8	9	9	9	9	9	9
MO.		DAY		YEAR																																																																																																																																														
0	0	0	0	0	0																																																																																																																																													
1	1	1	1	1	1																																																																																																																																													
2	2	2	2	2	2																																																																																																																																													
3	3	3		3	3																																																																																																																																													
4		4		4	4																																																																																																																																													
5		5		5	5																																																																																																																																													
6		6		6	6																																																																																																																																													
7		7		7	7																																																																																																																																													
8		8		8	8																																																																																																																																													
9	9	9	9	9	9																																																																																																																																													
MO.		DAY		YEAR																																																																																																																																														
0	0	0	0	0	0																																																																																																																																													
1	1	1	1	1	1																																																																																																																																													
2	2	2	2	2	2																																																																																																																																													
3	3	3		3	3																																																																																																																																													
4		4		4	4																																																																																																																																													
5		5		5	5																																																																																																																																													
6		6		6	6																																																																																																																																													
7		7		7	7																																																																																																																																													
8		8		8	8																																																																																																																																													
9	9	9	9	9	9																																																																																																																																													

**5. ANY LOCAL OR REGIONAL RESIDUAL DISEASE LEFT AFTER SURGERY:**

- No                       Yes - Microscopic  
 Yes - Macroscopic <2cm                       Not applicable  
 Yes - Macroscopic ≥ 2 cm                       Unknown



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**TREATMENT INFORMATION - OVARY VERSION 2 (TIO2/TOQ2)**

This form is to be completed by the Medical Record Abstractor and the CTR or CTR-eligible individual. Specifically, the CTR will be required to complete Item A.5 (Any Local or Regional Residual Disease Left After Surgery).

Refer to the General Abstracting Techniques, (Appendix K of the MOOP), for guidelines on general abstracting techniques. Some key guidelines are presented below:

- When abstracting date information for items with multiple treatments, record the dates in the order in which they are found in the medical record.
- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry. If the treatment is considered to be a non-traditional therapy that would not usually be mentioned in a medical record, it is acceptable to take the participant's self-report. In all other cases, a therapy that is not mentioned in the medical record should not be recorded.
- Information about treatment procedures should be collected for the first planned course of treatment (usually within 6 months of the cancer diagnosis). The maximum time period for which medical records could be collected for treatment information is about 1 year from the date of a cancer diagnosis.

This form includes items, which require that data be entered verbatim, such as recording "other (specify)," and recording comments. The abstractor should be sure to use clear and legible handwriting when completing these items.

- If additional space is needed to record treatment information, use the Comments section. Record the same type of data as requested in the treatment table.
- If any item has unclear, discrepant, or conflicting information, review this information with the SC Lead Abstractor, SC Coordinator or Principal Investigator prior to contacting the CC MRA Coordinator.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy black marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
  - Mark only one response for each question, unless the instructions tell you otherwise.
  - Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.
- 

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire form was completed. Month and day should be zero filled and two digits should be recorded for the year (e.g., 02/07/2000). The circles for “2” and “0” have been filled in. Darken the circle corresponding to each remaining number.

If the disposition of the form is “Interim Complete” (see Disposition below), record the date the interim disposition was assigned. When the form is finalized, erase the interim date and record the date the form was completed.

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the TI. If more than one abstractor completes the TI, the SC Lead Abstractor should determine which abstractor is responsible for the content of the form—this abstractor’s ID number should be recorded here. Darken the circles corresponding to the four digits.
3. **CTR ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting Item A.5. (Any Local or Regional Residual Disease Left After Surgery). Darken the circles corresponding to the four digits.
4. **Study Year:** Darken the circles corresponding to the study year, from T0 to T13. Zero fill the number for T0 - T9 (e.g., T00, T01, T02, etc.).
5. **Purpose of abstract:** This form may be used for either the initial abstracting of the medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
  - **Initial abstract:** Medical record information is being abstracted for the “first” time to confirm the treatment of ovarian cancer.

- **Re-abstract for QA:** Medical record information that has already been abstracted to confirm the treatment of ovarian cancer is being re-abstracted for the purpose of quality assurance. Not yet implemented.
6. **Form Processing:** These are the steps that should be completed in order to process the medical record abstract form. All of the items except "Disposition" are optional. "Disposition" is required and may be marked on the form or entered directly into DEES. Dispositions of "Final Complete" (FCM) may also be set automatically in DEES when the form is edited (See DEES User's Guide).
- **Form Received into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively or through the DEES to SMS Update. (Refer to Chapter 17 of the MOOP for instructions on receipting forms.)
  - **Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 of the MOOP for instructions on performing a manual review of forms.)
  - **Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 of the MOOP for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."
  - **Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."
  - **Disposition:** The SC is required to assign a disposition to each opscan form. There is one interim disposition and there are two final dispositions:
    - **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Once all data are abstracted, remove the ICM so that the appropriate disposition is assigned.
    - **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
    - **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.
- The disposition may be assigned in three ways:
- by darkening the bubble on the opscan form and scanning it;
  - by keying the disposition into DEES;
  - by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **Part A: Initial Treatment Information:**

In this section, record all treatments that make up the first course of treatment the participant received for ovarian cancer.

- If the treatment is intended as initial management, it should be recorded regardless of the timeframe or site.
- If the first course of treatment is directed toward a metastatic site, it is appropriate to code this treatment.
- Combination Treatments: If multiple treatments are given in combination, record the date treatment began for the combination treatments. If another treatment is added to this combination (or one is removed), the new combination should be listed as a new treatment entry with a new start date.
- Time period Rules for First Course of Treatment (in order of precedence):
  1. If there is a documented, planned first course of treatment, first course ends at the completion of this treatment plan, regardless of the duration of the treatment plan.
  2. If the patient is treated according to a facility's standards of practice, first course ends at the completion of the treatment.
  3. If there is no documentation of a planned first course of treatment or standard of practice, first course of treatment includes all treatment received before disease progression or treatment failure. If it is undocumented whether there is disease progression/treatment failure and the treatment in question begins more than one year after diagnosis, assume that the treatment is not part of the first course.
  4. If a patient refuses all treatment modalities and does not change his/her mind within a reasonable time frame, or if the physician opts not to treat the patient, record that there was no treatment in the first course.
- If treatment is given for symptoms/disease progression after a period of "watchful waiting," this treatment is not considered part of the first course. For example, if a physician and patient choose a "wait and watch" approach to ovarian cancer or chronic lymphocytic leukemia and the patient become symptomatic, consider the symptoms to be an indication that the disease has progressed and that any further treatment is not part of the first course.
- All modalities of treatment are included regardless of sequence or the degree of completion of any component method.

Reference: SEER Program Code Manual, Third Edition. Bethesda, MD: National Institutes of Health, National Cancer Institute; 1998, p.119.

- If there is a significant treatment that is not in the first course of treatment and the abstractor and the SC Principal Investigator feel it should be recorded, this will need to be sent to the CC MRA Coordinator. The relevant medical records should be copied (identifiers deleted) and sent to the CC MRA Coordinator with a memo describing the issue.
1. **Surgical Treatment for Ovarian Cancer:** This item is concerned with the surgical treatment that the participant received for ovarian cancer. Darken the circle corresponding to whether the participant received surgical treatment as follows:

**No:** The record clearly states that the participant did not receive surgical treatment, or there is no mention of surgical treatment (planned or given) in the records. Darken the circle for "No" and go to Item 2.

**Yes:** The record indicates that the participant received surgical treatment. Darken the circle for "Yes" and complete the table for Item 1. For each surgical procedure performed, complete the following items:

- **Type of Surgical Procedure:** Darken the circle corresponding to the type of surgical procedure performed. Refer to the Surgical Procedure Codes for the list of common surgical procedures for ovarian cancer. If the participant had a surgical procedure other than those listed, darken the circle for "Other (SPECIFY)" and record the surgical procedure performed on the line provided.

If surgical resection with removal of lymph nodes is performed, this should be coded as two *separate* procedures. Code the resection appropriately (such as 05 = bilateral salpingo-oophorectomy) and the lymph node removal as 12 = Lymphadenectomy/ lymph node sampling.

- **Date of Surgery:** Record the month, day and year that the surgical procedure was performed. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional surgical procedures, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional surgical treatment in Comments would be the fifth surgical treatment recorded:

Item B.8, Comments:

Item #	Comments
A.1	5; Type = ____; Date = ____

**Unknown:** The record states that a surgical treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 2.

2. **Radiation Treatment for Ovarian Cancer:** This item is concerned with the radiation treatment the participant received. Radiation treatment most commonly consists of either external photon beam therapy or brachytherapy (intraperitoneal implant). More rarely, radiation treatment may consist of either neutron or proton external beam therapy. Note that this item is concerned with radiation treatment and not diagnostic x-rays such as a CT scan.

External photon beam therapy is delivered by a machine, which generates x-rays or contains a large amount of a radioactive isotope (cobalt), or delivered by a linear accelerator. External beam treatments are given in one or more "series" or "courses." Each course of radiation is administered over a period of days or weeks in small daily doses.

Brachytherapy is a method of radiotherapy in which radioactive sources are applied on the external surface of the patient, implanted in tissue, or inserted into body cavities. Brachytherapy procedures usually are performed in an operating room since they require anesthesia. Although the brachytherapy treatment may be performed in a surgical suite and recorded in surgical notes, it is radiotherapy and should be recorded as such for purposes of describing the participant's treatment.

Some institutions may have the capability to deliver neutron beam therapy, via a hospital based high-energy cyclotron, or proton beam therapy, via a hospital-based synchrotron. Treatment via these modalities is usually administered in "courses" or "series" over a period of time. Most institutions, however, find these machines impractical for a hospital setting due to their cost and size.

Darken the circle corresponding to whether the participant received radiation treatment as follows:

**No:** The record clearly states that the participant did not receive radiation treatment, or there is no mention of radiation treatment (planned or given) in the records. Darken the circle for "No" and go to Item 3.

**Yes:** The record indicates that the participant received radiation treatment. Darken the circle for "Yes" and complete the table for Item 2. Record information for each course of radiation treatment received in a separate column. For each radiation treatment received, complete the following:

- **Date Radiation Treatment Began:** Record the month, day and year that the radiation treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional radiation treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional radiation treatment in Comments would be the third radiation treatment recorded:

Item B.8, Comments:

Item #	Comments
A.2	3; Date = ____

**Unknown:** The record states that radiation treatment is planned but then there is no mention of whether or not it was actually given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 3.

3. **Chemotherapeutic Treatment for Ovarian Cancer:** This item is concerned with any chemotherapeutic treatment the participant received. Chemotherapeutic treatment is the use of drugs given as treatment for cancer. Chemotherapeutic treatment may be the primary treatment, prescribed in cases of advanced cancer, or may be an adjuvant treatment, given in addition to surgery and/or radiation.

The participant's medical record may or may not contain chemotherapeutic treatment data. Unlike surgery and radiation, treatments, which must be performed at a hospital

or clinic, chemotherapeutic treatment may be administered at a physician's office or self-administered under the guidance and supervision of a physician. It is, therefore, especially important that the abstractor carefully review the record and, if necessary, contact the physician for information on chemotherapeutic treatment.

Darken the circle corresponding to whether the participant received chemotherapeutic treatment as follows:

**No:** The record clearly states that the participant did not receive chemotherapeutic treatment, or there is no mention of chemotherapeutic treatment (planned or given) in the records. Darken the circle for "No" and go to Item 4.

**Yes:** The record indicates that the participant received chemotherapeutic treatment. Darken the circle for "Yes" and complete the table for Item 3. For each protocol of chemotherapeutic treatment received, complete the following:

- **Date Chemotherapeutic Treatment Began:** Record the month, day and year that the chemotherapeutic treatment was begun for a particular course. If the day is not clear, year and month can usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record additional chemotherapeutic treatments, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional chemotherapeutic treatment in Comments would be the third chemotherapeutic treatment recorded:

Item B.8, Comments:

Item #	Comments
A.3	3; Date = _____

**Unknown:** The record states that chemotherapeutic therapy is planned but then there is no mention of whether or not it is given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 4.

4. **Other Type of Treatment for Ovarian Cancer:** This item is concerned with any treatment other than surgery, radiation, and chemotherapeutic treatment that the participant received for ovarian cancer. Other types of treatment include autologous bone marrow transplant and alternative treatments.

Darken the circle corresponding to whether the participant received some other type of treatment as follows:

**No:** The record clearly states that the participant did not receive any other type of treatment, or there is no mention of other treatments (planned or given) in the records. Darken the circle for "No" and go to Item 5.

**Yes:** The record indicates that the participant received some other type of treatment. Darken the circle for "Yes" and complete the table for Item 4. For each type of treatment received, complete the following:

- **Date Other Treatment Began:** Record the month, day and year that the other type of treatment began. If the day is not clear, year and month can

usually be assessed, even if the exact day cannot be determined. In this situation, record the exact month and year. Record the day as "99." Darken the circle corresponding to each number. Zero fill month and day, and record four digits for year.

If space is needed to record other type of treatments for ovarian cancer, use the Comments section to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, the first additional other type of treatment for ovarian cancer in Comments would be the third other type of treatment for ovarian cancer recorded:

Item B.8, Comments:

Item #	Comments
A.4	3; Date = _____

**Unknown:** The record states that an "other" type of treatment is planned but then there is no mention of whether or not it is given. This code should also be used if the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 5.

5. **Any Local or Regional Residual Disease Left After Surgery:** This item is to be completed only by a CTR or a CTR-eligible individual. This item documents whether the participant had any local or regional residual disease left after surgery. Record information for this item for any attempted surgical procedure even if the procedure was not completed. Surgery is defined as any of the surgical procedures listed in Item 1. If there are multiple surgeries, use the last surgery in the first course of treatment. Regional residual disease is defined as a cancer that remains after surgery and is related to the original site by direct extension. This regional disease refers to the site of the surgery (not necessarily the site of the primary cancer). It does not apply to metastases. Information should be taken from the pathology report since this is the most definitive source for determining residual disease and the operative report may be used for further clarification. If neither pathology nor operative reports are available, a discharge summary or doctor's note with treatment plan may be used to record this item. "Perineural or vascular invasion" noted on a surgical pathology report, does not infer that regional or residual disease is left after surgery. The pathology report refers only to the specimen or tissue removed during surgery, not to tumor that remains following surgery. Darken the circle corresponding to whether the participant had any local or regional residual disease left after surgery as follows:

**No:** The record indicates that the participant had no local or regional residual disease left after surgery. Darken the circle for "No" and go to Item 6.

**Yes - Macroscopic < 2 cm:** The record indicates that the participant had local or regional residual disease left after surgery that was macroscopic (visualized with the naked eye), and less than 2 centimeters in size. The pathology report may state "gross residual disease remaining" or "optimal debulking."

**Yes - Macroscopic > 2 cm:** The record indicates that the participant had local or regional residual disease left after surgery that was macroscopic (visualized with the naked eye), and greater than or equal to 2 centimeters in size. The pathology report may state "gross residual disease remaining" or "suboptimal debulking."

**Yes - Microscopic:** The record indicates that the participant had local or regional residual disease left after surgery that was microscopic (of minute size). The pathology report may state "tumor to surgical margin."

If more than one of these responses is noted in the record, the highest order of evidence should be coded. For example, if the operative report notes that gross disease < 2 cm remains, then the "macroscopic < 2cm" response should be coded. But if the report notes that there were positive surgical margins without gross evidence of disease, the "microscopic" response should be used.

**Not applicable:** The participant did not receive any surgical treatment for ovarian cancer or Item A.1, Surgical Treatment for Ovarian Cancer, is "No" or "Unknown." Darken the circle for "Not applicable" and go to Item 6.

**Unknown:** The record does not mention if the participant had local or regional residual disease left after surgery, or the record clearly states that this information is unknown. Darken the circle for "Unknown" and go to Item 6.

### **Part B: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant received treatment for ovarian cancer. Items B.6 and B.7 are not required, but it is recommended they be completed to facilitate collection of additional medical record data. This section also includes a comments item for recording additional information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the comments item will be entered.

6. **Physician for Treatment:** Record the name, address, and telephone number of the primary physician who provided care during the participant's treatment for ovarian cancer and/or the physician who provided or administered the treatment. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.
7. **Hospital or Clinic for Treatment:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent treatment for ovarian cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.
8. **Comments:** Use this section to record comments and any overflow information while abstracting from the participant's medical record. Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should review the discrepant information for the appropriate coding decision prior to contacting the CC MRA Coordinator.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as follows. First enter the item number indicating the item to which the comments are related, record the comments in the space provided to the right of the item number as in the following example when a fifth surgical procedure for ovarian cancer should be collected:

Item #	Comments:
A.1	5; Type = ____; Date = ____

Place an asterisk next to the item number being referenced in the main body of the TIO form. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

## **A-8-5**

A-8-5: Other Cancer Confirmation Form (OCF)

Specifications for the Other Cancer Confirmation  
Form

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

## OTHER CANCER FORM (OCF/OCQ) CONFIRMATION OF CANCERS OTHER THAN PLCO

<b>1. Date Abstracted:</b> MO. DAY YEAR	0 0 0 0	9 0 0 0
	1 1 1 1	1 1 1 1
	2 2 2 2	2 2 2 2
	3 3 3 3	3 3 3 3
	4 4 4 4	4 4 4 4
	5 5 5 5	5 5 5 5
	6 6 6 6	6 6 6 6
	7 7 7 7	7 7 7 7
	8 8 8 8	8 8 8 8
	9 9 9 9	9 9 9 9

<b>2. Satellite Center:</b>	0 0
	1 1
	2 2
	3 3
	4 4
	5 5
	6 6
	7 7
	8 8
	9 9

<b>3. Abstractor ID#:</b>	0 0 0 0
	1 1 1 1
	2 2 2 2
	3 3 3 3
	4 4 4 4
	5 5 5 5
	6 6 6 6
	7 7 7 7
	8 8 8 8
	9 9 9 9

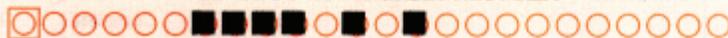
<b>4. Study Year:</b> T	0 0
	1 1
	2 2
	3 3
	4 4
	5 5
	6 6
	7 7
	8 8
	9 9

<b>5. Purpose of Abstract:</b>
<input type="radio"/> Initial abstract
<input type="radio"/> Re-abstract for QA

### PART A: CONFIRMATION OF CANCER

<b>6. Result of Confirmation of Reported Non-PLCO Cancer (MARK ONLY ONE):</b> <input type="radio"/> Primary Non-PLCO Cancer <input type="radio"/> Metastatic Site - Unknown Primary <input type="radio"/> Metastatic Site - PLCO Primary (GO TO ITEM A.7) (GO TO ITEM A.6a)	<b>10. Basis of Diagnosis: (MARK ONLY ONE)</b> <input type="radio"/> Histology <input type="radio"/> Cytology <input type="radio"/> Radiology <input type="radio"/> Other (SPECIFY): _____																																																																																																				
		<b>6a. Type of PLCO Cancer (MARK ONLY ONE):</b> <input type="radio"/> Prostate <input type="radio"/> Lung <input type="radio"/> Colorectum <input type="radio"/> Ovary (GO TO ITEM A.12)																																																																																																			
<b>7. Date of Cancer Diagnosis:</b> MO. DAY YEAR <table border="1"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<b>8. ICD-O-2 Cancer Classification of Primary Cancer:</b> <table border="1"> <tr> <th>CTR ID#</th> <th>Topography</th> <th>Morphology</th> <th>Behavior</th> <th>Grade</th> </tr> <tr> <td>0 0 0 0</td> <td>C</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>1 1 1 1</td> <td>C</td> <td>0 0 0 0</td> <td>-</td> <td>0</td> </tr> <tr> <td>2 2 2 2</td> <td>1 1 1 1</td> <td>1 1 1 1</td> <td>1</td> <td>1</td> </tr> <tr> <td>3 3 3 3</td> <td>2 2 2 2</td> <td>2 2 2 2</td> <td>2</td> <td>2</td> </tr> <tr> <td>4 4 4 4</td> <td>3 3 3 3</td> <td>3 3 3 3</td> <td>3</td> <td>3</td> </tr> <tr> <td>5 5 5 5</td> <td>4 4 4 4</td> <td>4 4 4 4</td> <td>4</td> <td>4</td> </tr> <tr> <td>6 6 6 6</td> <td>5 5 5 5</td> <td>5 5 5 5</td> <td>5</td> <td>5</td> </tr> <tr> <td>7 7 7 7</td> <td>6 6 6 6</td> <td>6 6 6 6</td> <td>6</td> <td>6</td> </tr> <tr> <td>8 8 8 8</td> <td>7 7 7 7</td> <td>7 7 7 7</td> <td>7</td> <td>7</td> </tr> <tr> <td>9 9 9 9</td> <td>8 8 8 8</td> <td>8 8 8 8</td> <td>8</td> <td>8</td> </tr> <tr> <td></td> <td>9 9 9 9</td> <td>9 9 9 9</td> <td>9</td> <td>9</td> </tr> </table>	CTR ID#	Topography	Morphology	Behavior	Grade	0 0 0 0	C	-	-	-	1 1 1 1	C	0 0 0 0	-	0	2 2 2 2	1 1 1 1	1 1 1 1	1	1	3 3 3 3	2 2 2 2	2 2 2 2	2	2	4 4 4 4	3 3 3 3	3 3 3 3	3	3	5 5 5 5	4 4 4 4	4 4 4 4	4	4	6 6 6 6	5 5 5 5	5 5 5 5	5	5	7 7 7 7	6 6 6 6	6 6 6 6	6	6	8 8 8 8	7 7 7 7	7 7 7 7	7	7	9 9 9 9	8 8 8 8	8 8 8 8	8	8		9 9 9 9	9 9 9 9	9	9
0	0	0	0																																																																																																		
1	1	1	1																																																																																																		
2	2	2	2																																																																																																		
3	3	3	3																																																																																																		
4	4	4	4																																																																																																		
5	5	5	5																																																																																																		
6	6	6	6																																																																																																		
7	7	7	7																																																																																																		
8	8	8	8																																																																																																		
9	9	9	9																																																																																																		
CTR ID#	Topography	Morphology	Behavior	Grade																																																																																																	
0 0 0 0	C	-	-	-																																																																																																	
1 1 1 1	C	0 0 0 0	-	0																																																																																																	
2 2 2 2	1 1 1 1	1 1 1 1	1	1																																																																																																	
3 3 3 3	2 2 2 2	2 2 2 2	2	2																																																																																																	
4 4 4 4	3 3 3 3	3 3 3 3	3	3																																																																																																	
5 5 5 5	4 4 4 4	4 4 4 4	4	4																																																																																																	
6 6 6 6	5 5 5 5	5 5 5 5	5	5																																																																																																	
7 7 7 7	6 6 6 6	6 6 6 6	6	6																																																																																																	
8 8 8 8	7 7 7 7	7 7 7 7	7	7																																																																																																	
9 9 9 9	8 8 8 8	8 8 8 8	8	8																																																																																																	
	9 9 9 9	9 9 9 9	9	9																																																																																																	
<b>9. Verbatim Description of Cancer Diagnosis:</b>     	<b>11. Photocopy of Report Confirming Cancer Attached?</b> <input type="radio"/> No <input type="radio"/> Yes																																																																																																				
	<b>12. Reported Metastatic Sites:</b> <input type="radio"/> None Reported (GO TO PART B) Record Up to Three Sites: Site: _____ <table border="1"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table> Site: _____  <table border="1"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table> Site: _____	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9																																								
	0	1	2	3	4	5	6	7	8	9																																																																																											
	0	1	2	3	4	5	6	7	8	9																																																																																											
0	1	2	3	4	5	6	7	8	9																																																																																												
0	1	2	3	4	5	6	7	8	9																																																																																												
0	1	2	3	4	5	6	7	8	9																																																																																												
0	1	2	3	4	5	6	7	8	9																																																																																												

PLEASE DO NOT WRITE IN THIS AREA



011200



## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE OTHER CANCER FORM (OCF/OCQ)

The purpose of the Other Cancer Form (OCF) is to document the SC investigation of non-PLCO cancers reported by the participant on the ASU, reported by a relative, friend or physician, identified by the SC during the completion of a Diagnostic Evaluation Form or identified during the death review process. Cancer diagnosis information such as ICD-O-2 code will be recorded on this form for primary cancers other than prostate, lung, colorectum and ovary. This form will also be used to document up to three metastatic sites when the primary cancer is unknown or if a metastatic cancer was erroneously reported as a primary cancer.

The OCF should be completed by the Medical Record Abstractor, and a Tumor (or Cancer) Registrar who is also a Certified Tumor Registrar (CTR) or CTR eligible. Specifically, the Abstractor will complete all items on the form, with the exception of medical coding. The medical coding item, Item A.8A.10, ICD-O-2 Cancer Classification of Primary, is to be completed by the CTR. All items may be completed by the Abstractor if s/he is also a CTR or CTR-eligible.

For guidelines on general abstracting techniques, refer to the General Abstracting Techniques, (Appendix K of the PLCO Manual of Operations and Procedures). Some key guidelines are presented below:

- This form includes items that require that data be entered verbatim, such as recording the cancer diagnosis and recording comments. The abstractor should be sure to use clear and legible handwriting when completing these items.
- If the medical record contains unclear, discrepant, or conflicting information for any item, the SC Lead Abstractor, SC Coordinator and/or Principal Investigator should first be consulted for a resolution and for making an appropriate coding decision, prior to contacting the CC MRA Coordinator.
- Tumor registry information may be used to help obtain additional source documents, but PLCO abstracts should not be completed on the basis of a tumor registry abstract.

Below are some specific guidelines for the collection of information about "other cancers" using this form:

- This form is to be completed only for a non-PLCO cancer diagnosed *after* the participant is enrolled in the study. If a participant reports a "cancer" after randomization that, upon investigation, is found to be a primary cancer, a metastasis from a primary cancer, or an active recurrence of a primary cancer, that was diagnosed *before* randomization, a Missing Data Form, with a reason code E (Erroneous Report of Cancer) should be completed in place of the OCF. If the primary cancer that was found to have been diagnosed before randomization is a PLCO cancer, an Administrative Tracking Form should also be completed to document the participant as a randomized ineligible. (See MOOP Chapter 4).
- NCI is interested in documenting detailed information, such as ICD-O-2 code and date of diagnosis, about primary cancers only. The SC's responsibility is to document the result of the investigation of each report of "cancer." When a participant, relative, etc. reports a cancer, the SC must first investigate whether it is primary, metastatic or an erroneous report. It is possible that the participant may report several "cancers" but upon investigation, it is determined that one or more of them is actually a metastatic site, not a primary cancer that was diagnosed after randomization and is previously confirmed. The SC is not required to complete an

OCF for multiple primaries of the same organ or subsequent primaries of the same organ (i.e. breast or skin). Repeat reports of confirmed primary cancers will be considered by SMS as “previously confirmed.” Should there be an expectation for an OCF for a primary cancer that was previously confirmed (such as a report of cancer that was really metastasis), a MDF with a code of E can be receipted.

When a cancer is reported on the ASU, in person, via phone, etc., the three-digit cancer code (from Appendix I of the MOOP) is recorded in the SMS and an expectation for an OCF is set. These OCF expectations are reflected on the Cancer Confirmation List. The expectation for an OCF **should first trigger an investigation by the SC. The result of the investigation should be recorded in Item A.6 of the OCF or a MDF may be completed if the original report was erroneous.**

- A separate OCF should be completed for each primary non-PLCO cancer diagnosed after randomization. If the investigation of the reported cancer reveals a metastasis from an unknown primary, the site and date of diagnosis of the metastasis will be recorded on the OCF.
- If a reported “cancer” is confirmed to be a primary non-PLCO cancer, the SC will not be required to complete another OCF for any subsequent reports of this cancer. The SC will not complete an OCF for any subsequent metastasis of cancer previously reported with an OCF completed. For multiple reports of a cancer that has been confirmed as a metastatic site in a previous study year, the SC will be required to determine (via a method chosen by the SC such as a review of diagnosis dates, contact with the participant, review of medical records, etc.) whether the cancer is the same metastatic disease which will require completion of an OCF-MDF or a new primary that would require the SC to complete another OCF. Only one OCF is expected per non-PLCO primary cancer (to include its metastases).

**Note:** Confirmed metastatic cancers in SMS will not be automatically updated by keying the same cancer site off the ASU in subsequent study years. Only confirmed primary cancers will be automatically updated in SMS by keying in the same cancer site off the ASU.

- When a non-PLCO cancer is reported via a Diagnostic Evaluation form, the ICD-9 code recorded in the non-PLCO Cancer Diagnosis section of the DE form will be translated into the three-digit cancer code and an expectation for an OCF will be set for that cancer.
- If, upon review of the medical record to confirm a reported other “cancer,” for example, it was found that there was no cancer, an OCF should not be completed. In this situation an MDF should be completed for an erroneous report of cancer.
- While confirming a reported non-PLCO cancer, if the primary cancer site is identified to be a PLCO site, it is necessary to indicate this in Items A.6 and A.6a of the OCF. Depending on whether or not the PLCO cancer was confirmed in the past, it may or may not be necessary to complete a DE form for the PLCO cancer. For example:

The SC reviews the medical record to confirm a reported liver cancer, and finds that the primary cancer site was prostate. The circle for prostate should be darkened in Item 6a. If the liver cancer was a metastasis from a prostate cancer that was already confirmed in the study (the cancer status code is “C”), then a new DE is not required. If the prostate cancer had never been confirmed in the study, a DEP form is now required.

- Item 12, Reported Metastatic Sites: The following three scenarios may be present following additional investigation of the medical records:
  - A cancer which was initially reported to be a primary is determined to be metastatic; or
  - The primary cancer is unknown but there are documented metastases; or
  - Metastases which were not initially reported as cancer (e.g., on the ASU or verbally) are later found during review of the records.

An OCF should be used only to document metastases in the first two scenarios above. In these cases, the metastases *should* be documented. If this is an unknown primary, record the Date of Diagnosis, Item A.7, as the date of the first metastasis diagnosis, and listing the metastases codes in Item A.12. Up to three metastatic sites may be recorded on one OCF. In a single study year, if there were more than three “cancers” reported to the SC that are metastases from the same primary cancer, the SC should contact the CC for an appropriate resolution. Although it is important to collect information about metastatic disease for the death review process, NCI requires the recording of metastatic cancers from unknown primaries only.

- There is no “window” for abstracting information about non-PLCO cancers, it is expected that once the SC is notified of the non-PLCO cancer, that every attempt should be made to investigate and complete the OCF, if appropriate, in a timely manner.
- If the cancer is confirmed by both a histopathology and a cytology report, information from the earliest procedure with adequate tissue, should be abstracted onto the OCF. medical record abstraction should be taken from the pathology report. Histology provides a more definitive diagnosis; therefore, every attempt should be made to verify if one exists. If multiple procedures with histology were performed and the earliest does not have a confirming histology report, a later procedure with a confirming histology report, should be used to code the ICD-O-2 Cancer Diagnosis. Other items must be coded from the earliest procedure, using other documentation, such as physician’s notes or progress reports. If the cancer is confirmed by cytologic diagnosis alone, then information should be taken from the earliest procedure with cytology. If the cancer is confirmed by clinical examination and diagnostic tests such as radiology, information may be taken from the earliest report if no histology or cytology report exists. NCI is interested in the earliest procedure with histology that gave a definitive diagnosis of cancer *and* also wants the most complete picture of the cancer. The earliest procedure with adequate histology is determined by date whereas the most complete picture of cancer is determined through a confirming histology report. Therefore, it is acceptable to use different sources to code these items.

Incorrectly coded cancers, that were entered into the cancers table from the ASU, should always be cleaned up prior to receipting the OCF. This should be done under the direction of the Lead Medical Record Abstractor. If the OCF was already receipted, the following steps should be taken to correct the ASU cancer code:

- The related OCF should be deleted.
- The original ASU should be deleted.
- The hardcopy ASU should be updated with the correct cancer code. This change should be initialed and dated.
- Re-receipt the ASU.

- Re-receipt the OCF.

The SC should review the Cancer Status screen after each step to verify that the updates took place as expected. If all of these steps are followed and there is still a problem with the cancer codes or expectations, the SC should contact User Support.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy black marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the upper right-hand corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

**Date Abstracted:** Record the date the medical record was abstracted. This is the date the entire OCF form was completed. Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1999). Darken the circle corresponding to each number.

If the disposition of the form is "Interim Complete" (see Disposition below), record the date the interim disposition was assigned. When the form is finalized, erase the interim date, record the date the form was finalized, and darken the circles accordingly.

1. **Satellite Center:** If the participant is assigned to a satellite center for the PLCO Trial, enter the 2-digit Satellite Center ID, and darken the circle corresponding to each number. If the participant is not assigned to a satellite center, leave this item blank.
2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the OCF. If more than one abstractor completes the OCF, the SC Abstractor should determine which abstractor is responsible for the content of the form -- it is this abstractor's ID number which should be

recorded here. If this abstract is for QA (see Item 5), this should be the QA abstractor's ID number. Darken the circles corresponding to the four digits.

- The CTR should not record his/her ID number in this item. There is space for the CTR to record his/her own staff ID number for the specific item which s/he completes.
3. **Study Year:** Record the study year, T0 to T10 T13. This is the study year in which the SC was notified of a suspicion of cancer. For example, if the cancer was reported:
- on a T1 ASU, the study year is T1;
  - by telephone in year T0, the study year is T0; or
  - on a T2 DEP, the study year is T2.

Darken the corresponding circles. Remember to right justify and zero-fill the number for study years T0 - T9 (e.g., T00, T01, T02, etc.).

4. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract as follows:
- **Initial abstract:** Medical record information is being abstracted for the "first" time to confirm a suspicion of cancer. If this bubble is darkened, the form type is considered to be "OCF."
  - **Re-abstract for QA:** Medical record information that has already been abstracted to confirm a suspicion of cancer is being re-abstracted for the purpose of quality assurance. If this bubble is darkened, the form type is considered to be "OCQ." Not yet implemented.

#### **Part A: Confirmation of Cancer:**

5. **Result of Confirmation of Reported Non-PLCO Cancer:** This item should be completed after the SC has investigated the reported cancer(s) and determined the primary cancer. Refer to the SMS report listing "other" cancers to be confirmed. PLCO cancers should not be listed on this report. Record the type of cancer to be verified as it is reported. Then assign the 3-digit code corresponding to the type of cancer. Refer to Appendix I of the Manual of Operations and Procedures (MOOP) for the list of Cancer Codes. Record the code in the boxes under "Cancer Code" then darken the circle corresponding to each number in the code. Only one circle may be darkened.

Complete this item as follows:

- **Primary Non-PLCO Cancer:**
  - The investigation of the reported "cancer(s)" reveals a primary non-PLCO cancer confirmed by histologic examination (study of tissue), cytologic examination (study of cells), clinical examination only, or clinical investigation (such as radiography, immunologic or biologic tests, exploratory surgery, etc.).
  - If the primary cancer was confirmed by both histologic and cytologic examination, information should be abstracted only from the earliest histology report, with an adequate sample, even if it has a later date than the cytology report. The histology report is more definitive, and therefore, every attempt should be made to verify if one exists before utilizing cytologic confirmation. Other documents such as physician's notes or progress reports may be used as confirmation of histologic diagnosis. If the primary cancer was confirmed by cytologic examination alone, then cancer diagnosis information should be taken from the cytology/cytopathology report.

In all cases, darken the circle and go to Item A.7, Date of Cancer Diagnosis.

- **Metastatic Site – Unknown Primary:** Darken this circle when the investigation of the reported “cancer(s)” reveals that the primary cancer could not be identified. Item 12 must have at least one metastatic site entered. In the case of an unknown primary with a PLCO metastatic cancer site, darken this circle and record the PLCO metastasis in Item 12. *The SMS and DEES options may reject the receipt of this data. (See the Attachment - OCF Forms with an Unknown Primary) for additional instructions. Go to Item A.7, Date of Cancer Diagnosis.*
- **Metastatic Site – PLCO Primary:** Darken this circle when the investigation of the reported “cancer(s)” reveals a primary PLCO cancer. Go to Item A.6a, to record the type of PLCO Cancer.

6a. **Type of PLCO Cancer:** If the reported cancer is a metastatic site of a PLCO primary cancer, darken a circle to indicate whether the primary cancer site was prostate, lung, colon, rectum or ovary. If the site is colon or rectum, darken the circle for “colorectum.” Completion of this item and receipt of the OCF will set the expectations for confirmation of the PLCO cancer and receipt of a DE form. If the PLCO cancer was already diagnosed and confirmed (and the SMS carries a cancer status of “Confirmed”), an additional DE form will not be required.

Darken only one circle. If the result of the investigation of a non-PLCO “cancer” revealed more than one primary PLCO cancer, record one primary PLCO cancer in this item. Enter the second PLCO cancer into the Participant Status screen in the SMS, with an identification source of “OTH” for Other. This will set the expectations for confirmation of the second PLCO cancer.

Go to Item A.12 to record any reported primary cancers that were later determined to be metastases.

*In the event that more than one primary cancer is identified at a particular site, only record information about the first primary cancer (chronologically) at that site in Items A.7 through A.11.*

6. **Date of Cancer Diagnosis:** Record the month, day and year of the cancer diagnosis that is confirmed by pathology/histology or cytology/cytopathology report. If the primary cancer is known, this should be the date the primary cancer was first diagnosed. If the primary cancer is unknown, this should be the first date of diagnosis for a metastasis from the unknown primary. This is the date on the report that the actual procedure was performed that confirmed this cancer diagnosis. If there are multiple reports that confirmed this cancer, record the earliest date available.
- If both a histology and cytology report are available confirming the cancer diagnosis, use the earliest histology report, with an adequate specimen, that provides definitive information for a cancer diagnosis. In most instances, the histology report should be used as the source for recording information, even if the histology report has a later date than the cytology report. If only a cytology report is available, then record the date from that report. If only a radiographic report or a report from some other diagnostic examination is available and there is no pathology report, record the date from the available report.
  - If a report that confirms Date of Cancer Diagnosis is unavailable, you may use another source from the medical record to complete this item. Examples of sources include physician’s notes, admission notes, history and physical, discharge summary, or surgical pathology report with a reference to the prior slide from the biopsy (with date of collection).

- In the rare occasion where the cancer is diagnosed by clinical examination only and not pathologically or cytologically, the date of the cancer diagnosis is the date of the clinical examination during which the cancer was diagnosed.
- Zero fill month and day, and record four digits for year. Month and year of primary cancer diagnosis must be known, however, if the day is unknown, record "99." Darken the circle corresponding to each number.

7. **ICD-O-2 Cancer Classification of Primary Cancer:** This item is for classifying the physician diagnosis of the primary cancer according to ICD-O-2 (*International Classification of Diseases for Oncology*, Second edition, 1990).

*This item is to be completed by a Tumor Registrar who is a Certified Tumor Registrar (CTR) or CTR eligible. The CTR should code the ten digit ICD-O-2 classification in the space provided. The CTR should also record his/her four-digit ID# in the space provided for "CTR ID#". If the Abstractor is also the CTR, this ID # may be the same as that recorded in the administrative section of the form.*

The ICD-O-2 code is used to identify the type of non-PLCO cancer to the SMS. Therefore, this item must be completed in order to receipt the OCF into the SMS and to turn off expectations for other cancer confirmation.

Darken the circles corresponding to each number or letters for each.

- The ICD-O-2 code should reflect the diagnosis from the *earliest* (chronological) histology report (or cytology report if the histology report is not available) with the initial definitive diagnosis. This item *must* be coded from histology, with an adequate sample, that has a confirming report in the medical record. If multiple procedures with histology were done, and the earliest does not have a confirming histology report, a later procedure with histology and a confirming histology report should be used to code this item. Other sources, [i.e. cytology report, physician's notes, admission notes, history and physical, discharge summary, or surgical pathology report with a reference to the prior slide from the biopsy (with date of collection)], may not be used to code this item. The source used to code this item may not be the same source used to code the Date of Diagnosis in Item A.7
  - Extranodal lymphomas arising in an "other cancer" may require the T-cell, B-cell, or NK cell designation. If so, enter the appropriate code from ICD-O-2 in the "Grade" space. The T-cell, B-cell or NK cell designation has priority over the grade when both are provided. NK cell designation = "8". A circle for "8" does not exist on the form. Darken the space for "8" under "Grade" for NK cell if this applies. *Refer to Appendix K of the MOOP for further definition of Nodal vs. Extra-nodal Lymphomas.*
  - If the primary cancer is unknown, the topography section of the ICD-O-2 code should be C809.
  - The ICD-O-2 cancer classification should be coded by the CTR, if the required documents are available in the medical record.
8. **Verbatim Description of Cancer Diagnosis:** This item is concerned with the actual physician diagnosis of the primary cancer. This item is optional except in the following situations:
- The diagnosis is based on clinical examination or clinical investigation (such as radiography), and not histology or cytology; or

- The SC is unable to obtain a copy of the histology, cytology, radiology, or other report that corresponds to the ICD-O-2 code in Item A.8.

Record the verbatim description of the primary cancer diagnosis from the report confirming the cancer. In the case of histology/cytology, the verbatim description should come from the diagnosis section of the earliest (chronological) histology/cytology report which confirms the cancer diagnosis. This should be the same report that was used as a source for the ICD-O-2 code in Item A.8.

- Occasionally, the diagnosis section will say “see above” or “see microscopic.” In this situation record verbatim all of the information from the appropriate section of the report which pertains to the cancer diagnosis.
  - Do not record any information about metastases or recurrent cancer, unless the site of the primary cancer is unknown. In this case, record information about the metastases that are identified.
  - Do not record any information about benign conditions listed in the diagnosis section of the histology or cytology report.
9. **Basis of Diagnosis:** The purpose of this item is to document the basis upon which the diagnosis was made. If the basis of the diagnosis was other than histology, cytology, or radiology, it must be specified (e.g., clinical exam, blood test, etc.). Only one circle may be darkened. Darken a circle to indicate the basis for the cancer as follows:
- **Histology:** The cancer was diagnosed via histopathology (study of tissue). This circle may be darkened even if the histology report is not available, but the record clearly indicates that the cancer was confirmed by histology.
  - **Cytology:** The cancer was diagnosed via cytopathology (study of cells). This circle may be darkened even if the cytology report is not available, but the record clearly indicates that the cancer was confirmed by cytology.
  - **Radiology:** The primary cancer (or metastatic site if the primary site is unknown) was diagnosed via a radiologic procedure such as x-ray, ultrasound, MRI, etc. (In this situation, Item A.9 (Verbatim Description of Primary Cancer Diagnosis) must be completed.) This circle may be darkened even if the radiology report is not available, but the record clearly indicates that the cancer was confirmed by radiology.
  - **Other (SPECIFY):** The primary cancer (or metastatic site if the primary site is unknown) was diagnosed via a clinical examination or diagnostic test other than radiology. Specify the type of examination or diagnostic test on the line provided (clinical exam, specific blood test, etc.) (In this situation, Item A.9 (Verbatim Description of Primary Cancer Diagnosis) must be completed.)
10. **Photocopy of Report Confirming Cancer Attached?:** This item documents whether the report that confirmed the cancer has been photocopied and attached to the OCF.
- If the cancer was confirmed via histology or cytology, the appropriate histology report is required. If the cancer was only diagnosed via clinical exam or clinical investigation (such as radiography), the report from the clinical exam or the diagnostic test is required.
  - If there are multiple reports confirming this cancer, the photocopy should be of the earliest report which was the source for recording the ICD-O-2 code recorded in Item A.8.

- A situation may arise in which an institution does not allow the photocopying of records. Every reasonable attempt should be made to obtain permission to photocopy the pathology or cytology report since it is a critical end-point of the screening trial. If special permission or approval is required, the abstractor should work with the SC Coordinator/Principal Investigator to obtain the necessary approval. If this item cannot be completed in a timely manner but it may be completed at a later date, leave it blank and attempt to obtain the information later via data retrieval.

Darken a circle to indicate whether the report is available as follows:

**No:** Either the report is referenced in the medical record, but a copy is not included in the records accessed by the SC; or the report exists, but could not be photocopied and attached to the OCF. (In this situation, Item A.9 (Verbatim Description of Primary Cancer Diagnosis) must be completed.)

**Yes:** The report is available; a photocopy of the report has been obtained; and the report is attached to the OCF. The photocopy should be labeled with the participant's ID number, the study year, titled "OCF/(type of report)," and inserted into the participant's folder.

**11. Reported Metastatic Sites:** The purpose of this item is to document that a condition reported as a "cancer" by the participant, a relative, friend, physician, on the ASU or via phone, etc. is in fact, a metastasis from another primary cancer. The following are examples of when this section of the form should be completed:

- A cancer that was initially reported to be a primary is determined to be metastatic.
 

*Example 1:* If a participant reports breast and brain cancer on the ASU, the SMS will expect an OCF for breast cancer and an OCF for brain cancer. If upon investigation, the SC determines that it is a primary breast cancer with metastases to the brain, only one OCF will be completed, with the ICD-O code for breast cancer recorded in Item A.8 and the brain metastasis recorded in this item (A.12). Receipt of the OCF coded in this way will turn off the OCF expectations for the reported breast cancer and the reported brain cancer.

*Example #2:* If a participant reports colon and liver cancer on the ASU, the SMS will expect a DEC for colon cancer and an OCF for liver cancer. If upon investigation, the SC determines that it is a colon cancer with metastases to the liver, two forms will be completed, a DEC and a OCF. The DEC will document the primary colon cancer. The OCF will document the fact that the primary was colon cancer (with a bubble in Item A.6a) and the liver metastasis will be recorded in this item (A.12). Another approach to this scenario is to delete the ASU. Correct the ASU by removing the liver metastasis and receipt it. Only an expectation for a DEC should exist. The OCF will not be expected (and is not needed).
- When the primary cancer is unknown but there are documented metastases, the abstractor should record codes for all metastases from the primary. The first metastasis recorded should correspond to the date of diagnosis recorded in Item A.7.
- PLCO metastatic sites that have an unknown primary should be recorded in this item. The SMS and DEES options may reject the receipt of this data. See the Attachment "Processing OCF Forms with an Unknown Primary" for additional instructions.
- Metastases which were not initially reported as cancer (e.g. on the ASU or verbally) are later found. If metastatic sites are revealed upon review of the medical record, that were not reported as a cancer to the SC (e.g., on the ASU or ver-

bally), they may be recorded on the OCF in Item 12. NCI does not require documentation of metastatic sites revealed upon review of the medical record.

*Example: If a participant reports pancreatic cancer and a breast cancer on an ASU, the SMS will expect an OCF for pancreatic cancer and an OCF for a breast cancer. If upon investigation, the SC determines that it is a primary pancreatic cancer with metastases to the breast and liver, the OCF should be completed with the ICD-O-2 code for pancreatic cancer recorded in Item A.8 and the breast metastasis recorded in Item A.12. The liver metastasis may be recorded in Item A.12, although this information is not required by NCI.*

- All of the metastatic sites reported in this item must be metastases from the same primary cancer (either the one reported in Item A.8 or a PLCO primary reported in Item A.6a). If there are metastases reported that derive from different primaries, a separate OCF should be completed for each primary cancer and its associated metastatic sites.
- Up to three metastatic sites may be recorded in this item. If there were more than three “cancers” reported to the SC that are metastases from the same primary cancer, the SC should contact the MRA Coordinator for an appropriate resolution.
- For multiple reports of a cancer that has been confirmed as a metastatic site in a previous study year, the SC will be required to determine whether or not it is the same metastasis or a new primary and to complete an MDF-OCF for the same metastasis and an OCF for a new primary.

Complete this item as follows:

- **None Reported** - Darken this circle to indicate that no primary cancers were reported that turned out to be metastatic sites. For example, if the participant reported breast cancer and it was confirmed to be a primary breast cancer, this circle should be darkened. Go to Part B.
- **Record up to Three Sites** – Using the Cancer Codes for Use on ASU and OCF from Appendix I of the MOOP, code the metastatic sites using the three digit cancer codes that are designated for use on the ASU if there is an unknown primary or the primary cancer was reported erroneously. Refer to the specifications for the code list as necessary. Record the 3-digit codes for up to three metastatic sites from top to bottom and darken the corresponding circles

*Note that the codes 888 (Other-Specify) and 998 (Don't Know) and 999 (Not Ascertained) cannot be used for metastatic sites. The codes for PLCO cancers should be recorded only if they are metastases from an unknown primary. The SMS and DEES options may reject the receipt of this data. See the Attachment “Processing OCF Forms with an Unknown Primary” for additional instructions.*

- The Abstractor may also record the site of the metastasis in English (e.g., brain, bone, etc.) on the line labeled “Site: \_\_\_\_\_” but this is optional. If the English description is also recorded, please ensure that no handwriting enters the scanning box below the text line.

### **Part B: Physician/Hospital Location Information:**

In this section, record physician and hospital location information, where the participant underwent diagnostic evaluation for the cancer(s) documented on this OCF primary or metastatic cancer, other than what was reported prior to abstracting. *Information on the physician who diagnosed the metastatic cancer should only be collected if the primary cancer is unknown.* Items B.137 and B.148 are optional/not required, but it is recommended that they be completed to facilitate collection of additional medical record data, including pathology

reports and slides. This section also includes a comments item for recording additional or discrepant information. The physician and hospital location information will not be entered into the Data Entry and Editing System (DEES), while all information recorded in the Comments item will be entered.

**12. Physician for Primary or Metastatic Cancer Diagnosis Information:** Record the name, address, and telephone number of the primary physician who provided care during the participant's diagnostic evaluation for the primary or metastatic cancer and/or the physician who performed the diagnostic evaluation procedures. Space has been allotted for entry of two physicians. Record the physician's office address, if available, otherwise record the physician's hospital address. Record the participant's medical record or chart number for each physician location.

**13. Hospital or Clinic for Primary or Metastatic Cancer Diagnosis Information:** Record the name, address, and telephone number of the hospital or clinic at which the participant underwent one or more diagnostic procedures for the primary or metastatic cancer. Space has been allotted for entry of two hospitals or clinics. Record the participant's medical record or chart number for each hospital or clinic location.

**14. Comments:** Use this section to record any overflow information or discrepant information while abstracting from the participant's medical record.

- If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator or, and if necessary, the Principal Investigator should review the discrepant information prior to contacting the CC MRA Coordinator.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes," then record the comments as follows:

- First enter the item number indicating the item to which the comments are related, record the comments in the space provided to the right of the item number, and then record your initials and the date.

Item A.15, Comments:

Item #	Comments
A.9	Text

- Place an asterisk next to the item number being referenced in the main body of the form.
- If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

**Forms Processing:** These are the steps that should be completed in order to process the Other Cancer Form. All of the items except "Final Disposition" are optional. "Disposition" is required and may be marked on the form or entered directly into DEES. Disposition of "Final Complete" (FCM) may also be set automatically in DEES when the form is edited (see DEES User's Guide/DEES Upgrade Documentation).

**Form Receipted into SMS:** This item is optional. Receipt the form into the SMS. Darken this circle after the form has been receipted into the SMS. The form may be receipted interactively (Refer to Chapter 17 for instructions on receipting forms).

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible,

and that all appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Retrieval:** This item is optional. Complete this item after data retrieval has been performed. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item after the form has been scanned, and items which could not be scanned, such as verbatim responses, have been keyed in the Data Entry and Editing System. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Disposition:** The SC is required to assign a final disposition to each opscan form. There is one interim disposition and two final dispositions:

- **Interim Complete (ICM):** This disposition may be assigned when there are outstanding data but the SC would like to scan the data that are available into the DEES. (Since it may take a number of months for all of the data to be abstracted, it is recommended that the form be scanned into the Data Entry and Editing System each time it is updated.) Note that receipt of a form with an ICM disposition will not turn off expectations for the OCF unless Item A.8 (ICD-O-2) is completed.
- **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The disposition may be assigned in three ways:

- by darkening the bubble circle on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## ATTACHMENT A

### PLCO All Cancer Confirmation Processing OCF Forms With An Unknown Primary Cancer

Reminder: NCI is only interested in collecting metastatic cancers from Confirmed Unknown Primaries.

As you may recall, Beth Bridgeman in the past has provided instructions for completing the OCF when you have a case of a confirmed unknown primary that has a PLCO metastatic site. This is an updated documented version of what was included in the last version of the MOOP due to the April 2004, SMS conversion upgrade. The SC Coordinators should notify the data managers as well as the abstractors of this clarification.

The Other Cancer Form (OCF) allows data collection for Unknown primary cancers. The DEES and SMS systems support processing of non-PLCO metastatic cancers but they do not totally support collection of PLCO metastatic cancers (from unknown primaries or other primaries). Westat assistance is no longer required to support the data collection of metastatic cancers from a PLCO site.

PLCO metastatic cancers from a "known or unknown primary" that have been investigated should still be tracked manually by the SC. If a DE expectation exists for the same study year and for the same PLCO metastatic site, an MDF-DEx should be receipted with a reason code of E (erroneous report).

**To successfully receipt an OCF with metastatic cancers from an unknown primary please follow the guidelines below:**

- Item A.6 record Metastatic Site - Unknown Primary. (Do not use the first bubble indicating Primary Non-PLCO Cancer).
- Item A.12 - Reported Metastatic Sites should be recorded with the appropriate 3-digit cancer code (refer to MOOP, Appendix I). If an expectation for the metastatic cancer code does not already appear in the SMS Participant Status Cancer History table, a record will automatically be added to the table. This includes the addition of plco metastatic sites.
- The SCs should assign an FIC (final incomplete) disposition if an INVALID DEES edit appears for item A. 12 only when the cancer code is one of the following codes: 021 (lung), 028 (ovary), 031 (prostate) or 080 (colorectal). The INVALID edit will be revised in a future DEES upgrade.
- The SCs should move the finalized OCF data to the SMS via the UPDSMS (Update SMS) module in DEES. Please note that these forms currently cannot be receipted interactively in the SMS through the FAST/ENTRY module.
- The SCs may ignore error #46, if received, on the SMS Intra-Form Edits report indicating that the PLCO metastatic code is invalid for the OCF or for the CANCERS data if the cancer code (ccode) is one of the following codes: 021 (lung), 028 (ovary), 031 (prostate) or 080 (colorectal). The edit error will be revised in a future SMS upgrade.
- Westat will no longer support Screening Center requests to add PLCO metastatic cancers for confirmed unknown primary cancers to the SMS Cancer History table. Therefore, for some previously processed cases and future cases, the metastatic data recorded for a PLCO site may only reside in the DEES data tables and in the SMS OCF data tables.

- Westat will no longer send Data Investigation Form (DIF) requests indicating that PLCO metastatic cancers recorded on the OCF do not appear in the SMS Cancer History table.
- Any confirmed prostate, lung, colorectal or ovarian metastatic cancers recorded on the OCF that do not appear in the SMS Cancer History table will not appear on the SMS Medical Background Report or in the Cancer History section of the SMS Participant Overview Report. The Screening Center now has the option to delete the OCF in SMS and DEES and using the DEES UPDSMS module move the data to SMS to synchronize the data between the Cancer History table and the OCF data.
- The SC staff should manually track all participants with a prostate, lung, colon or ovarian (PLCO) metastatic cancer. If a participant is in the Intervention arm, the related PLCO screen should not be performed. (Refer to PLCO Decision Log 43(5). The SMS will not turn off any expectations for future screens due to a PLCO metastatic cancer, only for PLCO primary cancers. It is recommended that a note be entered into the Scheduling Notes section on the SMS Participant Status Screen, which will then appear on the Participant Overview Report for future use in scheduling participants, etc.

Westat will routinely identify for the SCs PLCO metastatic cancer sites recorded on the OCF for use in manual tracking.

## **A-8-6**

**A-8-6: Diagnostic/Staging Procedures Supplement  
(DSS3)**

**Specifications for the Diagnostic/Staging Procedures  
Supplement**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version No.: 07/01

## MEDICAL RECORD ABSTRACT FORM DIAGNOSTIC EVALUATION - Diagnostic/Staging Procedures Supplement (DSS3)

1. Study Year  
T<sub>0</sub>-T<sub>13</sub>

T

0	0
1	1
2	
3	
4	
5	
6	
7	
8	
9	

2. Purpose of Abstract:

- Initial abstract  
 Re-abstract for QA

3. Supplement to:

- DEP3/DPQ3  
 DEL3/DLQ3  
 DEC3/DCQ3  
 DEO3/DOQ3

4. Diagnostic/Staging Procedures:

PROCEDURE #	13	14	15	16	17	
TYPE OF PROCEDURE	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88
	SPECIFY		SPECIFY		SPECIFY	
	MO.	DAY	YEAR	MO.	DAY	YEAR
	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9
	DATE OF PROCEDURE	MO. DAY YEAR				
MO. DAY YEAR	MO. DAY YEAR	MO. DAY YEAR	MO. DAY YEAR	MO. DAY YEAR	MO. DAY YEAR	

DesignExpert™ by NCS Printed in U.S.A. Mark Reflex® EM-215697-3-054321 HC05

PLEASE DO NOT WRITE IN THIS AREA



007769

PROCEDURE #	18	19	20																																																																																																																					
TYPE OF PROCEDURE	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88																																																																																																																					
	SPECIFY	SPECIFY	SPECIFY																																																																																																																					
DATE OF PROCEDURE	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR							0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR							0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR							0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																						
0	0	0																																																																																																																						
1	1	1																																																																																																																						
2	2	2																																																																																																																						
3	3	3																																																																																																																						
4	4	4																																																																																																																						
5	5	5																																																																																																																						
6	6	6																																																																																																																						
7	7	7																																																																																																																						
8	8	8																																																																																																																						
9	9	9																																																																																																																						
MO.	DAY	YEAR																																																																																																																						
0	0	0																																																																																																																						
1	1	1																																																																																																																						
2	2	2																																																																																																																						
3	3	3																																																																																																																						
4	4	4																																																																																																																						
5	5	5																																																																																																																						
6	6	6																																																																																																																						
7	7	7																																																																																																																						
8	8	8																																																																																																																						
9	9	9																																																																																																																						
MO.	DAY	YEAR																																																																																																																						
0	0	0																																																																																																																						
1	1	1																																																																																																																						
2	2	2																																																																																																																						
3	3	3																																																																																																																						
4	4	4																																																																																																																						
5	5	5																																																																																																																						
6	6	6																																																																																																																						
7	7	7																																																																																																																						
8	8	8																																																																																																																						
9	9	9																																																																																																																						
PROCEDURE #	21	22	23																																																																																																																					
TYPE OF PROCEDURE	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88	01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 88																																																																																																																					
	SPECIFY	SPECIFY	SPECIFY																																																																																																																					
DATE OF PROCEDURE	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR							0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR							0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9	<table border="1"> <thead> <tr> <th>MO.</th> <th>DAY</th> <th>YEAR</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td></tr> </tbody> </table>	MO.	DAY	YEAR							0	0	0	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	7	8	8	8	9	9	9
MO.	DAY	YEAR																																																																																																																						
0	0	0																																																																																																																						
1	1	1																																																																																																																						
2	2	2																																																																																																																						
3	3	3																																																																																																																						
4	4	4																																																																																																																						
5	5	5																																																																																																																						
6	6	6																																																																																																																						
7	7	7																																																																																																																						
8	8	8																																																																																																																						
9	9	9																																																																																																																						
MO.	DAY	YEAR																																																																																																																						
0	0	0																																																																																																																						
1	1	1																																																																																																																						
2	2	2																																																																																																																						
3	3	3																																																																																																																						
4	4	4																																																																																																																						
5	5	5																																																																																																																						
6	6	6																																																																																																																						
7	7	7																																																																																																																						
8	8	8																																																																																																																						
9	9	9																																																																																																																						
MO.	DAY	YEAR																																																																																																																						
0	0	0																																																																																																																						
1	1	1																																																																																																																						
2	2	2																																																																																																																						
3	3	3																																																																																																																						
4	4	4																																																																																																																						
5	5	5																																																																																																																						
6	6	6																																																																																																																						
7	7	7																																																																																																																						
8	8	8																																																																																																																						
9	9	9																																																																																																																						

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEDICAL RECORD ABSTRACT**  
**FORM:**  
**DIAGNOSTIC EVALUATION - DIAGNOSTIC/STAGING PROCEDURES SUPPLEMENT**  
**(DSS3)**

This form is a supplement to the Diagnostic Evaluation forms. – DEP3, DEL3, DEC3, and DEO3. It is to be completed by the Medical Record Abstractor when additional space is needed for recording more than 12 diagnostic/staging procedures when abstracting information for the DEP3, DEL3, DEC3, or DEO3. This form provides space for recording 11 additional diagnostic/staging procedures, numbered 13 through 23. The same General Abstracting Techniques and guidelines for the collection of diagnostic evaluation information presented in the specifications for each of the DE3 forms apply when utilizing the DSS. The Version 3 DSS may be used only with Version 3 DE forms.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy black marks that fill the circle completely.

Correct Mark



Incorrect Marks



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions have additional instructions next to certain answers. These instructions may ask you to skip questions that do not apply or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

Items 1, 2, 3 and 4, and the Participant ID number are used to link the DSS to the DE form for which it is serving as a supplement. Items 1 and 2 on the DSS are also found on the DE forms as Items 5 and 6. It is important that the same information that is recorded for these items on the DE form also be recorded on the DSS form.

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Study Year:** Record the study year, T0 to T13, as it appears on the DE form for which the DSS is being used as a supplement. This is the study year in which the SC was notified of a suspicion of the PLCO cancer. Darken the corresponding circles. Remember to right justify and zero-fill the number for study years T0 - T9 (e.g., T00, T01, T02, etc.).
2. **Purpose of Abstract:** This form may be used as a supplement to a DE form for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Darken the circle corresponding to the purpose of the abstract (either "Initial abstract" or "Re-abstract for QA") as it appears on the DE form for which the DSS is being used as a supplement. Re-abstract for QA is not yet implemented.
3. **Supplement to:** The DSS3 may be used as a supplement to any of the Version 3 DE forms, whether an initial abstract or a re-abstract for quality assurance is being performed. Darken the circle indicating the form to which the DSS is serving as a supplement.
4. **Diagnostic/Staging Procedures:** The remainder of this form is to be completed in the same manner as the "Diagnostic/Staging Procedures" section of the DE form for which the DSS is serving as a supplement. For each diagnostic/staging procedure performed, complete the "Type of Procedure," and "Date of Procedure" as indicated in the specifications for the appropriate DE form. When completing this section of the DSS, refer to the procedure codes on the appropriate DE form under "Diagnostic/Staging Procedures," or to the codes provided at the end of these specifications titled "Diagnostic/Staging Procedure Codes."
  - The DSS form provides eleven additional spaces for recording diagnostic/staging procedures, numbered 13 through 23. If there are more than 23 diagnostic/staging procedures, place an asterisk beside Item 4 (Diagnostic/Staging Procedures), and use the Comments section of the appropriate DE form to record the same type of data as requested in the table. In Comments, record the item numbers and labels followed by the data. For example, additional Diagnostic/Staging Procedures for colorectal cancer, should be recorded as follows in Comments on the DEC:

Item #	Comments
A.5	24; Type = _; Date =

## DIAGNOSTIC/STAGING PROCEDURE AND RESULT CODES

CANCER TYPE	PROCEDURE CODES
<b>PROSTATE</b>	01 = CT scan – abdominal 02 = CT scan - other (SPECIFY) 03 = CT scan - pelvic 04 = Intravenous pyelography (IVP)/excretory urography 05 = Laparoscopic lymph node biopsy 06 = Lymphangiogram 07 = MRI scan - abdominal 08 = MRI scan - other (SPECIFY) 09 = MRI scan - pelvic 10 = Other biopsy (SPECIFY) 11 = Preoperative prostatic acid phosphatase (PAP) (RECORD VALUE) 12 = Bone radiograph 13 = Chest radiograph 14 = Radioisotope bone scan 15 = TURP 16 = Lymphadenectomy/Lymph node sampling 17 = Cystoscopy 18 = Proctosigmoidoscopy 19 = Other endoscopy (SPECIFY) 20 = Prostatectomy 21 = Clinical evaluation 22 = CT scan – abdomen and pelvis combined 23 = Cystogram 24 = Cystourethroscopy/Cystopanendoscopy 25 = Other radiograph (SPECIFY) 26 = Record review 27 = Ultrasound (SPECIFY) 28 = Ureterogram 88 = Other (SPECIFY)

<b>CANCER TYPE</b>	<b>PROCEDURE CODES</b>
<b>LUNG</b>	01 = Bronchoscopy 02 = Chest radiograph 04 = Clinical evaluation 05 = CT scan - brain 06 = CT scan - chest 07 = CT scan - liver 08 = CT scan - other (SPECIFY) 09 = Cytology (sputum, bronchial washing/brushing) 10 = Mediastinoscopy/mediastinotomy 11 = MRA scan - brain 12 = MRA scan - chest 13 = MRA scan - liver 14 = MRA scan - other (SPECIFY) 15 = Biopsy, needle aspiration (SPECIFY) 16 = Biopsy, lymph node – other (SPECIFY) 17 = Biopsy, other (SPECIFY) 18 = Pulmonary function tests/Spirometry 19 = Radionuclide scan - bone 20 = Radionuclide scan - brain 21 = Radionuclide scan - liver 22 = Biopsy, scalene (supraclavicular) lymph nodes 23 = Biopsy, surgical open 24 = Thoracotomy 25 = Biopsy, transbronchial needle aspiration (TBNA) 26 = Biopsy, transthoracic needle aspiration (TNA) 27 = Resection 28 = Thoracoscopy 30 = Bone radiograph 31 = CT scan – chest and upper abdomen 32 = CT scan – abdomen and pelvis combined 33 = Biopsy, endobronchial 34 = Fluoroscopy 35 = Gallium scan 36 = Biopsy, liver 37 = Lymphadenectomy/lymph node sampling 38 = MRI scan – bone 39 = Radiograph, other (SPECIFY) 40 = CT scan, spiral – chest 41 = Thoracentesis 42 = Biopsy, transbronchial 43 = Ultrasound (SPECIFY) 44 = Ventilation perfusion lung scan/scintigraphy 45 = Internal referral 46 = Record review 88 = Other (SPECIFY)

CANCER TYPE	PROCEDURE CODES
<b>COLORECTAL</b>	01 = Abdominal flat plate (plain film) 02 = Barium enema radiograph 03 = Biopsy (SPECIFY) 04 = Chest radiograph 05 = Clinical evaluation 06 = CT scan - abdominal 07 = CT scan - other (SPECIFY) 08 = CT scan - pelvic 09 = Cystoscopy 10 = DRE 11 = Intravenous pyelography (IVP)/excretory urography 12 = MRI scan - abdominal 13 = MRI scan - other (SPECIFY) 14 = MRI scan - pelvic 15 = Preoperative carcinoembryonic antigen (CEA) (Record value) 16 = Stool occult blood 17 = Record review 18 = Resection (SPECIFY) 19 = Abdominal ultrasound 20 = CT scan – abdomen and pelvis combined 21 = Hemicolectomy 22 = Laparoscopy 23 = Laparotomy 24 = Lymphadenectomy/Lymph node sampling 25 = Other radiograph (SPECIFY) 26 = Ultrasound (SPECIFY) 27 = Upper GI evaluation – endoscopic/radiographic 88 = Other (SPECIFY)

CANCER TYPE	PROCEDURE CODES
-------------	-----------------

<b>OVARIAN</b>	<ul style="list-style-type: none"> <li>01 = Barium enema</li> <li>02 = Biopsy (SPECIFY)</li> <li>03 = Chest radiograph</li> <li>04 = Color doppler</li> <li>05 = CT scan - abdominal</li> <li>06 = CT scan - other (SPECIFY)</li> <li>07 = CT scan - pelvic</li> <li>08 = Culdocentesis</li> <li>09 = Intra-abdominal washings (peritoneal or pelvic)</li> <li>10 = Intravenous pyelography (IVP)/excretory urography</li> <li>11 = Laparotomy</li> <li>12 = Lymphangiogram</li> <li>13 = MRI scan - abdominal</li> <li>14 = MRI scan - other (SPECIFY)</li> <li>15 = MRI scan - pelvic</li> <li>16 = Needle aspiration</li> <li>17 = Paracentesis</li> <li>21 = Transabdominal/Pelvic ultrasound or sonogram</li> <li>22 = Transvaginal ultrasound</li> <li>23 = Oophorectomy/Salpingoophorectomy</li> <li>24 = Abdominal/vaginal hysterectomy</li> <li>25 = Clinical evaluation</li> <li>26 = CT scan – abdomen and pelvis combined</li> <li>27 = CT scan – chest</li> <li>28 = Hysteroscopy</li> <li>29 = Laparoscopy</li> <li>30 = Lymphadenectomy/Lymph node sampling</li> <li>31 = Omentectomy, complete/NOS</li> <li>32 = Omentectomy, partial</li> <li>33 = Radiograph, other (SPECIFY)</li> <li>34 = Record review</li> <li>35 = Resection (SPECIFY)</li> <li>36 = Sigmoidoscopy/Colonoscopy</li> <li>37 = Thoracentesis</li> <li>38 = Transabdominal/pelvic and transvaginal ultrasounds combined</li> <li>39 = Ultrasound, other (SPECIFY)</li> <li>88 = Other (SPECIFY)</li> </ul>
----------------	--

## **A-9-1**

A-9-1: Death Documentation Sheet (DDS)

Specifications for the Death Documentation Sheet

**DEATH DOCUMENTATION SHEET (DDS)**

Screening Center .....|\_|\_|  
 Satellite Center .....|\_|\_|  
 Participant's Date of Death .....|\_|\_|-|\_|\_|-|\_|\_|\_|\_|

Participant ID Label

**PART A: CANCER CONFIRMATION**

Check each step as it is completed:

- All ASUs received.
- All other methods of cancer ascertainment completed.
- All suspected cancers confirmed.

Was this case selected for review?  Yes, by the CC (COMPLETE PARTS B AND C)  
 No (END)

**PART B: MEDICAL DOCUMENTATION**

Complete the following chart as documents are collected for death review.

Document Type	Requested	Not Applicable
Terminal events		
Hospital admission history/physical		
Operative procedures reports		
Pathology reports		
Chemotherapy notes		
Radiotherapy notes		
Management of co-existing cancers		
Hospital discharge abstracts		
Hospital discharge summary		
Diagnostic procedure reports		
Diagnostic imaging reports		
Outpatient notes		
Other diagnosis documents		
Other treatment documents		

The following documents could not be obtained:

Document Type	Date	Comments

**PART C: EDITING AND SHIPPING DRP DOCUMENTS**

Check each step as it is completed:

**Editing of Documentation:**

- Identifiers Removed
- References to PLCO removed or Not Applicable
- References to participant allocation (Intervention or Control) removed or Not Applicable
- Method of cancer detection removed or Not Applicable
- Each page labeled with PID

**Medical Record Documentation Complete?**  Yes  
 No

**Shipping of Materials:**

- One copy of DRP folder
- 10 extra PID labels
- Folders organized
- Transmittal log completed

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE DEATH DOCUMENTATION SHEET**  
**(DDS)**

The Death Documentation Sheet (DDS) is provided as a manual tracking record to document and monitor completion of each step of the DRP. It should be initiated when the death certificate is receipted into the SMS and should be used as a checklist to indicate completion of cancer ascertainment, ongoing medical record collection and editing, and shipment of DRP materials. The SCs are required to use this form for the 25 cases that are included in the death review pilot, however, its usefulness will be evaluated after the pilot and it may be discontinued for the main death review effort. The SC will submit copies of the 25 DDSs to the CC during the pilot period.

Specifications for completing each item of the form are given below:

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the upper right section of the form.

**Screening Center:** Enter the 2-digit screening center ID.

**Satellite Center:** If a participant is affiliated with a satellite center, enter the 2-digit satellite center ID. If the participant is not affiliated with a satellite center, leave this item blank.

**Date of Death:** Record the participant's date of death.

**Part A: Cancer Confirmation:** This section documents the cancer confirmation activities that must take place prior to submission of the case to be evaluated for death review (the algorithm run at the CC). In this section, the SC staff member should check off each task as it is completed. The tasks are described below.

**History of Malignancy administered and followed up:** The SC has administered the History of Malignancy Form to the participant's primary care physician as noted on the locator form in the SMS. The SC has completed all follow-up for non-response. If the HOM is not returned to the SC within 4 weeks of the followup mailing, the followup is considered complete.

**All ASUs receipted:** The SC has receipted an ASU or an MDF for an ASU for each study year in which it is expected for the participant.

**All other methods of cancer ascertainment completed:** The SC has receipted information from any outside contacts that reported participant cancer, as well as any searches of cancer registries and hospital records that the SC routinely performs for cancer identification.

**All suspected cancers confirmed:** The SC has completed all medical record abstracting for diagnostic information and there are no open expectations for any DE or OCF forms (i.e., there are no cancer records with a status of S (Suspected). They are all closed out as C (Confirmed), P (Previously Confirmed), M (Missing Data), or N (Confirmed as No Cancer).

**Was this case selected for review?:** This item indicates whether or not this death was selected for review by the death review algorithm (run by the CC), or by the PI.

**Yes, by the CC:** Check this item if the case was classified by the algorithm as "R" (Review).

**No:** Check this item only to indicate that the algorithm determined that the case does not need review and classified it as "C" (Certified). If this item is checked, the DRP is considered completed for this participant.

**Part B: Medical Documentation:** The purpose of this section is to document the medical record collection process. The chart will serve as a checklist to help the SC ensure complete records collection and will help NCI assess the scope and success of the medical records collection task.

**Document Type:** This is the type of document that may be collected for death review. Not all document types will be collected for a single case.

**Requested:** Place a check mark in this column if all applicable documents of this type were requested.

**Not Applicable:** Place a check mark in this column if this type of document is not applicable to this case.

The second chart in this section is to be used to document documents that were requested, but could not be obtained. This is important as it will advise the DRC reviewers of the disposition of documents that are missing from the DRP folder.

**Document Type:** This is the type of document that could not be obtained (e.g., pathology report, history and physical, etc.) Record whether it is inpatient or outpatient documentation.

**Date:** Record the date of the document (e.g., the date of the visit or the procedure to which it corresponds)

**Comments:** Use this space to record any comments related to why this document could not be obtained, including the number of attempts made to obtain it.

**Part C: Editing and Shipping DRP Documents:** The purpose of this section is to document the editing of the medical records for the Death Review Committee and the shipping of one copy to the CC for distribution to the committee.

**Editing of Documentation:**

Identifiers Removed – all participant and relative names and participant medical record number or social security number removed.

References to PLCO removed or Not Applicable – If there were references to PLCO or to cancer screening in the record, they have been removed.

Reference to participant allocation (Intervention or Control) removed or Not Applicable – If there were references to the participant's randomization group assignment, they were removed.

Method of cancer detection removed or Not Applicable – If there were references to whether the cancer was detected as a result of a screening examination, they were removed.

Each page labeled with PID – each page has either a PID label, or PID stamp, on it.

When the SC considers the editing to be complete, all boxes should be checked.

**Medical Record Documentation Complete?:** Check the appropriate response as follows:

Yes – All available records have been collected.

No - All available records have not been collected. The SC did attempt to obtain some records that may have been appropriate for the DRP but were not available. Details should be provided in chart 2 of section B.

### **Shipping of Materials**

One copy made (including DDS) – Check this item when all photocopies have been made. Ensure that the photocopies are readable before shipping to the CC.

Ten (10) extra PID labels - Check this item when the 10 extra PID labels have been enclosed in the DRP folder.

Folders organized – Check this item when the folders are organized in the order they appear on the transmittal log and secured with rubber bands to prevent documents from falling out of the folders.

Transmittal log completed – Check this item when the DRP Material Transmittal Log is completed and checked against the folders.

**After completing the form:** File the original DDS in the participant's DRP folder. It will be photocopied for review by the DRC if the case is selected for review.

## **A-9-2**

A-9-2: History of Malignancy Form (HOM)

Specifications for the History of Malignancy Form

## Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial History of Malignancy Form

To Dr. _____	Date: ___/___/___
Re: _____	Address: _____
Date of Birth: ___/___/___	_____
Date of Death: ___/___/___	SSN: _____

**Please answer the following questions. Check only one box, unless instructed otherwise.**

1. On what date did you last see this patient? \_\_\_/\_\_\_/\_\_\_
2. During which years was this patient seen at your facility? 19\_\_\_ to 20\_\_\_
3. Have you ever diagnosed cancer in this patient?  No (Go to 4)  
 Yes
  - a. On what date was the diagnosis made? \_\_\_/\_\_\_/\_\_\_
  - b. Diagnosing Physician's Name and Address: \_\_\_\_\_  
\_\_\_\_\_
  - c. At what institution(s) were the diagnostic tests performed?
    1. Hospital/Clinic/Physician Office: \_\_\_\_\_  
Address: \_\_\_\_\_
    2. Hospital/Clinic/Physician Office: \_\_\_\_\_  
Address: \_\_\_\_\_
  - d. Was it possible to determine the organ within which the tumor arose (primary site)?  
 No  
 Yes (Site: \_\_\_\_\_)
4. If you have not diagnosed a malignancy in this patient, are you aware of a diagnosis of cancer made by another physician caring for your patient?  
 No  
 Yes (Site and type of cancer: \_\_\_\_\_)  
Diagnosing physician's name and address:  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**

**Form completed by:** Signature: \_\_\_\_\_

Print name: \_\_\_\_\_

**Date Completed:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE HISTORY OF MALIGNANCY FORM**  
**(HOM)**

The History of Malignancy Form (HOM) is to be administered to the primary care physician for deceased PLCO participants whose cause of death is listed as 'Natural Causes'. SC staff should identify the appropriate physicians and complete the top administrative section of the form. The HOM should be sent to the physicians with a cover letter.

Specifications for completing each item of the form are given below:

**Administrative Section:**

This section should be completed by the SC staff prior to sending the HOM to each physician. The PID should not be written on the form, nor should a PID label be applied to the form prior to mailing, since this would provide a link between the participant's name and the PID and could compromise participant confidentiality.

- To Dr.:** Record the name of the physician.  
**Date:** Record today's date.  
**Re:** Record the name of the participant.  
**Address:** Record the last known address of the participant.  
**Date of Birth:** Record the participant's date of birth.  
**Date of Death:** Record the participant's date of death.  
**SSN:** Record the participant's social security number, if available.

**Question 1: On what date did you last see this patient?**

The physician should record date of the most recent office visit or examination by the physician at a hospital.

**Question 2: During which years was this patient seen at your facility?**

The physician should record the year of the first encounter between the participant and himself/herself, and the year of the last encounter between them, even if there was a gap of several years between encounters. The year of the last encounter should correspond with the date of the last visit in Question 1.

**Question 3: Are you aware of any cancer diagnosis in this patient?**

The physician should record "Yes" if s/he diagnosed the cancer or if s/he is aware of a cancer diagnosed by another physician. If there were several cancers diagnosed, the physician should record the information for one cancer in items 3a – 3c and the same information for additional cancers on a separate sheet or on the back of the form.

**a. On what date was the diagnosis made?**

The physician should record the date of the first diagnosis of this cancer in this participant.

**b. Diagnosing physician's name and address.**

The physician should record the name and address of the physician who diagnosed the cancer. The physician may write "self" if s/he personally diagnosed the cancer.

**c. At what institution(s) were the diagnostic tests performed?**

The physician should record up to two hospitals, clinics or physician offices in which the main diagnostic procedures were performed.

**d. Was it possible to determine the organ within which the tumor arose (primary site)?**

**Form completed by:** The physician should sign his/her full name, and print his/her full name.

**Date Completed:** The physician should record the date on which s/he completed this form.

**After the form is completed:**

The HOM should be reviewed for reported cancer in Questions 3 and 4, and the SMS should be updated as appropriate. If another physician was listed in Question 3b, the SC should follow-up with this physician to obtain information concerning this cancer diagnosis. The HOM form should be filed in the participant's DRP folder.

The physician should mark the appropriate box indicating if he/she knows the primary site of the cancer. If the physician marks "yes" then the site must also be written.

**A-9-3**

A-9-3: Diagnostic Tests for PLCO Cancers

## DIAGNOSTIC TESTS FOR PLCO CANCERS

Cancer Type	Diagnostic Tests
<b>Prostate</b>	CT scan- abdominal, pelvic or other Intravenous pyelography (IVP)/excretory urography Laparoscopic lymph node biopsy Lymphangiogram MRI scan- abdominal, pelvic, other Other biopsy Preoperative Prostatic Acid Phosphatase (PAP) Bone Radiograph Chest radiograph Radioisotope bone scan TURP Lymphadenectomy Cystoscopy Proctosigmoidoscopy Other endoscopy Prostatectomy
<b>Lung</b>	Bronchoscopy Chest radiograph Comparison of chest x-rays Clinical exam CT scan- brain, chest, liver, other Cytology (sputum, bronchial washing/brushing) Mediastinoscopy/mediastinotomy MRA scan- brain, chest, liver, other Needle aspiration biopsy Other lymph node biopsy Other organ biopsy Pulmonary function tests Radionuclide scan- bone, brain, liver Scalene (supraclavicular) node biopsy Surgical open biopsy Thoracotomy Transbronchial needle aspiration (TBNA) Transthoracic needle aspiration (TNA) Resection Thoracoscopy

Cancer Type	Diagnostic Tests
<b>Colorectal</b>	Abdominal flat plain (plain film) Barium enema radiograph Other biopsy Chest radiograph CT scan- abdominal, pelvic, other Cystoscopy DRE Intravenous pyelography (IVP)/excretory urography MRI scan- abdominal, pelvic , other Preoperative Carcinoembryonic Antigen (CEA) Resection Stool occult blood
<b>Ovarian</b>	Barium enema Other biopsy Chest Radiograph Color Doppler CT Scan- abdominal, pelvic, other Culdocentesis Intra-abdominal washings (peritoneal or pelvic) Intravenous pyelography (IVP)/excretory urography Laparotomy Lymphangiogram MRI scan- abdominal, pelvic, other Needle aspiration Oophorectomy Paracentesis Pelvic exam Pelvic laparoscopy Transabdominal/Pelvic ultrasound or sonogram Transvaginal ultrasound

**A-9-4**

A-9-4: DRP Material Transmittal



## **A-9-5**

A-9-5: Additional Documentation Request Form  
(ADR)

Specifications for the Additional Documentation

**ADDITIONAL DOCUMENTATION REQUEST FORM (ADR)**

Screening Center ..... |\_\_|\_\_|

Satellite Center ..... |\_\_|\_\_|

Participant's Date of Death ..... |\_\_|\_\_|\_|\_\_|\_\_|\_|\_\_|\_\_|\_\_|\_\_|

Requested by:  CC  
 NCI  
 DRC Reviewer Name: \_\_\_\_\_

Date Requested.....|\_\_|\_\_|\_|\_\_|\_\_|\_|\_\_|\_\_|\_\_|\_\_|

Participant ID Label

**Documents:**

Document Type	Date	Physician/Clinic Name
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE**  
**ADDITIONAL DOCUMENTATION REQUEST FORM (ADR)**

The Additional Documentation Request Form (ADR) for the death review process is used by the CC, NCI and the DRC to request additional medical record documents from the SC to support the death review process.

Specifications for completing each item of the form are given below:

**Administrative Section:**

**Participant ID:** A Participant ID label will be pre-applied in the space provided in the upper right section of the form.

**Screening Center:** Record the two digit SC ID.

**Satellite Center:** If a participant is affiliated with a satellite center, enter the 2-digit satellite center ID. If the participant is not affiliated with a satellite center, leave this item blank.

**Participant Date of Death:** Record the month day and year of the participant's death. Record 4 digits for the year.

**Requested by:** Check a box to indicate whether the request is from the CC the NCI consultant or a member of the Death Review Committee. If the request is from the DRC, record the name of the reviewer.

**Date Requested:** Record the date that the request for additional documentation is made.

**Document Request Section:**

This section is used to request additional documents relating to the diagnosis and treatment of the PLCO cancer. The requestor should provide the type of document (e.g., pathology report, operative report, discharge summary, etc.), the date of the document (approximate or exact), and the physician's office or clinic name where the procedures were performed. This will help the SC to determine from whom the document be requested (hospital or physician office).

**After this form is completed:** The DRC requestors should fax the form to:

Joseph Eisen  
TB 268 –DRP Coordinator  
(240) 453-2726  
Fax: (301) 610-5516

The DRP Coordinator will make a note of the request and will forward the form to the SC Coordinator. Copies of the ADR should be kept with the DRP folder both at the SC and the DRC.

## **A-9-6**

A-9-6: Pathology Review Request (PRR)

Specifications for the Pathology Review Request

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**

**PATHOLOGIC REVIEW REQUEST (PRR)**

Participant ID Label  
or  
PID \_\_\_\_\_

SCID: \_\_\_\_\_

DATE OF DEATH: \_\_\_\_\_

REQUESTED BY: \_\_\_\_\_

LOCATION	PATHOLOGY NUMBER	DATE
1.		
2.		
3.		
4.		
5.		

**Comments:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**DRP COORDINATOR USE ONLY**

Date sent to SC: \_\_\_\_\_  
Date received from SC: \_\_\_\_\_  
Date sent to UCLA: \_\_\_\_\_  
Date received from UCLA: \_\_\_\_\_  
Date sent to DRC: \_\_\_\_\_

# Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

## PATHOLOGIC REVIEW REQUEST TRANSMITTAL FORM

**PID:** \_\_\_\_\_

**TOTAL NUMBER  
OF SLIDES SENT:** \_\_\_\_\_

**DATE SLIDES SENT :** \_\_\_\_\_

LOCATION	SLIDE NUMBER	RETURN REQUESTED (yes/no)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

**Staff ID #:** \_\_\_\_\_

**Comments:**

---

---

---

## **A-9-7**

A-9-7: Pathology Review Request Transmittal Log

Specifications for the Pathology Review Request  
Transmittal Log

**PATHOLOGY REVIEW REQUEST TRANSMITTAL LOG**

**PID:** \_\_\_\_\_

**TOTAL NUMBER OF SLIDES SENT:** \_\_\_\_\_

**DATE SLIDES SENT :** \_\_\_\_\_

<b>ORGAN SITE</b>	<b>SLIDE NUMBER</b>	<b>RETURN REQUESTED (yes/no)</b>
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

**Staff ID #:** \_\_\_\_\_

**Comments:**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **A-10-1**

A-10-1: Blood Collection Form (BCF3)

Specifications for the Blood Collection Form







**PART C: BLOOD COLLECTION AND PROCESSING FOR BIOREPOSITORY SAMPLES: (cont'd)**

**Note: Items 10 and 11 were intentionally omitted.**

**9. 2-inch Biorepository Storage Box #:**

<b>B</b>	-				
		0	0	0	0
		1	1	1	1
		2	2	2	2
		3	3	3	3
		4	4	4	4
		5	5	5	5
		6	6	6	6
		7	7	7	7
		8	8	8	8
		9	9	9	9

**(T0, T1, OR T2 - GO TO ITEM C.14)**

**T3 Biorepository Samples Only**

**12. Yellow Top Tubes Storage Box #:**

<b>Y</b>	-				
		0	0	0	0
		1	1	1	1
		2	2	2	2
		3	3	3	3
		4	4	4	4
		5	5	5	5
		6	6	6	6
		7	7	7	7
		8	8	8	8
		9	9	9	9

**(optional)**

**13. Shipment of Yellow Top Tubes:**

Shipped same date drawn

Not shipped

OR

Date of shipment:

MO.	DAY	YEAR
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

<b>14. Result of Blood Draw and Processing for Biorepository:</b>	<b>15. Reason for Partial or Inadequate:</b> (MARK ALL THAT APPLY)	<b>16. Comments:</b> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY)		<b>17. Lab Tech's Initials/ID#:</b>																																																	
		<b>Item #</b>	<b>Comments</b>																																																		
<input type="radio"/> Complete - all vials filled to required capacity (GO TO C.16) <input type="radio"/> Partial - not all vials filled to required capacity <input type="radio"/> Inadequate - no vials filled	<input type="radio"/> Participant refusal <input type="radio"/> Poor venous access <input type="radio"/> Tube(s) damaged, lost, or destroyed <input type="radio"/> Equipment problems <input type="radio"/> Blood component QNS <input type="radio"/> Vial(s) damaged, lost, or destroyed <input type="radio"/> Other (SPECIFY) _____			<table border="1"> <tr> <th colspan="4">Initials</th> <th rowspan="2">ID#</th> </tr> <tr> <td></td><td></td><td></td><td></td> </tr> <tr> <td>0</td><td>0</td><td>0</td><td>0</td> </tr> <tr> <td>1</td><td>1</td><td>1</td><td>1</td> </tr> <tr> <td>2</td><td>2</td><td>2</td><td>2</td> </tr> <tr> <td>3</td><td>3</td><td>3</td><td>3</td> </tr> <tr> <td>4</td><td>4</td><td>4</td><td>4</td> </tr> <tr> <td>5</td><td>5</td><td>5</td><td>5</td> </tr> <tr> <td>6</td><td>6</td><td>6</td><td>6</td> </tr> <tr> <td>7</td><td>7</td><td>7</td><td>7</td> </tr> <tr> <td>8</td><td>8</td><td>8</td><td>8</td> </tr> <tr> <td>9</td><td>9</td><td>9</td><td>9</td> </tr> </table>	Initials				ID#					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9
		Initials				ID#																																															
		0	0		0	0																																															
		1	1		1	1																																															
		2	2		2	2																																															
		3	3		3	3																																															
		4	4		4	4																																															
		5	5		5	5																																															
		6	6		6	6																																															
7	7	7	7																																																		
8	8	8	8																																																		
9	9	9	9																																																		
		<input type="radio"/> Continued																																																			

**For Office Use Only**

**Forms Processing (DARKEN CIRCLES AS STEPS ARE COMPLETED)**

Form Received into SMS <input type="radio"/>	<b>Data Retrieval:</b>	<b>Data Entry of Non-Scannable Items:</b>	<b>Final Disposition:</b>
Manual Review Completed <input type="radio"/>	Attempted <input type="radio"/> OR None <input type="radio"/> Required	Completed <input type="radio"/> OR None <input type="radio"/> Required	Final Complete (FCM) <input type="radio"/> OR Final Incomplete (FIC) <input type="radio"/>

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

PLEASE DO NOT WRITE IN THIS AREA



084632

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE BLOOD COLLECTION FORM -**  
**VERSION 3 (BCF3)**

This form is to be completed by an SC staff member and the Examiner(s) (Phlebotomist/Laboratory Technologist). The SC staff member will complete the top administrative section and the Forms Processing section. The Phlebotomist will complete Part A, and sections of Parts B and C. Items the Phlebotomist may complete are shaded in pink and have item numbers with a white background. The Laboratory Technologist will complete sections of Parts B and C of the form. Items the Laboratory Technologist may complete have a white background and have pink shaded item numbers. The Laboratory Technologist may also complete the result of blood draw and processing and reasons for inadequate items for both PSA/CA-125II vials and Biorepository samples (items B.8, B.9, C.14, and C.15).

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy marks that fill the circle completely.**

Correct Mark



Incorrect Marks



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

**Sample ID:** Affix a Sample ID label to the horizontal space provided in the lower left corner of the form, above the Participant ID label. The sample ID should be aligned directly over the large shaded box on the left and the vial number should be aligned over the small shaded box on the right.

In cases where the participant was willing to participate in the blood exam and was stuck with a needle, but a blood sample was not obtained, complete the Administrative Section and Part A of the Blood Collection Form, but do not affix a Sample ID label to the form.

1. **Date of Blood Draw:** Record the date of the blood draw. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Satellite Center:** Enter the 2-digit Satellite Center ID number where the blood draw is taking place. Darken the circle corresponding to each number. If the examination is not taking place at a satellite center, leave this item blank.
3. **Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2 or T3 for the follow-up examinations.
4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the PSA/CA-125II blood collection in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the PSA/CA-125II blood collection was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the PSA/CA-125II blood collection, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:  

*"Participant fainted - unable to obtain PSA/CA-125II blood sample tube during previous visit for blood draw."*

This might be entered if the participant's previous blood draw attempt was inadequate due to the inability to obtain the red top-SST tube, the first priority tube required for the blood protocol, and the participant was willing to return to the SC to attempt the blood draw again. This information will alert the Examiner to the participant's status at the previous visit.
6. **Participant Gender:** Darken a circle to indicate whether the participant is male or female. This will alert the laboratory technologist to the type of vial that should be processed (i.e., PSA for males or CA-125II for females).
7. **Participant Has Reported Cancer or No Organ:** If the participant has a reported prostate or ovarian cancer, darken the circle next to the appropriate type of cancer. If the participant has had his entire prostate removed or both of her ovaries removed, darken the circle next to the appropriate type of organ removed. If the participant has both a reported cancer and an entire organ removed, darken two circles, one circle to record the type of cancer and the other circle to record the type of organ removed. Mark only the appropriate conditions; if a condition is not applicable or unknown, leave it blank. A reported cancer includes both confirmed and unconfirmed cancers. If a prostate or ovarian cancer has been reported, and/or the entire prostate or both ovaries have been removed, the blood for the PSA/CA-125II will not be drawn and Part B will be skipped entirely. If one condition has been bubbled, no additional research is required for a secondary condition.

*If item 7 is bubbled (the participant has a reported prostate or ovarian cancer and/or has had his entire prostate removed or both of her ovaries removed), and the blood for the PSA/CA-125II was drawn in error, complete the following steps:*

1. Enter a comment in item A.5 (comments) stating why the red top-SST was drawn and that the blood was collected in error. This comment does not need to be keyed. If this is the only comment in A.5, bubble comments as "No."
  2. Erase all bubbles and marks in Part B (items B1 through B11).
  3. In the SMS Participant Status Screen, under Participant's Notes, record that the blood was collected in error.
  4. Complete a protocol violation form and submit it to the CC.
  5. Refer to Chapter 10 (Blood Sample Protocol) for procedures on handling PSA/CA-125II blood samples collected in error.
- 8. No Biorepository Samples Expected:** If the participant has not signed an Etiologic Studies Consent (ESC) form darken the circle next to "No Biorepository Samples Expected." If the participant has signed an ESC, leave this item blank. Biorepository blood will not be drawn without a signed ESC, and Part C of the form will be skipped entirely. Collection of the blood for the PSA/CA-125II is not dependent on the ESC status.

If Biorepository samples are not expected due to SC protocol (regardless of signed ESC), darken the "No Biorepository Samples Expected" bubble and skip all of Part C.

If the participant signs the ESC during his/her visit, Biorepository blood is collected as specified in Part C. In this situation, forms must be processed in this order: first delete any MDFs for the ESC and BCF, receipt the ESC, and then receipt the BCF3 or scan the BCF3 and update SMS.

**If items 7 and 8 are both bubbled, do not complete a BCF3. Instead, complete an MDF-BCF.**

### **Part A: Blood Draw:**

Part A is to be completed by the Phlebotomist.

1. **Time of Blood Draw:** Record the time the blood sample is drawn. Darken the circle corresponding to each number. Remember to zero-fill numbers which are less than ten. Darken the circle to indicate the time as AM or PM.
2. **Position of Participant:** Darken the circle corresponding to the position of the participant during the blood draw.
3. **Medical Complications:** Darken one or more circles corresponding to any medical complication which occurred during the blood draw.

None: There are no medical complications that occurred during the blood draw. (If this circle is darkened, no other circles may be darkened; continue with item A.4).

Fainting: A temporary loss of consciousness. Feeling faint or dizzy is not considered fainting.

Light-headedness: A temporary feeling of lightheadedness or feeling faint or dizzy.

Hematoma: A localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue.

Bruising: A localized collection of blood under the skin in the venipuncture space or surrounding tissue.

Other (SPECIFY): Describe any other medical complication that occurred during the blood draw in the space provided.

4. **Phlebotomist's Initials/ID#**: The Phlebotomist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.
5. **Comments**: Additional comments may include reasons for short draws or difficulties with the participant's venous system. Comments recorded in this section should pertain only to items related to the administrative section and to the blood draw. This includes administrative section items 1 through 8, and Part A items A.1 through A.4.

If an extra red top tube was drawn for the Biorepository, this does not need to be noted in comments. However, if it is noted, it does not need to be keyed into DEES.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

#### **Part B: Blood Processing for PSA/CA-125II Samples:**

**If the participant has a reported prostate or ovarian cancer, and/or has had his entire prostate removed or both of her ovaries removed, do not draw the red top SST tube and leave Part B blank.**

Items 1-2a of Part B are to be completed by the Phlebotomist. If the red top SST tube is not drawn for a reason other than prostate/ovarian cancer or no organ, the Phlebotomist must also complete items B.8 and B.9. If the red top SST tube is processed, items 3-11 of Part B are to be completed by the Laboratory Technologist.

1. **Red Top SST Tube Drawn for PSA or CA-125II**: Darken a circle to indicate whether or not the red top SST tube was drawn. Darken the circle next to "Yes" if the tube was partially filled or filled to capacity. The red top SST tube should be obtained at the T0, T1, T2, and T3 visits.

If a tube is not drawn but it is required (i.e., the tube is part of the protocol and the participant does not have a reported prostate or ovarian cancer, and has not had his entire prostate removed or both of her ovaries removed), darken the circle next to "No." Then skip to item B.8, and record the result of the blood draw and processing for PSA/CA-125II as "Inadequate." Record the reason(s) for "Inadequate" in item B.9.

The red top SST tube, which is for the PSA/CA-125II sample, will always be the first priority tube to be collected at each screening visit. If the PSA/CA-125II blood sample is not collected for any reason during a screening visit (except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries), the participant should be rescheduled for a redraw of the PSA/CA-125II sample. If a re-draw for PSA/CA125II blood is conducted, darken item C.1b to indicate that no Biorepository tubes will be drawn. Darken "Inadequate" in item C14 and darken "Other (SPECIFY)" in item C15. Record "UCLA re-draw" on the SPECIFY line. Redraws will be scheduled only when the PSA/CA-125II sample was not

obtained. A redraw should not be scheduled solely for the purpose of obtaining the Biorepository samples.

If the blood draw is not successfully completed for the red top SST tube, another draw should be attempted from the participant's other arm. If attempts from both arms are unsuccessful, the participant should be scheduled for a repeat visit for the blood exam.

**2. Problems with Red Top SST Tube Draw:** If the tube was drawn and there is no problem with it, darken the circle for "No" and go to item B.3. If there is a problem with the red top SST tube, darken the circle for "Yes" and code the problem in item B.2a. If the red top SST tube was not drawn (item #1 above is coded "No" for red top SST tube drawn), leave this item blank.

**2a. Code Problems with Draw:** If there is a problem with the red top SST tube (item #2 above is coded "Yes"), darken one or more circles corresponding to the appropriate problem code(s). If there is no problem with the red top SST tube (item #2 above is coded "No"), leave this item blank. The definitions for the problem codes are provided below.

1 = Short Draw: There is a short draw in the tube collected.

2 = Damaged: The tube was drawn but became damaged after the blood was collected.

3 = Multiple Attempts Required: More than one attempt ("stick") was needed to obtain blood.

8 = Other (SPECIFY): Describe any other type of problem with the tube in the space provided.

**3. 3.Time Centrifuged:** Record the time the blood sample is centrifuged. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.

**4. 4.Vial Filled:** Darken the circle to indicate which vial is filled. A vial is considered "filled" even if it was only partially filled, and not filled to capacity. Definitions for the responses are listed below.

Yes - Vial 001 for PSA (Blue Cap): If the participant is male and blood was processed for PSA, darken the circle for "Yes."

Yes - Vial 002 for CA-125II (Red Cap): If the participant is female and blood was processed for CA-125II, darken the circle for "Yes."

No – Neither Vial 001 nor 002 filled: If no PSA/CA-125II vials were filled for any reason except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries, darken the circle for "No – Neither Vial 001 nor 002 filled." Then, skip to item B.8 and record the result of blood draw and processing for PSA/CA-125II as "Inadequate." Record the reason(s) for "Inadequate" in item B.9.

If a vial was filled and frozen but lost or damaged before shipping, the "vial filled" circle should be changed from "Yes" to "No," any responses in items B.5 and B.5a should be deleted, and item B.8 should be changed from "adequate" to "inadequate." In item B.9, mark the reason for inadequate as "PSA/CA 125II vial damaged, lost, or destroyed." The form should then be rescanned, edited and that data updated to SMS. A modified transmittal should be generated before the shipment is sent.

5. **Processing Problems:** If the vial was filled and there is no problem with it, darken the circle for "No" and go to item B.6. If there is a processing problem with the specimen vial, darken the circle for "Yes" and code the problem in item B.5a. A partially filled vial is considered a "problem" and should be marked with problem code of "04" in item B.5a. If the vial was not filled (item #4 above is coded "No – Neither Vial 001 nor 002 filled" for the PSA/CA–125II vial), leave this item blank.
- 5a. **Code Problems with Processing:** If there is a problem with the PSA/CA-125II (item #5 above is coded "Yes"), darken one or more circles corresponding to the appropriate problem code(s). If there is no problem with the PSA/CA-125II vial (item #5 above is coded "No"), leave this item blank. The definitions for the problem codes are provided below.
- 01 = Hemolyzed serum: The hemoglobin has separated from the red cells causing the serum to turn red.
  - 02 = Icteric serum: The serum is a deep yellow (jaundice) color.
  - 03 = Turbid serum: The serum is cloudy.
  - 04 = Partially filled vial: The specimen vial is not filled to capacity (2 ml) and is only partially filled.
6. **UCLA Storage Box Number:** Record the storage box number for the PSA or CA-125II specimen. If the specimen being stored is a CA-125II vial, the first two characters will always be "UC." If the specimen being stored is a PSA vial, the first two characters of the storage box number will always be "UP." Darken the circle corresponding to "C" or "P," then darken the circles corresponding to each of the four digits.
7. **Time Frozen:** Record the time the PSA/CA-125II blood sample is frozen. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.
8. **Result of Blood Draw and Processing for PSA/CA-125II:** Darken the circle corresponding to the result of the PSA/CA-125II blood draw and processing. Definitions of PSA/CA-125II results are given below:
- Adequate - PSA/CA-125II vial obtained: The red top-SST tube was obtained and the vial filled. (Go to item B.10.)
  - Inadequate - PSA/CA-125II vial not obtained: Either the red top-SST tube was not obtained (for any reason, except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries) or the red top-SST tube was obtained but the vial was not filled, lost or damaged. Record the reason(s) for the inadequate result of the blood draw and processing in item B.9 below.
9. **Reason for Inadequate:** Darken one or more circles to indicate the reason(s) for the inadequate result of the blood draw and processing.
- Participant refusal: The participant is unwilling to allow completion of the blood draw procedure. Therefore, the tube was not obtained. (Only the Phlebotomist may assign this reason.)
  - Poor venous access: The blood draw was attempted, but due to the participant's poor venous access, the tube was not obtained. (Only the Phlebotomist may assign this reason.)
  - Red Top-SST tube damaged, lost or destroyed: The blood draw procedure was attempted, but the red top-SST tube was either: damaged, lost, or destroyed

prior to/during/or after processing, and the PSA/CA-125II vial could not be filled. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Equipment problems: Blood was drawn, but due to equipment problems during the blood collection and/or processing a serum sample is not available for testing. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Serum QNS: The red top-SST tube was obtained during the blood draw procedure, however, the serum quantity was not sufficient to fill the PSA/CA-125II vial. (Only the Laboratory Technologist may assign this reason.)

PSA/CA-125II vial damaged, lost, or destroyed: The red top-SST tube was obtained during the blood draw procedure and the PSA/CA-125II vial was filled, but the vial was subsequently damaged, lost, or destroyed and could not be shipped. (Only the Laboratory Technologist may assign this reason.)

Other (SPECIFY): Describe any other reason for inadequate in the space provided. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

10. **Comments:** If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., B.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF). Comments recorded in this box should pertain only to items related to the processing of the PSA/CA-125II vial. This includes Part B items B.1. through B.9.
11. **Lab Tech's Initials/ID#:** The Laboratory Technologist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.

### **Part C: Blood Processing for Biorepository Samples:**

**If the participant has not signed an Etiologic Studies Consent form, do not collect any of the Biorepository tubes, and leave Part C blank. If Biorepository samples are not expected due to SC protocol (regardless of signed ESC), do not collect any of the Biorepository tubes and leave Part C blank.**

Items 1-3 of Part C are to be completed by the Phlebotomist. If none of the required Biorepository samples are drawn, the Phlebotomist must also complete items C.14 and C.15. If the Biorepository samples are processed, items 4-17 of Part C are to be completed by the Laboratory Technologist.

- 1a. **All Required Biorepository Tubes Drawn; No Problems:** Darken this bubble if all Biorepository tubes appropriate to the participant's study year were successfully drawn and skip to item C.4. If this circle is darkened, items C.2 and C.3 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "all required Biorepository tubes drawn; no problems" circle is darkened and one or more circles are darkened in C.2 or C.3, the system will not automatically complete C.2 and C.3.

If the SC has a modified blood collection protocol in which an additional tube of blood is obtained, this bubble may be used to document successful collection of tubes required by the regular PLCO protocol as well as the additional tube. If the

additional tube is not collected or has problems, but the regular PLCO tubes were collected without problems, then this bubble should be darkened. Non-collection or problems with the collection of the extra tube should be documented in item C.16 (Comments).

- 1b. No Biorepository Tubes Drawn:** Darken this bubble if none of the tubes appropriate to the participant's study year were successfully drawn and skip to item C.14. If this circle is darkened, then items C.2 and C.3 must be left blank. These data items will be completed automatically in DEES when the form is scanned. If the "no Biorepository tubes drawn" circle is darkened and one or more circles are darkened in C.2 or C.3, the system will not automatically complete C.2 and C.3. If no Biorepository tubes are drawn, then C.14 and C.15 must be answered and C.17 will be blank.
- 2. Required Biorepository Tubes Drawn:** Darken a circle to indicate whether or not each tube of blood was drawn. Darken the circle next to "Yes" if the tube was partially filled or filled to capacity. If a tube is not drawn but it is required (i.e., the tube is part of the protocol for the current study year), darken the circle next to "No." If a tube is not drawn and it is not required, leave the item blank

Biorepository tubes appropriate to the participant's study year should be obtained as follows:

Baseline Visit (T0), T1 and T2

Red top #1

Baseline Visit (T0) Only

Green top

Red top #2

Royal blue top

T3 Visit Only

Yellow top #1

Yellow top #2

Green top

Lavender top

If yellow top tubes are not collected due to holiday shipping and receiving schedules, bubble, "no" for the yellow top tubes in item C.2 and enter "Holiday" in item C.16, Comments.

If the participant has signed an ESC, Biorepository tubes should be drawn as appropriate to the study year even if the participant has a reported prostate or ovarian cancer and/or has had his entire prostate or both of her ovaries removed.

If the blood draw is not successfully completed for all tubes (all tubes filled to capacity), another draw should be attempted from the participant's other arm. A redraw at a subsequent study visit should not be scheduled solely for the purpose of obtaining the Biorepository samples. The green top tube must be filled to at least fifty percent of capacity to allow effective mixing of the anticoagulant.

- 3. Problems with Draw:** If the tube was drawn and there is no problem with it, darken the circle for "No." If there is a problem with the tube of blood drawn, darken the circle for "Yes" and then darken one or more circles corresponding to the appropriate problem code(s). If the tube of blood was not drawn (item #2 above is coded "No" for the tube drawn), leave this item blank. The definitions for the problem codes are provided below.

1 = Short Draw: There is a short draw in the tube collected.

2 = Damaged: The tube was drawn but became damaged after the blood was collected.

3 = Multiple Attempts Required: More than one attempt ("stick") was needed to obtain blood.

8 = Other (SPECIFY): Describe any other type of problem with the tube in the space provided.

4. **Time Centrifuged**: Record the time the blood samples are centrifuged. Darken the circle corresponding to each number. Remember to zero-fill numbers which are less than ten. Darken the circle to indicate the time as AM or PM.

5a. **All Required Biorepository Vials Filled; No Problems**: Darken this bubble if all vials appropriate to the participant's study year were filled and skip to item C.8. A partially filled vial is considered a "problem" and this bubble may not be darkened if there are any partially filled vials. Definitions for additional processing problems are provided in item C.7. If this circle is darkened, items C.6 and C.7 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "all required Biorepository vials filled; no problems" circle is darkened and one or more circles are darkened in C.6 or C.7, the system will not automatically complete C.6 and C.7.

5b. **No Biorepository Vials filled**: Darken this bubble if none of the vials appropriate to the participant's study year were filled and skip to item C.14. A vial is considered "filled" even if it was only partially filled, and not filled to capacity. This bubble may not be darkened if there are any partially filled vials. If this circle is darkened, items C.6 and C.7 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "no Biorepository vials filled" circle is darkened and one or more circles are darkened in C.6 and C.7, the system will not automatically complete C.6 and C.7.

6. **Required Biorepository Vials Filled**: Darken the circles corresponding to vials filled. If a vial is completely or partially filled, darken the circle for "Yes." If a vial is not filled but it is required (i.e., the vial is part of the protocol for the current study year), darken the circle next to "No." If a vial is not filled and it is not required, leave the item blank.

If a vial was filled and frozen but lost or damaged before shipping, the "vial filled" circle should be changed from "Yes" to "No," any processing problem codes should be deleted, and if necessary, items C.14 (result of blood draw and processing for Biorepository) and C.15 (reason for partial or inadequate), should be corrected. Then, the form should be rescanned, edited, and the data updated to SMS. A modified transmittal should be generated before the shipment is sent.

Biorepository vials appropriate to the participant's study year should be filled as follows:

T0, T1, and T2		
Red Top #1	Serum	Vial 003
	Serum	Vial 004

**NOTE:** When filling the vials with serum, if there is not enough serum to fill both vials, fill one vial first until full (2.0 ml), then fill the second vial with the remaining serum.

<b>T0 Only</b>		
Green Top	Plasma	Vial 005
	Plasma	Vial 006
	Buffy coat	Vial 007
	RBC	Vial 008
Red Top #2	Serum	Vial 009
	Serum	Vial 010
Royal Blue Top*	Serum	Vial 011

*(In study years T1, T2, and T3, vials 005-011 are not filled. These circles should be left blank.)*

**Processing Notes for T0:**

**Plasma:** When filling the vials with plasma, if there is not enough plasma to fill both vials, fill one vial first until full (2.0 ml), then fill the second vial with the remaining plasma.

**Serum:** Vials 009 and 010 (from red top tube #1 or #2): An attempt should be made to fill these vials with serum from red top #2. If red top #2 was not collected or if sufficient serum could not be obtained from red top #2, any extra serum from red top #1 may be used to fill these vials. If serum was collected from red top #2 and/or red top #1, darken the circle for "Yes." If serum was not collected from red top #2 or red top #1, darken the circle for "No."

When filling the vials with serum, if there is not enough serum to fill both vials, fill one vial first until full (2.0 ml), then fill the second vial with the remaining serum.

\*Serum: Vial 011 (from royal blue top tube) The royal blue top tube should always be aliquoted first.

<b>T3 Only</b>		
Green Top	Plasma	Vial 014
	Plasma	Vial 015
	Buffy coat	Vial 016
Lavender Top	Plasma	Vial 017
	Plasma	Vial 018
	Plasma	Vial 019
	Plasma	Vial 020
	Buffy coat	Vial 021

		Vial 022 - Not implemented.
	RBC	Vial 023

(In study years T0, T1, and T2, vials 014-021, and 023 are not filled. These circles should be left blank.)

**Processing Notes for T3:**

**Plasma:** When filling the vials with plasma, if there is not enough plasma to fill all of the vials: first, fill one vial until it is filled to capacity; then, continue filling vials in this fashion until the specified vials are filled or until no more plasma remains (which ever occurs first).

7. **Processing Problems:** If the vial was filled and there is no problem with it, darken the circle for "No." If there is a problem with the vial, darken the circle for "Yes" and then darken one or more circles corresponding to the appropriate problem code(s). If the vial was not filled (item #6 above is coded "No" for the vial), leave this item blank. The definitions for the problem codes are provided below.

01 = Hemolyzed serum: The hemoglobin has separated from the red cells causing the serum to turn red.

02 = Icteric serum: The serum is a deep yellow (jaundice) color.

03 = Turbid serum: The serum is cloudy.

04 = Partially filled vial: The specimen vial is not filled to the required capacity and is only partially filled.

8. **Time Biorepository Vials Frozen:** Record the time the appropriate Biorepository blood samples are frozen. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.
9. **2-inch Biorepository Storage Box Number:** Record the storage box number for the storage of all Biorepository. The first character of the storage box number for vials 003-011, 014--021, and 023 will always be "B." Darken the circle corresponding to each of the four digit numbers. If none of the Biorepository vials were filled, leave this item blank For study years T0, T1, or T2, complete this item and skip to item C.14.
10. **Intentionally Omitted on form – formerly the T Box.**
11. **Intentionally Omitted on form – formerly the I Box.**
12. **Yellow Top Tubes Storage Box Number:** OPTIONAL Record the storage box number for the two yellow top tubes. The first character of the storage box number for yellow top tubes will always be "Y." Darken the circle corresponding to each of the four digit numbers. This box will only be used for T3 blood collection. If yellow top tubes were not collected, leave this box blank. Leave this box blank for T0, T1, and T2 visits.
13. **Shipment of Yellow Top Tubes:** Designate the status of the shipment of yellow top tubes as one of the following:

Shipped same date drawn: Darken this circle if the yellow top tubes are shipped on the same day they are collected.

Not shipped: Darken this circle if the yellow top tubes were not shipped to the Processing Laboratory and document the reasons the tubes were not shipped in item C.16 (comments). If applicable, change items C14 and C15 to indicate that the tubes were lost or destroyed.

Date of shipment: If the tubes were shipped, but not on the same day they were drawn, record the date they were shipped. Month and day should be zero filled (e.g., 02/07). Enter all four digits for the year (e.g., 1998, or 1999). Darken the circles corresponding to the month, day, and year.

This item will only be used for T3 blood collection. Leave this box blank for T0, T1, and T2 visits. If yellow top tubes were not collected, leave this item blank.

*The T3 protocol requires that yellow top tubes be shipped to the Processing Laboratory on the same day they are drawn. If the SC is unable, under unusual circumstances, to ship the yellow top tubes on the same day they are drawn, the yellow top tubes may be shipped to the Processing Laboratory the next day. Yellow top tubes not shipped on the same day or next day after they are drawn will be destroyed. The reason the samples were not shipped within the required time frame must be noted in item C. 16 (comments). The Processing Laboratory will receive packages on Saturdays. (For example, yellow top tubes were drawn on Thursday, March 26, 1998, but because a blizzard caused the airport to close, samples could not be shipped on Thursday. The samples could be shipped on Friday, March 27, but are not to be shipped on any day after Friday.) For specific shipping instructions regarding Saturday deliveries, refer to Chapter 10 (Blood Sample Protocol), section 10.10.5 Labeling Shipping Containers for Yellow Top Tubes.*

If the yellow top tubes were drawn, but they were not shipped to the Processing Laboratory, complete the following steps:

- If item C.13 was originally bubbled as "Shipped same date drawn" or the "Date of shipment" was entered, erase all bubbles (and marks), and darken the bubble for "not shipped."
- Document the reasons the tubes were not shipped in item C.16 (comments).
- Rescan and edit the form, and update the data into the SMS.
- Make the necessary corrections to the Processing Laboratory Transmittal Log (Appendix A-10-4) before the shipment is sent.

**14. Result of Blood Draw and Processing for Biorepository:** Darken the circle corresponding to the result of the Biorepository blood draw and processing. Definitions of the Biorepository results are given below:

Complete – all vials filled to required capacity: Darken this bubble, if all vials appropriate to the participant's study year were filled to the required capacity. This bubble may not be darkened if there are any partially filled vials. For T3 participants, both yellow top tubes must also be filled to the required capacity if this bubble is darkened. (Go to item C.16.)

Partial – not all vials filled to required capacity: Darken this bubble, if at least one, but not all of the vials (or yellow top tubes for T3 participants) appropriate to the participant's study year were filled to the required capacity. This bubble should be darkened if there are any partially filled vials (or yellow top tubes for T3 participants) or any missing vials. Record the reason(s) for the partial result of the Biorepository blood draw and processing in item C.15 below.

Inadequate – no vials filled: Darken this bubble, if either none of the Biorepository tubes were obtained or the Biorepository tubes were obtained but none of the vials were filled. Record the reason(s) for the inadequate result of the Biorepository blood draw and processing in item C.15 below.

- 15. Reason for Partial or Inadequate:** Darken one or more circles to indicate the reason(s) for the partial or inadequate result of the Biorepository blood draw and processing.

Participant refusal: The participant is unwilling to allow completion of the blood draw procedure and some or all of the Biorepository tubes could not be obtained. (Only the Phlebotomist may assign this reason.)

Poor venous access: The blood draw was attempted, but due to the participant's poor venous access some or all of the Biorepository tubes were not obtained. (Only the Phlebotomist may assign this reason.)

Tube(s) damaged, lost, or destroyed: The blood draw procedure was attempted, but some or all of the Biorepository tubes were either: damaged, lost, or destroyed prior to/during/or after processing and some or all of the Biorepository vials could not be filled. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Equipment problems: Blood was drawn, but due to equipment problems during the blood collection and/or processing one or more of the Biorepository vials are not available for testing. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Blood component QNS: Some or all of the Biorepository tubes were drawn during the blood draw procedure, however, one or more of the blood component quantities was not sufficient to fill the required vials to capacity. (Only the Laboratory Technologist may assign this reason.)

Vial(s) damaged, lost or destroyed: Some or all of the Biorepository tubes were obtained during the blood draw procedure and some or all of the Biorepository vials were filled, but one or more vials were subsequently damaged, lost, or destroyed and could not be shipped. (Only the Laboratory Technologist may assign this reason.)

Other (SPECIFY): Describe any other reason for inadequate in the space provided. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

- 16. Comments:** If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., C.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF). Comments recorded in this box should pertain only to items related to the processing of the Biorepository vials or the shipment of the yellow top tubes. This includes Part C items C1a through C.15.

- 17. Lab Tech's Initials/ID#:** The Laboratory Technologist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.

## **Forms Processing:**

The Forms Processing box is to be completed by the SC staff member.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each OpScan form in the system, but is not required to mark the disposition on the hard copy form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional Forms Processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the OpScan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-10-2**

A-10-2: UCLA Discrepancy Notification

**PLCO DISCREPANCY NOTIFICATION**

Date: \_\_\_\_\_

TO: \_\_\_\_\_  
Study Coordinator, PLCO project

FROM: \_\_\_\_\_  
UCLA

SUBJECT: Request for New Transmittal

REASON:     \_\_\_ Specimens were received that were not on the transmittal file  
              \_\_\_ Specimens were on the transmittal file that were not received  
              \_\_\_ Specimens were not correctly labeled  
              \_\_\_ Other: \_\_\_\_\_

The discrepancy reports accompanying this memo indicate problems encountered with your shipment dated: \_\_\_\_\_.

The boxes involved are: \_\_\_\_\_.

Your samples cannot be tested until a corrected transmittal log is received. Please make the necessary corrections and regenerate a transmittal for these boxes. The corrected hardcopy log should be faxed to me at \_\_\_\_\_.

Should you require more information, you may telephone me at \_\_\_\_\_.

Thank you in advance.

cc: Karen Petit, Westat  
Revised: 7/28/03

## **A-10-3**

A-10-3: Biorepository Discrepancy Notification

## **EXAMPLE MEMORANDUM #1**

1/13/95

To: Teri Truhart  
Screening Center Coordinator

From: Janis Koci, BS  
Coordinator, East Street Repository

Subject: Request for New Transmittal  
Specimens Not in the Shipment, but in the Transmittal

The discrepancy report accompanying this memorandum indicates that the listed vials were in the Transmittal for your Shipment of 1/5/95, box(es) B0044, but the vials were not included in this shipment.

Please prepare a corrected and complete transmittal by deleting these vials and fax a copy of the corrected hard copy transmittal to me at fax number (301) 846-6941 within the next few days. For this correction there is no need to send a revised electronic Transmittal to the NIH Computer Center.

Thank you for your help.

**EXAMPLE DISCREPANCY REPORT #1**

**Screening Center: 15**

**City University**

1/05/95            Blood Transmittal Records Unmatched with Specimens

Vial ID	Date Received	Box #
-----	-----	-----
XY 0540 006	1/05/95	B0044

## **EXAMPLE MEMORANDUM #2**

1/13/95

To: Teri Truhart  
Screening Center Coordinator

From: Janis Koci, BS  
Coordinator, East Street Repository

Subject: Request for New Transmittal  
Specimens In the Shipment, but Not in the Transmittal

The discrepancy report accompanying this memorandum indicates vials that were included in your shipment of 1/5/95, box(es) B0043, but were not in the Transmittal.

Please prepare a corrected and complete Transmittal including these vials, using the same box number(s), and transmit it to the NIH Computer Center within the next few days. Also please fax the revised hard copy Transmittal to me at fax number (301) 846-6941

Thank you for your help.

**EXAMPLE DISCREPANCY REPORT #2**

**Screening Center: 15**

**City University**

1/05/95            Blood Vials Missing from Transmittal

Vial ID	Date Received	Box #
-----	-----	-----
XY 0538 006	1/05/95	B0043

## **A-10-4**

### A-10-4: Processing Laboratory Transmittal Log

#### Specifications for the Processing Laboratory Transmittal Log

## PLCO CANCER SCREENING TRIAL PROCESSING LABORATORY TRANSMITTAL LOG

Screening Center: \_\_\_\_\_ Study ID: **PLC**

SC ID#: \_\_\_\_\_ Storage Box Number: Y\_\_\_\_

Satellite Center: \_\_\_\_\_ Total Number of Tubes: \_\_\_\_\_

Study Year: T3 Total Number of Ppts: \_\_\_\_\_

Shipment Date: |\_\_|\_| - |\_\_|\_| - |\_\_|\_|  
MO DA YR Receipt Date: |\_\_|\_| - |\_\_|\_| - |\_\_|\_|  
MO DA YR

Time of Shipment: |\_\_|\_| : |\_\_|\_| AM  
PM Time of Receipt: |\_\_|\_| : |\_\_|\_| AM  
PM

FOR SC USE		
SC Sample ID	Circle Tube Seq.#	Draw Date
PASTE Sample ID Label (specimen # 000) Here	012	__ _ - __ _ - __ _  MO DA YR
	013	
PASTE Sample ID Label (specimen # 000) Here	012	__ _ - __ _ - __ _  MO DA YR
	013	
PASTE Sample ID Label (specimen # 000) Here	012	__ _ - __ _ - __ _  MO DA YR
	013	

FOR PROCESSING LABORATORY USE		
Received at Processing Laboratory?	PL Sample ID	Processing Laboratory Notes
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _
Y N	PASTE Sample ID Label (specimen # 000) Here	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
		Processing codes: ____ _

## PLCO CANCER SCREENING TRIAL

### Processing Laboratory Transmittal Log

FOR SC USE																						
SC Sample ID	Circle Tube Seq.#	Draw Date																				
PASTE Sample ID Label (specimen # 000) Here	012	<table style="margin: auto; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">MO</td> <td style="text-align: center;">DA</td> <td style="text-align: center;">YR</td> <td colspan="7"></td> </tr> </table>											MO	DA	YR							
MO	DA	YR																				
013																						
PASTE Sample ID Label (specimen # 000) Here	012	<table style="margin: auto; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">MO</td> <td style="text-align: center;">DA</td> <td style="text-align: center;">YR</td> <td colspan="7"></td> </tr> </table>											MO	DA	YR							
MO	DA	YR																				
013																						
PASTE Sample ID Label (specimen # 000) Here	012	<table style="margin: auto; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">MO</td> <td style="text-align: center;">DA</td> <td style="text-align: center;">YR</td> <td colspan="7"></td> </tr> </table>											MO	DA	YR							
MO	DA	YR																				
013																						
PASTE Sample ID Label (specimen # 000) Here	012	<table style="margin: auto; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">MO</td> <td style="text-align: center;">DA</td> <td style="text-align: center;">YR</td> <td colspan="7"></td> </tr> </table>											MO	DA	YR							
MO	DA	YR																				
013																						

FOR PROCESSING LABORATORY USE		
Received at Processing Laboratory?	PL Sample ID	Processing Laboratory Notes
Y	N	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
Y	N	Processing codes: _____
		Number of vials stored: _____
Y	N	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
Y	N	Processing codes: _____
		Number of vials stored: _____
Y	N	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
Y	N	Processing codes: _____
		Number of vials stored: _____
Y	N	Condition of tubes upon receipt: <input type="checkbox"/> 1 Good condition <input type="checkbox"/> 2 One or more tubes spilled <input type="checkbox"/> 3 One or more tubes broken <input type="checkbox"/> 4 Other (SPECIFY) _____
Y	N	Processing codes: _____
		Number of vials stored: _____

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE PROCESSING LABORATORY TRANSMITTAL LOG**

A Processing Laboratory Transmittal Log must be completed for each shipment of yellow top tubes. This log is to be completed by the SC staff member who is responsible for shipping the yellow top tubes to the Processing Laboratory.

Depending on the number of T3 and/or Vanguard participants scheduled each day, more than one page of the Processing Laboratory Transmittal Log may be needed to record all of the samples included in the shipment. The first page of the log must contain the Administrative Section. Pages with only sample information (no Administrative Section) may be added as needed.

Specifications for completing each item of the form are given below:

**Administrative Section:**

- **Page \_\_\_\_ of \_\_\_\_:** Record the current page number and the total number of pages included.
- **Screening Center:** Record the name of the screening center (SC) on the line provided.
- **SC ID#:** Record the SC's Identification number on the line provided.
- **Satellite Center:** Enter the 2-digit Satellite Center ID number of the location from where the shipment is being sent. If the shipment is not being sent from a satellite center, leave this item blank.
- **Study Year:** T3 is preprinted.
- **Shipment Date:** Record the date the shipment is being sent. Month and day should be zero filled (e.g., 02/07). For the year, only the last two digits need to be entered (e.g., 98 for 1998, 99 for 1999).
- **Time of Shipment:** Record the time the shipment is being sent. Remember to zero-fill numbers, which are less than ten. Circle "AM" or "PM" to indicate the time of day the shipment is being sent.
- **Study ID:** PLC is preprinted.
- **Storage Box Number:** Record the storage box number of the yellow top shipment box. The first character of the storage box number for yellow top tubes will always be "Y."
- **Total Number of Tubes:** Record the total number of yellow top tubes included in the shipment.
- **Total Number of Participants:** Record the total number of T3 participants from which yellow top tubes are being shipped.
- **Receipt Date:** This item will be completed by the Processing Laboratory upon receipt of the shipment.
- **Time of Receipt:** This item will be completed by the Processing Laboratory upon receipt of the shipment.

### **For SC Use**

- **SC Sample ID:** Affix a Sample ID label (with specimen ID # 000) in the space provided in the first column of the log. If two tubes are shipped, only one sample ID label is required and only one entry will be made. If a sample ID label is not available, clearly write the sample ID (AA NNNN) in the box.
- **Circle Tube Seq. #:** Circle the specimen number (012 and/or 013) of any tubes being included in the shipment. For example, if two yellow top tubes are being shipped, circle 012 and 013. If only one tube is being shipped, circle the specimen ID that corresponds with the tube's specimen ID.
- **Draw Date:** Record the date of the blood draw as listed on the BCF3. Month and day should be zero filled (e.g., 02/07). For the year, only the last two digits need to be entered (e.g., 98 for 1998, 99 for 1999).

### **For Processing Laboratory Use**

- **Received at Processing Laboratory:** This item will be completed by the Processing Laboratory upon receipt of the shipment.
- **Processing Laboratory Sample ID:** This item will be completed by the Processing Laboratory upon receipt of the shipment.
- **Processing Laboratory Notes:** This section will be completed by the Processing Laboratory upon receipt of the shipment.

## **A-10-5**

A-10-5: PLCO Shipment Notification for UCLA

PLCO Weekly Projection for Processing Laboratory

PLCO Shipment Notification for Biorepository

PLCO Shipment Notification for Processing Laboratory

# PLCO SHIPMENT NOTIFICATION

For UCLA

To: David Chia  
Company: UCLA Tissue Typing Laboratory  
Fax: (310) 206-0224

From: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_

SC Name: \_\_\_\_\_

SC ID #: \_\_\_\_\_

Shipment Date: \_\_\_\_\_

Total number of shipping boxes in shipment: \_\_\_\_\_ boxes

Federal Express air bill number: \_\_\_\_\_

This message is intended for the sole use of the individual or entity to which it is addressed and may contain information that is proprietary, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or is not responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender at the number listed above. Thank you.

If you do not receive all pages or transmission is unclear, please notify sender identified above.

**PLCO WEEKLY PROJECTION**  
**For Processing Laboratory**

To: Craig Smith  
Company: SAIC-Frederick  
Fax: (301) 846-6022

From: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_

SC Name: \_\_\_\_\_

SC ID #: \_\_\_\_\_

Projection for the week of Monday \_\_\_\_\_ to Saturday \_\_\_\_\_  
(Month/Day) (Month/Day)

Total Number of T3 participants scheduled for visits on:

Monday \_\_\_\_\_

Tuesday \_\_\_\_\_

Wednesday \_\_\_\_\_

Thursday \_\_\_\_\_

Friday \_\_\_\_\_

Saturday \_\_\_\_\_

This message is intended for the sole use of the individual or entity to which it is addressed and may contain information that is proprietary, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or is not responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender at the number listed above. Thank you.

If you do not receive all pages or transmission is unclear, please notify sender identified above.

# PLCO SHIPMENT NOTIFICATION

## For Biorepository

To: Irma Flores  
Company: DCE Repository  
Fax: (301) 846-6108

From: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_

SC Name: \_\_\_\_\_

SC ID #: \_\_\_\_\_

Shipment Date: \_\_\_\_\_

Total number of shipping boxes in shipment: \_\_\_\_\_ boxes

Federal Express airbill number: \_\_\_\_\_

This message is intended for the sole use of the individual or entity to which it is addressed and may contain information that is proprietary, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or is not responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender at the number listed above. Thank you.

If you do not receive all pages or transmission is unclear, please notify sender identified above.

# PLCO SHIPMENT NOTIFICATION

## For Processing Laboratory

To: Bill Kopp  
Company: SAIC-Frederick  
Fax: (301) 846-6022

From: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_

SC Name: \_\_\_\_\_

SC ID #: \_\_\_\_\_

Shipment Date: \_\_\_\_\_

Total number of tubes in shipment: \_\_\_\_\_ tubes

Total number of shipping boxes in shipment: \_\_\_\_\_ boxes

Federal Express airbill number: \_\_\_\_\_

This message is intended for the sole use of the individual or entity to which it is addressed and may contain information that is proprietary, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or is not responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender at the number listed above. Thank you.

If you do not receive all pages or transmission is unclear, please notify sender identified above.

## **A-10-6**

A-10-6: PLCO Discrepancy Notification from  
Processing Laboratory

**PLCO DISCREPANCY NOTIFICATION FROM PROCESSING LABORATORY**

Date: \_\_\_\_\_

TO: \_\_\_\_\_  
SC Coordinator, PLCO project                      Screening Center (and Satellite Center if applicable)

FROM: \_\_\_\_\_  
Processing Laboratory

SUBJECT: Request for Written Clarification

REASON:     \_\_\_\_\_ Specimens were received that were not on the transmittal log  
  
                  \_\_\_\_\_ Specimens were on the transmittal log that were not received  
  
                  \_\_\_\_\_ Specimens were not correctly labeled  
  
                  \_\_\_\_\_ Other: \_\_\_\_\_

Problems encountered with your shipment dated: \_\_\_\_\_.

The boxes involved are: \_\_\_\_\_.

Please provide me with written clarification within the next seven days. If you prefer, make the necessary corrections to the transmittal log and fax me a copy of the corrected log. My fax number is (301) 846-6022 and my email address is Internet: wkopp@mail.ncifcrf.gov.

Should you require more information, you may telephone me at (301) 846-1491. Thank you in advance.

cc: Karen Turk, Westat

Revised: 9/15/00

## **A-10-7**

A-10-7: T4/T5 Blood Collection Form (BFF2)

Specifications for the T4/T5 Blood Collection Form





IF NO T4/T5 BIOREPOSITORY SAMPLES EXPECTED, SKIP PART C.

**PART C: BLOOD COLLECTION AND PROCESSING FOR BIOREPOSITORY SAMPLES**

**1a.** All Required Biorepository Tubes Drawn; No Problems:  
 (GO TO ITEM C.4)

**1b.** No Biorepository Tubes Drawn:  
 (GO TO ITEM C.10)

2. Required Biorepository Tubes Drawn: (COMPLETE FOR EACH REQUIRED TUBE)			3. Problems with Draw: (MARK ALL THAT APPLY)		
T4	NO	YES	NO	YES	CODE
RED TOP	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 2 3 8 _____
LAVENDER TOP	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 2 3 8 _____
T5	NO	YES	NO	YES	CODE
RED TOP	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 2 3 8 _____
LAVENDER TOP (#1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 2 3 8 _____
LAVENDER TOP (#2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	1 2 3 8 _____

**4. Time Centrifuged:**

AM  PM

HOUR MIN.

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**PROBLEMS WITH DRAW CODES**

1 = Short draw    2 = Damaged    3 = Multiple attempts required    8 = Other (SPECIFY)

**5a.** All Required Biorepository Vials Filled; No Problems:  
 (GO TO ITEM C.8)

**5b.** No Biorepository Vials Filled:  
 (GO TO ITEM C.10)

6. Required Biorepository Vials Filled: (COMPLETE FOR EACH REQUIRED VIAL)					7. Processing Problems: (MARK ALL CODES THAT APPLY)		
T4		VIAL	NO	YES	NO	YES	CODE
Red Top	Serum	028	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Serum	029	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
Lavender Top	Plasma	030	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Buffy coat and RBC	031	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
T5		VIAL	NO	YES	NO	YES	CODE
Red Top	Serum	038	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Serum	039	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
Lavender Top (#1)	Plasma	040	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Plasma	041	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Buffy coat	042	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	RBC	043	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
Lavender Top (#2)	Plasma	044	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Plasma	045	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04
	Buffy coat	046	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	01 02 03 04

**8. Time Biorepository Vials Frozen:**

AM  PM

HOUR MIN.

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**PROCESSING PROBLEM CODES**

01 = Hemolyzed serum    02 = Icteric serum    03 = Turbid serum    04 = Partially filled vial



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE T4/T5 BLOOD COLLECTION**  
**FORM - (BFF2)**

This form is to be completed by an SC staff member and the Examiner(s) (Phlebotomist/Laboratory Technologist). The SC staff member will complete the top administrative section and the Forms Processing section. The Phlebotomist will complete Part A, and sections of Parts B and C. Items the Phlebotomist may complete are shaded in tan and have item numbers with a white background. The Laboratory Technologist will complete sections of Parts B and C of the form. Items the Laboratory Technologist may complete have a white background and have tan shaded item numbers. The Laboratory Technologist may also complete the result of blood draw and processing and reasons for inadequate items for both PSA/CA-125II vials and Biorepository samples (items B.8, B.9, C.10, and C.11).

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy marks that fill the circle completely.**

Correct Mark



Incorrect Marks



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

**Sample ID:** Affix a Sample ID label to the horizontal space provided in the lower left corner of the form, above the Participant ID label. The sample ID should be aligned directly over the large shaded box on the left and the vial number should be aligned over the small shaded box on the right.

In cases where the participant was willing to participate in the blood exam, was stuck with a needle, but a blood sample was not obtained, complete the Administra-

tive Section and Part A of the Blood Collection Form, but do not affix a Sample ID label to the form.

1. **Date of Blood Draw:** Record the date of the blood draw. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day and all four (4) digits of the year.
2. **Satellite Center:** Enter the 2-digit Satellite Center ID number where the blood draw is taking place. Darken the circle corresponding to each number. If the examination is not taking place at a satellite center, leave this item blank.
3. **Study Year:** Darken the circle corresponding to study year T4.
4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the PSA/CA-125II blood collection in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the PSA/CA-125II blood collection was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the PSA/CA-125II blood collection, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Participant fainted - unable to obtain PSA/CA-125II blood sample tube during previous visit for blood draw."*

This might be entered if the participant's previous blood draw attempt was inadequate due to the inability to obtain the red top-SST tube, the first priority tube required for the blood protocol, and the participant was willing to return to the SC to attempt the blood draw again. This information will alert the Examiner to the participant's status at the previous visit.

6. **Participant Gender:** Darken a circle to indicate whether the participant is male or female. This will alert the laboratory technologist to the type of vial that should be processed (i.e., PSA for males or CA-125II for females).
7. **Participant Has Reported Cancer or No Organ:** If the participant has a reported prostate or ovarian cancer, darken the circle next to the appropriate type of cancer. If the participant has had his entire prostate removed or both of her ovaries removed, darken the circle next to the appropriate type of organ removed. If the participant has both a reported cancer and an entire organ removed, darken two circles, one circle to record the type of cancer and the other circle to record the type of organ removed. Mark only the appropriate conditions; if a condition is not applicable or unknown, leave it blank. A reported cancer includes both confirmed and unconfirmed cancers. If a prostate or ovarian cancer has been reported, and/or the entire prostate or both ovaries have been removed, the blood for the PSA/CA-125II will not be drawn and Part B will be skipped entirely. If one condition has been bubbled, no additional research is required for a secondary condition.

*If item 7 is bubbled (the participant has a reported prostate or ovarian cancer and/or has had his entire prostate removed or both of her ovaries removed) and the blood for the PSA/CA-125II was drawn in error, complete the following steps:*

1. Enter a comment in item A.5 (comments) stating why the red top-SST was drawn and that the blood was collected in error. This comment does not need to be keyed. If this is the only comment in A.5, bubble comments as "No."
2. Erase all bubbles and marks in Part B (items B1 through B11).
3. In the SMS Participant Status Screen, under Participant's Notes, record that the blood was collected in error.
4. Complete a protocol violation form and submit it to the CC.
5. Refer to Chapter 10 (Blood Sample Protocol) for procedures on handling PSA/CA-125II blood samples collected in error.

*If the blood was drawn in error and has already been shipped, leave the data as is and contact the Specimen Coordinator at Westat.*

- 8. No Biorepository Samples Expected:** If the participant has not signed an Etiologic Studies Consent (ESC) form or another SC version of a document which obtains consent of collection and use of blood for etiologic studies (genetic and cancer research) darken the circle next to "No Biorepository Samples Expected." If the participant has signed an ESC, leave this item blank. Biorepository blood will not be drawn without a signed ESC, and Part C of the form will be skipped entirely. Collection of the blood for the PSA/CA-125II is not dependent on the ESC status.

If Biorepository samples are not expected due to SC protocol (regardless of signed ESC), darken the "No Biorepository Samples Expected" bubble and skip all of Part C.

If the participant signs the ESC during his/her visit, Biorepository blood is collected as specified in Part C. In this situation, forms must be processed in this order: first delete any MDFs for the ESC and BFF, receipt the ESC, and then receipt the BFF or scan the BFF and update SMS.

**If items 7 and 8 are both bubbled for a T4 participant, his/her blood should not have been drawn. Do not complete a BFF but complete an MDF-BFF then discard the BFF.**

### **Part A: Blood Draw:**

Part A is to be completed by the Phlebotomist.

1. **Time of Blood Draw:** Record the time the blood sample is drawn. Darken the circle corresponding to each number. Remember to zero-fill numbers which are less than ten. Darken the circle to indicate the time as AM or PM.
2. **Position of Participant:** Darken the circle corresponding to the position of the participant during the blood draw.
3. **Medical Complications:** Darken one or more circles corresponding to any medical complication which occurred during the blood draw.

None: There are no medical complications that occurred during the blood draw. (If this circle is darkened, no other circles may be darkened; continue with item A.4).

Fainting: A temporary loss of consciousness. Feeling faint or dizzy is not considered fainting.

Light-headedness: A temporary feeling of lightheadedness or feeling faint or dizzy.

Hematoma: A localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue.

Bruising: A localized collection of blood under the skin in the venipuncture space or surrounding tissue.

Other (SPECIFY): Describe any other medical complication that occurred during the blood draw in the space provided.

4. **Phlebotomist's Initials/ID#**: The Phlebotomist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.
5. **Comments**: Additional comments may include reasons for short draws or difficulties with the participant's venous system. Comments recorded in this section should pertain only to items related to the administrative section and to the blood draw. This includes administrative section items 1 through 8, and Part A items A.1 through A.4.

If an extra red top tube was drawn for the Biorepository, this does not need to be noted in comments. However, if it is noted, it does not need to be keyed into DEES.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

### **Part B: Blood Collection and Processing for PSA/CA-125II Samples:**

**If the participant has a reported prostate or ovarian cancer, and/or has had his entire prostate removed or both of her ovaries removed, do not draw the red top SST tube and leave Part B blank.**

Items 1-2a of Part B are to be completed by the Phlebotomist. If the red top SST tube is not drawn for a reason other than prostate/ovarian cancer or no organ, the Phlebotomist must also complete items B.8 and B.9. If the red top SST tube is processed, items 3-11 of Part B are to be completed by the Laboratory Technologist.

1. **Red Top SST Tube Drawn for PSA or CA-125II**: Darken a circle to indicate whether or not the red top SST tube was drawn. Darken the circle next to "Yes" if the tube was partially filled or filled to capacity. The red top SST tube should be obtained at the T4 visit.

If a tube is not drawn but it is required (i.e., the tube is part of the protocol and the participant does not have a reported prostate or ovarian cancer, and has not had his entire prostate removed or both of her ovaries removed), darken the circle next to "No." Then skip to item B.8, and record the result of the blood draw and processing for PSA/CA-125II as "Inadequate." Record the reason(s) for "Inadequate" in item B.9.

The red top SST tube, which is for the PSA/CA-125II sample, will always be the first priority tube to be collected at each screening visit. If the PSA/CA-125II blood sample is not collected for any reason during a screening visit (except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries), the participant should be rescheduled for a redraw of the PSA/CA-125II sample. If a re-draw for PSA/CA125II blood is conducted, darken item C.1b to indi-

cate that no Biorepository tubes will be drawn. Darken "Inadequate" in item C14 and darken "Other (SPECIFY)" in item C15. Record "UCLA re-draw" on the SPECIFY line. Redraws will be scheduled only when the PSA/CA-125II sample was not obtained. A redraw should not be scheduled solely for the purpose of obtaining the Biorepository samples.

If the blood draw is not successfully completed for the red top SST tube, another draw should be attempted from the participant's other arm. If attempts from both arms are unsuccessful, the participant should be scheduled for a repeat visit for the blood exam.

**2. Problems with Red Top SST Tube Draw:** If the tube was drawn and there is no problem with it, darken the circle for "No" and go to item B.3. If there is a problem with the red top SST tube, darken the circle for "Yes" and code the problem in item B.2a. If the red top SST tube was not drawn (item #1 above is coded "No" for red top SST tube drawn), leave this item blank.

**2a. Code Problems with Draw:** If there is a problem with the red top SST tube (item #2 above is coded "Yes"), darken one or more circles corresponding to the appropriate problem code(s). If there is no problem with the red top SST tube (item #2 above is coded "No"), leave this item blank. The definitions for the problem codes are provided below.

1 = Short Draw: There is a short draw in the tube collected.

2 = Damaged: The tube was drawn but became damaged after the blood was collected.

3 = Multiple Attempts Required: More than one attempt ("stick") was needed to obtain blood.

8 = Other (SPECIFY): Describe any other type of problem with the tube in the space provided.

**3. Time Centrifuged:** Record the time the blood sample is centrifuged. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.

**4. Vial Filled:** Darken the circle to indicate which vial is filled. A vial is considered "filled" even if it was only partially filled, and not filled to capacity. Definitions for the responses are listed below.

Yes - Vial 001 for PSA (Blue Cap): If the participant is male and blood was processed for PSA, darken the circle for "Yes."

Yes - Vial 002 for CA-125II (Red Cap): If the participant is female and blood was processed for CA-125II, darken the circle for "Yes."

No – Neither Vial 001 nor 002 filled: If no PSA/CA-125II vials were filled for any reason except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries, darken the circle for "No – Neither Vial 001 nor 002 filled." Then, skip to item B.8 and record the result of blood draw and processing for PSA/CA-125II as "Inadequate." Record the reason(s) for "Inadequate" in item B.9.

If a vial was filled and frozen but lost or damaged before shipping, the "vial filled" circle should be changed from "Yes" to "No," any responses in items B.5 and B.5a should be deleted, and item B.8 should be changed from "adequate" to "inadequate." In item B.9, mark the reason for inadequate as "PSA/CA 125II vial damaged, lost, or destroyed." The form should then be rescanned, edited and

that data updated to SMS. A modified transmittal should be generated before the shipment is sent.

5. **Processing Problems:** If the vial was filled and there is no problem with it, darken the circle for "No" and go to item B.6. If there is a processing problem with the specimen vial, darken the circle for "Yes" and code the problem in item B.5a. A partially filled vial is considered a "problem" and should be marked with problem code of "04" in item B.5a. If the vial was not filled (item #4 above is coded "No – Neither Vial 001 nor 002 filled" for the PSA/CA–125II vial), leave this item blank.

- 5a. **Code Problems with Processing:** If there is a problem with the PSA/CA-125II (item #5 above is coded "Yes"), darken one or more circles corresponding to the appropriate problem code(s). If there is no problem with the PSA/CA-125II vial (item #5 above is coded "No"), leave this item blank. The definitions for the problem codes are provided below.

01 = Hemolyzed serum: The hemoglobin has separated from the red cells causing the serum to turn red.

02 = Icteric serum: The serum is a deep yellow (jaundice) color.

03 = Turbid serum: The serum is cloudy.

04 = Partially filled vial: The specimen vial is not filled to capacity (2 ml) and is only partially filled.

6. **UCLA Storage Box Number:** Record the storage box number for the PSA or CA-125II specimen. If the specimen being stored is a CA-125II vial, the first two characters will always be "UC." If the specimen being stored is a PSA vial, the first two characters of the storage box number will always be "UP." Darken the circle corresponding to "C" or "P," then darken the circles corresponding to each of the four digits.

7. **Time Frozen:** Record the time the PSA/CA-125II blood sample is frozen. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.

8. **Result of Blood Draw and Processing for PSA/CA-125II:** Darken the circle corresponding to the result of the PSA/CA-125II blood draw and processing. Definitions of PSA/CA-125II results are given below:

Adequate - PSA/CA-125II vial obtained: The red top-SST tube was obtained and the vial filled. (Go to item B.10.)

Inadequate - PSA/CA-125II vial not obtained: Either the red top-SST tube was not obtained (for any reason, except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries) or the red top-SST tube was obtained but the vial was not filled, lost or damaged. Record the reason(s) for the inadequate result of the blood draw and processing in item B.9 below.

9. **Reason for Inadequate:** Darken one or more circles to indicate the reason(s) for the inadequate result of the blood draw and processing.

Participant refusal: The participant is unwilling to allow completion of the blood draw procedure. Therefore, the tube was not obtained. (Only the Phlebotomist may assign this reason.)

Poor venous access: The blood draw was attempted, but due to the participant's poor venous access, the tube was not obtained. (Only the Phlebotomist may assign this reason.)

Red Top-SST tube damaged, lost or destroyed: The blood draw procedure was attempted, but the red top-SST tube was either: damaged, lost, or destroyed prior to/during/or after processing, and the PSA/CA-125II vial could not be filled. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Equipment problems: Blood was drawn, but due to equipment problems during the blood collection and/or processing a serum sample is not available for testing. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Serum QNS (quantity not sufficient): The red top-SST tube was obtained during the blood draw procedure, however, the serum quantity was not sufficient to fill the PSA/CA-125II vial. (Only the Laboratory Technologist may assign this reason.)

PSA/CA-125II vial damaged, lost, or destroyed: The red top-SST tube was obtained during the blood draw procedure and the PSA/CA-125II vial was filled, but the vial was subsequently damaged, lost, or destroyed and could not be shipped. (Only the Laboratory Technologist may assign this reason.)

Other (SPECIFY): Describe any other reason for inadequate in the space provided. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

- 10. Comments:** If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., B.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF). Comments recorded in this box should pertain only to items related to the processing of the PSA/CA-125II vial. This includes Part B items B.1. through B.9.
- 11. Lab Tech's Initials/ID#:** The Laboratory Technologist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.

### **Part C: Blood Collection and Processing for T4 Biorepository Samples:**

**If the participant has not signed an Etiologic Studies Consent form, do not collect any of the Biorepository tubes, and leave Part C blank. If T4 Biorepository samples are not expected due to SC protocol (regardless of signed ESC), do not collect any of the Biorepository tubes and leave Part C blank.**

Items 1-3 of Part C are to be completed by the Phlebotomist. If none of the required Biorepository samples are drawn, the Phlebotomist must also complete items C.10 and C.11. If the Biorepository samples are processed, items 4-13 of Part C are to be completed by the Laboratory Technologist.

- 1a. All Required Biorepository Tubes Drawn; No Problems:** Darken this bubble if all Biorepository tubes were successfully drawn and skip to item C.4. If this circle is darkened, items C.2 and C.3 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "all required Biorepository tubes drawn; no problems" circle is darkened and one or more circles are darkened in C.2 or C.3, the system will not automatically complete C.2 and C.3.

If the SC has a modified blood collection protocol in which an additional tube of blood is obtained, this bubble may be used to document successful collection of tubes required by the regular PLCO protocol as well as the additional tube. If the additional tube is not collected or has problems but the regular PLCO tubes were collected without problems, this bubble should be darkened. Non-collection or problems with the collection of the extra tube should be documented in item C.12 (Comments).

- 1b. No Biorepository Tubes Drawn:** Darken this bubble if none of the tubes were successfully drawn and skip to item C.10. If this circle is darkened, items C.2 and C.3 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "no Biorepository tubes drawn" circle is darkened and one or more circles are darkened in C.2 or C.3, the system will not automatically complete C.2 and C.3.
- 2. Required Biorepository Tubes Drawn:** Darken a circle to indicate whether or not each tube of blood was drawn. Darken the circle next to "Yes" if the tube was partially filled or filled to capacity. If a tube is not drawn but it is required (i.e., the tube is part of the protocol for the current study year), darken the circle next to "No."

Biorepository tubes for the T4 study year should be obtained as follows:

T4 Visit

Red top

Lavender top

T5 Visit

Red Top

Lavender top #1

Lavender top #2

Biorepository tubes should be drawn for the T4 study year even if the participant has a reported prostate or ovarian cancer and/or has had his entire prostate or both of her ovaries removed.

If the blood draw is not successfully completed for all tubes (all tubes filled to capacity), another draw should be attempted from the participant's other arm. *A redraw should not be scheduled solely for the purpose of obtaining the Biorepository samples.*

- 3. Problems with Draw:** If the tube was drawn and there is no problem with it, darken the circle for "No." If there is a problem with the tube of blood drawn, darken the circle for "Yes" and then darken one or more circles corresponding to the appropriate problem code(s). If the tube of blood was not drawn (item #2 above is coded "No" for the tube drawn), leave this item blank. The definitions for the problem codes are provided below.

1 = Short Draw: There is a short draw in the tube collected.

2 = Damaged: The tube was drawn but became damaged after the blood was collected.

3 = Multiple Attempts Required: More than one attempt ("stick") was needed to obtain blood.

8 = Other (SPECIFY): Describe any other type of problem with the tube in the space provided.

4. **Time Centrifuged:** Record the time the blood samples are centrifuged. Darken the circle corresponding to each number. Remember to zero-fill numbers which are less than ten. Darken the circle to indicate the time as AM or PM.
- 5a. **All Required Biorepository Vials Filled; No Problems:** Darken this bubble if all vials were filled and skip to item C.8. A partially filled vial is considered a "problem" and this bubble may not be darkened if there are any partially filled vials. Definitions for additional processing problems are provided in item C.7. If this circle is darkened, items C.6 and C.7 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "all required Biorepository vials filled; no problems" circle is darkened and one or more circles are darkened in C.6 or C.7, the system will not automatically complete C.6 and C.7.
- 5b. **No Biorepository Vials filled:** Darken this bubble if none of the vials were filled and skip to item C.10. A vial is considered "filled" even if it was only partially filled, and not filled to capacity. This bubble may not be darkened if there are any partially filled vials. If this circle is darkened, items C.6 and C.7 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "no Biorepository vials filled" circle is darkened and one or more circles are darkened in C.6 and C.7, the system will not automatically complete C.6 and C.7.
6. **Required Biorepository Vials Filled:** Darken the circles corresponding to vials filled. If a vial is completely or partially filled, darken the circle for "Yes." If a vial is not filled but it is required darken the circle next to "No."

If a vial was filled and frozen but lost or damaged before shipping, the "vial filled" circle should be changed from "Yes" to "No," any processing problem codes should be deleted, and if necessary, items C.10 (result of blood draw and processing for Biorepository) and C.11 (reason for partial or inadequate), should be corrected. Then, the form should be rescanned, edited, and the data updated to SMS. A modified transmittal should be generated before the shipment is sent.

Biorepository vials for the T4 study year should be filled as follows:

T4		
Red Top	Serum	Vial 028
	Serum	Vial 029
Lavender Top	Plasma	Vial 030
	Buffy Coat & RBC	Vial 031

**Processing Notes for T4:**

**Serum:** Vials 028 and 029 When filling the vials with serum, if there is not enough serum to fill both vials, fill one vial first until full (2.0 ml), then fill the second vial with the remaining serum.

**Plasma:** Vial 030 Fill the vial to the 3.6-ml line with plasma.

**Buffy Coat & RBC:** Vial 031 Collect the buffy coat and RBCs by suctioning from the top of the buffy coat layer then gradually moving downward in a circular motion as the buffy coat and RBCs are aspirated. Aliquot until the 3.6-ml fill line is reached.

T5

T5		
<b>Red Top</b>	Serum	Vial 038
	Serum	Vial 039
<b>Lavender Top #1</b>	Plasma	Vial 040
	Plasma	Vial 041
	Buffy coat	Vial 042
	RBC	Vial 043
<b>Lavender Top #2</b>	Plasma	Vial 044
	Plasma	Vial 045
	Buffy Coat	Vial 046

**Processing Notes for T5:**

**Serum:** Vials 038 and 039 When filling the vials with serum, if there is not enough serum to fill both vials, fill one vial first until full (2.0 ml), then fill the second vial with the remaining serum.

**Plasma:** Vials 040, 041, 044 and 045 (from lavender top #1 or #2) An attempt should be made to fill vials 040 and 041 with plasma from lavender top #1 and to fill vials 044 and 045 with plasma from lavender top #2. If sufficient plasma is not obtained from lavender top #2, any extra plasma from lavender top #1 may be used to fill these vials and vice versa. If plasma was collected from lavender top #1 and/or #2, darken the circle for "Yes". If plasma was not collected from lavender top #1 or #2, darken the circle for "No".

**Buffy Coat:** Vials 042 and 046 (from lavender top #1 and #2) Collect the buffy coat by suctioning from the top of the buffy coat layer then gradually moving downward in a circular motion as the buffy coat is aspirated. Aliquot until the 2.0-ml fill line is reached. In order to maximize buffy coat yield, when removing plasma leave a small amount of plasma above the buffy coat and when removing buffy coat include a small amount of RBC in the sample.

**RBC** Vial 043 Collect the RBCs by suctioning from the top of the RBC layer then gradually moving downward in a circular motion as the RBCs are aspirated. Aliquot until the 2.0-ml fill line is reached.

7. **Processing Problems:** If the vial was filled and there is no problem with it, darken the circle for "No." If there is a problem with the vial, darken the circle for "Yes" and then darken one or more circles corresponding to the appropriate problem code(s). If the vial was not filled (item #6 above is coded "No" for the vial), leave this item blank. The definitions for the problem codes are provided below.

01 = Hemolyzed serum: The hemoglobin has separated from the red cells causing the serum to turn red.

02 = Icteric serum: The serum is a deep yellow (jaundice) color.

03 = Turbid serum: The serum is cloudy.

04 = Partially filled vial: The specimen vial is not filled to the required capacity and is only partially filled.

8. **Time Biorepository Vials Frozen:** Record the time the appropriate Biorepository blood samples are frozen. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.

9. **3-inch Biorepository Storage Box Number:** Record the storage box number for the storage of all Biorepository vials. The first character of the storage box number for vials 028-031 will always be "B." Darken the circle corresponding to each of the four digit numbers. If none of the Biorepository vials were filled, leave this item blank.

10. **Result of Blood Draw and Processing for Biorepository:** Darken the circle corresponding to the result of the Biorepository blood draw and processing. Definitions of the Biorepository results are given below:

Complete – all vials filled to required capacity: Darken this bubble, if all vials were filled to the required capacity. This bubble may not be darkened if there are any partially filled vials. If this bubble is darkened, skip to item C.12.

Partial – not all vials filled to required capacity: Darken this bubble, if at least one, but not all of the vials were filled to the required capacity. This bubble should be darkened if there are any partially filled or missing vials. Record the reason(s) for the partial result of the Biorepository blood draw and processing in item C.11 below.

Inadequate – no vials filled: Darken this bubble, if either none of the Biorepository tubes were obtained or the Biorepository tubes were obtained but none of the vials were filled. Record the reason(s) for the inadequate result of the Biorepository blood draw and processing in item C.11 below.

11. **Reason for Partial or Inadequate:** Darken one or more circles to indicate the reason(s) for the partial or inadequate result of the Biorepository blood draw and processing.

Participant refusal: The participant is unwilling to allow completion of the blood draw procedure and some or all of the Biorepository tubes could not be obtained. (Only the Phlebotomist may assign this reason.)

Poor venous access: The blood draw was attempted, but due to the participant's poor venous access some or all of the Biorepository tubes were not obtained. (Only the Phlebotomist may assign this reason.)

Tube(s) damaged, lost, or destroyed: The blood draw procedure was attempted, but some or all of the Biorepository tubes were either: damaged, lost, or destroyed prior to/during/or after processing and some or all of the Bioreposi-

tory vials could not be filled. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Equipment problems: Blood was drawn, but due to equipment problems during the blood collection and/or processing one or more of the Biorepository vials are not available for testing. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Blood component QNS (quantity not sufficient): Some or all of the Biorepository tubes were drawn during the blood draw procedure, however, one or more of the blood component quantities was not sufficient to fill the required vials to capacity. (Only the Laboratory Technologist may assign this reason.)

Vial(s) damaged, lost or destroyed: Some or all of the Biorepository tubes were obtained during the blood draw procedure and some or all of the Biorepository vials were filled, but one or more vials were subsequently damaged, lost, or destroyed and could not be shipped. (Only the Laboratory Technologist may assign this reason.)

Other (SPECIFY): Describe any other reason for inadequate in the space provided. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

- 12. Comments:** If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., C.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF). Comments recorded in this box should pertain only to items related to the processing of the Biorepository vials or the shipment of the yellow top tubes. This includes Part C items C1a through C.11.
- 13. Lab Tech's Initials/ID#:** The Laboratory Technologist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.

### **Forms Processing:**

The Forms Processing box is to be completed by the SC staff member.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not

additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicated the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each OpScan form in the system, but is not required to mark the disposition on the hard copy form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional Forms Processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the OpScan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-10-8**

A-10-8: BCF3 Vanguard  
Vanguard Blood Collection Procedures  
Vanguard Blood Collection Form

Specifications for the Vanguard Blood Collection  
Form





IF NO BIOREPOSITORY SAMPLES EXPECTED, SKIP PART C.

**PART C: BLOOD COLLECTION AND PROCESSING FOR BIOREPOSITORY SAMPLES**

**1a.** All Required Biorepository Tubes Drawn; No Problems:  
 (GO TO ITEM C.4)

**1b.** No Biorepository Tubes Drawn:  
 (GO TO ITEM C.14)

**2. Required Biorepository Tubes Drawn:**  
 (COMPLETE FOR EACH REQUIRED TUBE)

Vanguard	NO	YES
YELLOW TOP #1 (012)	<input type="radio"/>	<input type="radio"/>
YELLOW TOP #2 (013)	<input type="radio"/>	<input type="radio"/>
GREEN TOP	<input type="radio"/>	<input type="radio"/>
LAVENDER TOP	<input type="radio"/>	<input type="radio"/>

**3. Problems with Draw:** (MARK ALL THAT APPLY)

NO	YES	CODE
<input type="radio"/>	<input type="radio"/>	① ② ③ ④ _____
<input type="radio"/>	<input type="radio"/>	① ② ③ ④ _____
<input type="radio"/>	<input type="radio"/>	① ② ③ ④ _____
<input type="radio"/>	<input type="radio"/>	① ② ③ ④ _____

**4. Time Centrifuged:**

AM  PM

HOUR		MIN.	
0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**PROBLEMS WITH DRAW CODES**

1 = Short draw    2 = Damaged    3 = Multiple attempts required    8 = Other (SPECIFY)

**5a.** All Required Biorepository Vials Filled; No Problems:  
 (GO TO ITEM C.8)

**5b.** No Biorepository Vials Filled:  
 (GO TO ITEM C.14)

**6. Required Biorepository Vials Filled:**  
 (COMPLETE FOR EACH REQUIRED VIAL)

Vanguard			NO	YES
Green Top	Plasma	014	<input type="radio"/>	<input type="radio"/>
	Plasma	015	<input type="radio"/>	<input type="radio"/>
	Buffy coat	016	<input type="radio"/>	<input type="radio"/>
Lavender Top	Plasma	017	<input type="radio"/>	<input type="radio"/>
	Plasma	018	<input type="radio"/>	<input type="radio"/>
	Plasma	019	<input type="radio"/>	<input type="radio"/>
	Plasma	020	<input type="radio"/>	<input type="radio"/>
	Buffy coat	021	<input type="radio"/>	<input type="radio"/>
	RBC	023	<input type="radio"/>	<input type="radio"/>

**7. Processing Problems:**  
 (MARK ALL CODES THAT APPLY)

NO	YES	CODE
<input type="radio"/>	<input type="radio"/>	①① ①② ①③ ①④
<input type="radio"/>	<input type="radio"/>	②① ②② ②③ ②④
<input type="radio"/>	<input type="radio"/>	③① ③② ③③ ③④
<input type="radio"/>	<input type="radio"/>	④① ④② ④③ ④④
<input type="radio"/>	<input type="radio"/>	⑤① ⑤② ⑤③ ⑤④
<input type="radio"/>	<input type="radio"/>	⑥① ⑥② ⑥③ ⑥④
<input type="radio"/>	<input type="radio"/>	⑦① ⑦② ⑦③ ⑦④
<input type="radio"/>	<input type="radio"/>	⑧① ⑧② ⑧③ ⑧④
<input type="radio"/>	<input type="radio"/>	⑨① ⑨② ⑨③ ⑨④

**8. Time Biorepository Vials Frozen:**

AM  PM

HOUR		MIN.	
0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

**PROCESSING PROBLEM CODES**    01 = Hemolyzed serum    02 = Icteric serum    03 = Turbid serum    04 = Partially filled vial

**PART C: BLOOD COLLECTION AND PROCESSING FOR BIOREPOSITORY SAMPLES: (cont'd)**

**Note:**  
Items 10 and 11 were intentionally omitted

**9. 2-inch Biorepository Storage Box #:**

B	-				
		0	0	0	0
		1	1	1	1
		2	2	2	2
		3	3	3	3
		4	4	4	4
		5	5	5	5
		6	6	6	6
		7	7	7	7
		8	8	8	8
		9	9	9	9

**For Vanguard Biorepository Samples Only**

**12. Yellow Top Tubes Storage Box #:**

Y	-				
		0	0	0	0
		1	1	1	1
		2	2	2	2
		3	3	3	3
		4	4	4	4
		5	5	5	5
		6	6	6	6
		7	7	7	7
		8	8	8	8
		9	9	9	9

(Optional)

**13. Shipment of Yellow Top Tubes:**

Shipped same date drawn

Not shipped

OR

Date of shipment:

MO.	DAY	YEAR
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

<b>14. Result of Blood Draw and Processing for Biorepository:</b>	<b>15. Reason for Partial or Inadequate:</b> (MARK ALL THAT APPLY)	<b>16. Comments:</b> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY)		<b>17. Lab Tech's Initials/ID#:</b>																																												
		Item #	Comments																																													
<input type="radio"/> Complete - all vials filled to required capacity (GO TO C.16)  <input type="radio"/> Partial - not all vials filled to required capacity  <input type="radio"/> Inadequate - no vials filled	<input type="radio"/> Participant refusal <input type="radio"/> Poor venous access <input type="radio"/> Tube(s) damaged, lost, or destroyed <input type="radio"/> Equipment problems <input type="radio"/> Blood component QNS <input type="radio"/> Vial(s) damaged, lost, or destroyed <input type="radio"/> Other (SPECIFY) _____			Initials <table border="1"> <tr><td></td><td></td><td></td><td></td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9
		0	0	0	0																																											
		1	1	1	1																																											
		2	2	2	2																																											
		3	3	3	3																																											
		4	4	4	4																																											
		5	5	5	5																																											
		6	6	6	6																																											
		7	7	7	7																																											
8	8	8	8																																													
9	9	9	9																																													
				ID#																																												

Continued

**For Office Use Only**

**Forms Processing (DARKEN CIRCLES AS STEPS ARE COMPLETED)**

Form Received into SMS <input type="radio"/>	<b>Data Retrieval:</b>	<b>Data Entry of Non-Scannable Items:</b>	<b>Final Disposition:</b>
Manual Review Completed <input type="radio"/>	Attempted <input type="radio"/> OR None <input type="radio"/> Required	Completed <input type="radio"/> OR None <input type="radio"/> Required	Final Complete (FCM) <input type="radio"/> OR Final Incomplete (FIC) <input type="radio"/>

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

PLEASE DO NOT WRITE IN THIS AREA

	089693
--	--------

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE VANGUARD BLOOD COLLECTION**  
**FORM - (BCF3)**

This form is to be completed by an SC staff member and the Examiner(s) (Phlebotomist/Laboratory Technologist). The SC staff member will complete the top administrative section and the Forms Processing section. The Phlebotomist will complete Part A, and sections of Parts B and C. Items the Phlebotomist may complete are shaded in orange and have item numbers with a white background. The Laboratory Technologist will complete sections of Parts B and C of the form. Items the Laboratory Technologist may complete have an orange background and have blue shaded item numbers. The Laboratory Technologist may also complete the result of blood draw and processing and reasons for inadequate items for both PSA/CA-125II vials and Biorepository samples (items B.8, B.9, C.14, and C.15).

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- **Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.**
- **Make heavy marks that fill the circle completely.**

Correct Mark



Incorrect Marks



- **If you need to change an answer, be sure to erase completely.**
- **Mark only one response for each question, unless the instructions tell you otherwise.**
- **Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, and then follow the instructions as directed. Unless instructed otherwise, go to the next question.**

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the lower left corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

**Sample ID:** Affix a Sample ID label to the horizontal space provided in the lower left corner of the form, above the Participant ID label. The sample ID should be aligned directly over the large shaded box on the left and the vial number should be aligned over the small shaded box on the right.

In cases where the participant was willing to participate in the blood exam, was stuck with a needle, but a blood sample was not obtained, complete the Administrative Section and Part A of the Blood Collection Form, but do not affix a Sample ID label to the form.

1. **Date of Blood Draw:** Record the date of the blood draw. Month and day should be zero filled (e.g., 02/07). For the year all four (4) digits need to be entered. Darken the circles corresponding to the month, day and year.
2. **Satellite Center:** Enter the 2-digit Satellite Center ID number where the blood draw is taking place. Darken the circle corresponding to each number. If the examination is not taking place at a satellite center, leave this item blank.
3. **Study Year:** The study year identifier for the vanguard group has been pre-filled. Vanguard blood collection will occur either in T5 or T7 depending upon when the participant was randomized.
4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the PSA/CA-125II blood collection in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the PSA/CA-125II blood collection was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the PSA/CA-125II blood collection, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Participant fainted—unable to obtain PSA/CA-125II blood sample tube during previous visit for blood draw."*

This might be entered if the participant's previous blood draw attempt was inadequate due to the inability to obtain the red top-SST tube, the first priority tube required for the blood protocol, and the participant was willing to return to the SC to attempt the blood draw again. This information will alert the Examiner to the participant's status at the previous visit.

6. **Participant Gender:** Darken a circle to indicate whether the participant is male or female. This will alert the laboratory technologist to the type of vial that should be processed (i.e., PSA for males or CA-125II for females).
7. **Participant Has Reported Cancer or No Organ:** If the participant has a reported prostate or ovarian cancer, darken the circle next to the appropriate type of cancer. If the participant has had his entire prostate removed or both of her ovaries removed, darken the circle next to the appropriate type of organ removed. If the participant has both a reported cancer and an entire organ removed, darken two circles, one circle to record the type of cancer and the other circle to record the type of organ removed. Mark only the appropriate conditions; if a condition is not applicable or unknown, leave it blank. A reported cancer includes both confirmed and unconfirmed cancers. If a prostate or ovarian cancer has been reported, and/or the entire prostate or both ovaries have been removed, the blood for the PSA/CA-125II will not be drawn and Part B will be skipped entirely. If one condition has been bubbled, no additional research is required for a secondary condition.

*If item 7 is bubbled (the participant has a reported prostate or ovarian cancer and/or has had his entire prostate removed or both of her ovaries removed) and the blood for the PSA/CA-125II was drawn in error, complete the following steps:*

1. Enter a comment in item A.5 (comments) stating why the red top-SST was drawn and that the blood was collected in error. This comment does not need to be keyed. If this is the only comment in A.5, bubble comments as "No."
  2. Erase all bubbles and marks in Part B (items B1 through B11).
  3. In the SMS Participant Status Screen, under Participant's Notes, record that the blood was collected in error.
  4. Complete a protocol violation form and submit it to the CC.
  5. Refer to Chapter 10 (Blood Sample Protocol) for procedures on handling PSA/CA-125II blood samples collected in error.
- 8. No Biorepository Samples Expected:** If the participant has not signed an Etiologic Studies Consent (ESC) form or another SC version of a document which obtains consent of collection and use of blood for etiologic studies (genetic and cancer research) darken the circle next to "No Biorepository Samples Expected." If the participant has signed an ESC, leave this item blank. Biorepository blood will not be drawn without a signed ESC, and Part C of the form will be skipped entirely. Collection of the blood for the PSA/CA-125II is not dependent on the ESC status.

If Biorepository samples are not expected due to SC protocol (regardless of signed ESC), darken the "No Biorepository Samples Expected" bubble and skip all of Part C.

If the participant signs the ESC during his/her visit, Biorepository blood is collected as specified in Part C. In this situation, forms must be processed in this order: first delete any MDFs for the ESC and the Vanguard BCF3, receipt the ESC, and then receipt the Vanguard BCF3 or scan the Vanguard BCF3 and update SMS.

**If items 7 and 8 are both bubbled for participant, his/her blood should not have been drawn. Do not complete the Vanguard BCF3 but complete an MDF-Vanguard BCF3 then discard the Vanguard BCF3.**

**Part A: Blood Draw:**

Part A is to be completed by the Phlebotomist.

1. 1. Time of Blood Draw: Record the time the blood sample is drawn. Darken the circle corresponding to each number. Remember to zero-fill numbers which are less than ten. Darken the circle to indicate the time as AM or PM.
2. 2. Position of Participant: Darken the circle corresponding to the position of the participant during the blood draw.
3. 3. Medical Complications: Darken one or more circles corresponding to any medical complication which occurred during the blood draw.

None: There are no medical complications that occurred during the blood draw. (If this circle is darkened, no other circles may be darkened; continue with item A.4).

Fainting: A temporary loss of consciousness. Feeling faint or dizzy is not considered fainting.

Light-headedness: A temporary feeling of lightheadedness or feeling faint or dizzy.

Hematoma: A localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue.

Bruising: A localized collection of blood under the skin in the venipuncture space or surrounding tissue.

Other (SPECIFY): Describe any other medical complication that occurred during the blood draw in the space provided.

4. **Phlebotomist's Initials/ID#**: The Phlebotomist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.
5. **Comments**: Additional comments may include reasons for short draws or difficulties with the participant's venous system. Comments recorded in this section should pertain only to items related to the administrative section and to the blood draw. This includes administrative section items 1 through 8, and Part A items A.1 through A.4.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

#### **Part B: Blood Collection and Processing for PSA/CA-125II Samples:**

**If the participant has a reported prostate or ovarian cancer, and/or has had his entire prostate removed or both of her ovaries removed, do not draw the red top SST tube and leave Part B blank.**

Items 1-2a of Part B are to be completed by the Phlebotomist. If the red top SST tube is not drawn for a reason other than prostate/ovarian cancer or no organ, the Phlebotomist must also complete items B.8 and B.9. If the red top SST tube is processed, items 3-11 of Part B are to be completed by the Laboratory Technologist.

1. **Red Top SST Tube Drawn for PSA or CA-125II**: Darken a circle to indicate whether or not the red top SST tube was drawn. Darken the circle next to "Yes" if the tube was partially filled or filled to capacity.

If a tube is not drawn but it is required (i.e., the tube is part of the protocol and the participant does not have a reported prostate or ovarian cancer, and has not had his entire prostate removed or both of her ovaries removed), darken the circle next to "No." Then skip to item B.8, and record the result of the blood draw and processing for PSA/CA-125II as "Inadequate." Record the reason(s) for "Inadequate" in item B.9.

The red top SST tube, which is for the PSA/CA-125II sample, will always be the first priority tube to be collected. If the PSA/CA-125II blood sample is not collected for any reason (except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries), the participant should be rescheduled for a redraw of the PSA/CA-125II sample. If a re-draw for PSA/CA125II blood is conducted, darken item C.1b to indicate that no Biorepository tubes will be drawn. Darken "Inadequate" in item C14 and darken "Other (SPECIFY)" in item C15. Record "UCLA re-draw" on the SPECIFY line. *Redraws will be scheduled only when the PSA/CA-125II sample was not obtained. A redraw should not be scheduled solely for the purpose of obtaining the Biorepository samples.*

If the blood draw is not successfully completed for the red top SST tube, another draw should be attempted from the participant's other arm. If attempts from both

arms are unsuccessful, the participant should be scheduled for a repeat visit for the blood exam.

2. **Problems with Red Top SST Tube Draw:** If the tube was drawn and there is no problem with it, darken the circle for "No" and go to item B.3. If there is a problem with the red top SST tube, darken the circle for "Yes" and code the problem in item B.2a. If the red top SST tube was not drawn (item #1 above is coded "No" for red top SST tube drawn), leave this item blank.

- 2a. **Code Problems with Draw:** If there is a problem with the red top SST tube (item #2 above is coded "Yes"), darken one or more circles corresponding to the appropriate problem code(s). If there is no problem with the red top SST tube (item #2 above is coded "No"), leave this item blank. The definitions for the problem codes are provided below.

1 = Short Draw: There is a short draw in the tube collected.

2 = Damaged: The tube was drawn but became damaged after the blood was collected.

3 = Multiple Attempts Required: More than one attempt ("stick") was needed to obtain blood.

8 = Other (SPECIFY): Describe any other type of problem with the tube in the space provided.

3. **Time Centrifuged:** Record the time the blood sample is centrifuged. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.

4. **Vial Filled:** Darken the circle to indicate which vial is filled. A vial is considered "filled" even if it was only partially filled, and not filled to capacity. Definitions for the responses are listed below.

Yes - Vial 001 for PSA (Blue Cap): If the participant is male and blood was processed for PSA, darken the circle for "Yes."

Yes - Vial 002 for CA-125II (Red Cap): If the participant is female and blood was processed for CA-125II, darken the circle for "Yes."

No – Neither Vial 001 nor 002 filled: If no PSA/CA-125II vials were filled for any reason except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries, darken the circle for "No – Neither Vial 001 nor 002 filled." Then, skip to item B.8 and record the result of blood draw and processing for PSA/CA-125II as "Inadequate." Record the reason(s) for "Inadequate" in item B.9.

If a vial was filled and frozen but lost or damaged before shipping, the "vial filled" circle should be changed from "Yes" to "No," any responses in items B.5 and B.5a should be deleted, and item B.8 should be changed from "adequate" to "inadequate." In item B.9, mark the reason for inadequate as "PSA/CA 125II vial damaged, lost, or destroyed." The form should then be rescanned, edited and that data updated to SMS. A modified transmittal should be generated before the shipment is sent.

5. **Processing Problems:** If the vial was filled and there is no problem with it, darken the circle for "No" and go to item B.6. If there is a processing problem with the specimen vial, darken the circle for "Yes" and code the problem in item B.5a. A partially filled vial is considered a "problem" and should be marked with problem code

of "04" in item B.5a. If the vial was not filled (item #4 above is coded "No – Neither Vial 001 nor 002 filled" for the PSA/CA-125II vial), leave this item blank.

- 5a. Code Problems with Processing:** If there is a problem with the PSA/CA-125II (item #5 above is coded "Yes"), darken one or more circles corresponding to the appropriate problem code(s). If there is no problem with the PSA/CA-125II vial (item #5 above is coded "No"), leave this item blank. The definitions for the problem codes are provided below.

01 = Hemolyzed serum: The hemoglobin has separated from the red cells causing the serum to turn red.

02 = Icteric serum: The serum is a deep yellow (jaundice) color.

03 = Turbid serum: The serum is cloudy.

04 = Partially filled vial: The specimen vial is not filled to capacity (2 ml) and is only partially filled.

- 6. UCLA Storage Box Number:** Record the storage box number for the PSA or CA-125II specimen. If the specimen being stored is a CA-125II vial, the first two characters will always be "UC." If the specimen being stored is a PSA vial, the first two characters of the storage box number will always be "UP." Darken the circle corresponding to "C" or "P," then darken the circles corresponding to each of the four digits.
- 7. Time Frozen:** Record the time the PSA/CA-125II blood sample is frozen. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.
- 8. Result of Blood Draw and Processing for PSA/CA-125II:** Darken the circle corresponding to the result of the PSA/CA-125II blood draw and processing. Definitions of PSA/CA-125II results are given below:

Adequate - PSA/CA-125II vial obtained: The red top-SST tube was obtained and the vial filled. (Go to item B.10.)

Inadequate - PSA/CA-125II vial not obtained: Either the red top-SST tube was not obtained (for any reason, except a reported prostate or ovarian cancer and/or removal of the participant's entire prostate or both ovaries) or the red top-SST tube was obtained but the vial was not filled, lost or damaged. Record the reason(s) for the inadequate result of the blood draw and processing in item B.9 below.

- 9. Reason for Inadequate:** Darken one or more circles to indicate the reason(s) for the inadequate result of the blood draw and processing.

Participant refusal: The participant is unwilling to allow completion of the blood draw procedure. Therefore, the tube was not obtained. (Only the Phlebotomist may assign this reason.)

Poor venous access: The blood draw was attempted, but due to the participant's poor venous access, the tube was not obtained. (Only the Phlebotomist may assign this reason.)

Red Top-SST tube damaged, lost or destroyed: The blood draw procedure was attempted, but the red top-SST tube was either: damaged, lost, or destroyed prior to/during/or after processing, and the PSA/CA-125II vial could not be filled. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Equipment problems: Blood was drawn, but due to equipment problems during the blood collection and/or processing a serum sample is not available for testing. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Serum QNS (quantity not sufficient): The red top-SST tube was obtained during the blood draw procedure, however, the serum quantity was not sufficient to fill the PSA/CA-125II vial. (Only the Laboratory Technologist may assign this reason.)

PSA/CA-125II vial damaged, lost, or destroyed: The red top-SST tube was obtained during the blood draw procedure and the PSA/CA-125II vial was filled, but the vial was subsequently damaged, lost, or destroyed and could not be shipped. (Only the Laboratory Technologist may assign this reason.)

Other (SPECIFY): Describe any other reason for inadequate in the space provided. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

- 10. Comments:** If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., B.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF). Comments recorded in this box should pertain only to items related to the processing of the PSA/CA-125II vial. This includes Part B items B.1. through B.9.
- 11. Lab Tech's Initials/ID#:** The Laboratory Technologist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.

### **Part C: Blood Collection and Processing for Vanguard Biorepository Samples:**

**If the participant has not signed an Etiologic Studies Consent form, do not collect any of the Biorepository tubes, and leave Part C blank. If Biorepository samples are not expected due to SC protocol (regardless of signed ESC), do not collect any of the Biorepository tubes and leave Part C blank.**

Items 1-3 of Part C are to be completed by the Phlebotomist. If none of the required Biorepository samples are drawn, the Phlebotomist must also complete items C.14 and C.15. If the Biorepository samples are processed, items 4-9 and 12-17 of Part C are to be completed by the Laboratory Technologist.

- 1a. All Required Biorepository Tubes Drawn; No Problems:** Darken this bubble if all Biorepository tubes were successfully drawn and skip to item C.4. If this circle is darkened, items C.2 and C.3 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "all required Biorepository tubes drawn; no problems" circle is darkened and one or more circles are darkened in C.2 or C.3, the system will not automatically complete C.2 and C.3.

If the SC has a modified blood collection protocol in which an additional tube of blood is obtained, this bubble may be used to document successful collection of tubes required by the regular PLCO protocol as well as the additional tube. If the additional tube is not collected or has problems but the regular PLCO tubes were collected without problems, this bubble should be darkened. Non-collection or prob-

lems with the collection of the extra tube should be documented in item C.16 (Comments).

- 1b. No Biorepository Tubes Drawn:** Darken this bubble if none of the tubes were successfully drawn and skip to item C.14. If this circle is darkened, items C.2 and C.3 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "no Biorepository tubes drawn" circle is darkened and one or more circles are darkened in C.2 or C.3, the system will not automatically complete C.2 and C.3.
- 2. Required Biorepository Tubes Drawn:** Darken a circle to indicate whether or not each tube of blood was drawn. Darken the circle next to "Yes" if the tube was partially filled or filled to capacity. If a tube is not drawn but it is required (i.e., the tube is part of the protocol for the current study year), darken the circle next to "No."

Biorepository tubes for the vanguard participants should be obtained as follows:

- Yellow top #1
- Yellow top #2
- Green top
- Lavender top

If yellow top tubes are not collected due to holiday shipping and receiving schedules, bubble "no" for the yellow top tubes in item C.2 and enter "holiday" in item C.16, Comments.

Biorepository tubes should be drawn for the vanguard participants even if the participant has a reported prostate or ovarian cancer and/or has had his entire prostate or both of her ovaries removed.

If the blood draw is not successfully completed for all tubes (all tubes filled to capacity), another draw should be attempted from the participant's other arm. *A redraw should not be scheduled solely for the purpose of obtaining the Biorepository samples.*

- 3. Problems with Draw:** If the tube was drawn and there is no problem with it, darken the circle for "No." If there is a problem with the tube of blood drawn, darken the circle for "Yes" and then darken one or more circles corresponding to the appropriate problem code(s). If the tube of blood was not drawn (item #2 above is coded "No" for the tube drawn), leave this item blank. The definitions for the problem codes are provided below.

1 = Short Draw: There is a short draw in the tube collected.

2 = Damaged: The tube was drawn but became damaged after the blood was collected.

3 = Multiple Attempts Required: More than one attempt ("stick") was needed to obtain blood.

8 = Other (SPECIFY): Describe any other type of problem with the tube in the space provided.

- 4. Time Centrifuged:** Record the time the blood samples are centrifuged. Darken the circle corresponding to each number. Remember to zero-fill numbers which are less than ten. Darken the circle to indicate the time as AM or PM.
- 5a. All Required Biorepository Vials Filled; No Problems:** Darken this bubble if all vials were filled and skip to item C.8. A partially filled vial is considered a "problem"

and this bubble may not be darkened if there are any partially filled vials. Definitions for additional processing problems are provided in item C.7. If this circle is darkened, items C.6 and C.7 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "all required Biorepository vials filled; no problems" circle is darkened and one or more circles are darkened in C.6 or C.7, the system will not automatically complete C.6 and C.7.

**5b. No Biorepository Vials filled:** Darken this bubble if none of the vials were filled and skip to item C.14. A vial is considered "filled" even if it was only partially filled, and not filled to capacity. This bubble may not be darkened if there are any partially filled vials. If this circle is darkened, items C.6 and C.7 must be left blank; these data items will be completed automatically in DEES when the form is scanned. If the "no Biorepository vials filled" circle is darkened and one or more circles are darkened in C.6 and C.7, the system will not automatically complete C.6 and C.7.

**6. Required Biorepository Vials Filled:** Darken the circles corresponding to vials filled. If a vial is completely or partially filled, darken the circle for "Yes." If a vial is not filled but it is required darken the circle next to "No."

If a vial was filled and frozen but lost or damaged before shipping, the "vial filled" circle should be changed from "Yes" to "No," any processing problem codes should be deleted, and if necessary, items C.14 (result of blood draw and processing for Biorepository) and C.15 (reason for partial or inadequate), should be corrected. Then, the form should be rescanned, edited, and the data updated to SMS. A modified transmittal should be generated before the shipment is sent.

Biorepository vials appropriate to the participant's vanguard visit should be filled as follows:

<b>Green Top</b>	Plasma	Vial 014
	Plasma	Vial 015
	Buffy coat	Vial 016
<b>Lavender Top</b>	Plasma	Vial 017
	Plasma	Vial 018
	Plasma	Vial 019
	Plasma	Vial 020
	Buffy coat	Vial 021
	RBC	Vial 023

**Note:** Vial 22 is not used.

Processing Notes:

**Plasma:** When filling the vials with plasma, if there is not enough plasma to fill all of the vials: first, fill one vial until it is filled to capacity; then, continue filling vials in this fashion until the specified vials are filled or until no more plasma remains (which ever occurs first).

**7. Processing Problems:** If the vial was filled and there is no problem with it, darken the circle for "No." If there is a problem with the vial, darken the circle for "Yes" and then darken one or more circles corresponding to the appropriate problem code(s).

If the vial was not filled (item #6 above is coded "No" for the vial), leave this item blank. The definitions for the problem codes are provided below.

01 = Hemolyzed serum: The hemoglobin has separated from the red cells causing the serum to turn red.

02 = Icteric serum: The serum is a deep yellow (jaundice) color.

03 = Turbid serum: The serum is cloudy.

04 = Partially filled vial: The specimen vial is not filled to the required capacity and is only partially filled.

8. **Time Biorepository Vials Frozen:** Record the time the appropriate Biorepository blood samples are frozen. Remember to zero-fill numbers which are less than ten. Darken the circle corresponding to each number. Darken the circle to indicate the time as AM or PM.
9. **2-inch Biorepository Storage Box Number:** Record the storage box number for the storage of all Vanguard Biorepository vials. The first character of the storage box number for vials 014-021 and 023 will always be "B." Darken the circle corresponding to each of the four digit numbers. If none of the Biorepository vials were filled, leave this item blank.
10. **Intentionally Omitted on form – formerly the T Box.**
11. **Intentionally Omitted on form – formerly the I Box.**
12. **Yellow Top Tubes Storage Box Number (Optional):** Record the storage box number for the two yellow top tubes. The first character of the storage box number for yellow top tubes will always be "Y." Darken the circle corresponding to each of the four digit numbers. This box will only be used for T3 Vanguard blood collection. If yellow top tubes were not collected, leave this box blank.
13. **Shipment of Yellow Top Tubes:** Designate the status of the shipment of yellow top tubes as one of the following:

Shipped same date drawn: Darken this circle if the yellow top tubes are shipped on the same day they are collected.

Not shipped: Darken this circle if the yellow top tubes were not shipped to the Processing Laboratory and document the reasons the tubes were not shipped in item C.16 (comments).

Date of shipment: If the tubes were shipped, but not on the same day they were drawn, record the date they were shipped. Month and day should be zero filled (e.g., 02/07). Enter all four digits for the year (e.g., 1998, or 1999). Darken the circles corresponding to the month, day, and year.

If yellow top tubes were not collected, leave this item blank.

*The blood collection protocol requires that yellow top tubes be shipped to the Processing Laboratory on the same day they are drawn. If the SC is unable, under unusual circumstances, to ship the yellow top tubes on the same day they are drawn, the yellow top tubes may be shipped to the Processing Laboratory the next day. Yellow top tubes not shipped on the same day or next day after they are drawn will be destroyed. The reason the samples were not shipped within the required time frame must be noted in item C.16 (Comments). The Processing Laboratory will receive packages on Saturdays. (For example, yellow top tubes were drawn on Thursday, March 26, 1998, but due to a blizzard that caused the airport to close, samples could not be shipped on Thursday. The samples could be shipped on Friday,*

March 27, but are not to be shipped on any day after Friday.) For specific shipping instructions regarding Saturday deliveries, refer to Chapter 10 (Blood Sample Protocol), section 10.9.5 Labeling Shipping Containers for Yellow Top Tubes.

If the yellow top tubes were drawn, but they were not shipped to the Processing Laboratory, complete the following steps:

- If item C.13 was originally bubbled as "Shipped same date drawn" or the "Date of shipment" was entered, erase all bubbles (and marks), and darken the bubble for "not shipped."
- Document the reasons the tubes were not shipped in item C.16 (comments).
- Rescan and edit the form, and update the data into the SMS.
- Make the necessary corrections to the Processing Laboratory Transmittal Log (Appendix A-10-4) before the shipment is sent.

**14. Result of Blood Draw and Processing for Biorepository:** Darken the circle corresponding to the result of the Biorepository blood draw and processing. Definitions of the Biorepository results are given below:

Complete – all vials filled to required capacity: Darken this bubble, if all vials were filled to the required capacity. This bubble may not be darkened if there are any partially filled vials. If this bubble is darkened, skip to item C.16. For Vanguard participants, both yellow top tubes must also be filled to the required capacity if this bubble is darkened.

Partial – not all vials filled to required capacity: Darken this bubble, if at least one, but not all of the vials were filled to the required capacity. This bubble should be darkened if there are any partially filled vials (or yellow top tubes for Vanguard participants) or missing vials. Record the reason(s) for the partial result of the Biorepository blood draw and processing in item C.15 below.

Inadequate – no vials filled: Darken this bubble, if either none of the Biorepository tubes were obtained or the Biorepository tubes were obtained but none of the vials were filled. Record the reason(s) for the inadequate result of the Biorepository blood draw and processing in item C.15 below.

**15. Reason for Partial or Inadequate:** Darken one or more circles to indicate the reason(s) for the partial or inadequate result of the Biorepository blood draw and processing.

Participant refusal: The participant is unwilling to allow completion of the blood draw procedure and some or all of the Biorepository tubes could not be obtained. (Only the Phlebotomist may assign this reason.)

Poor venous access: The blood draw was attempted, but due to the participant's poor venous access some or all of the Biorepository tubes were not obtained. (Only the Phlebotomist may assign this reason.)

Tube(s) damaged, lost, or destroyed: The blood draw procedure was attempted, but some or all of the Biorepository tubes were either: damaged, lost, or destroyed prior to/during/or after processing and some or all of the Biorepository vials could not be filled. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Equipment problems: Blood was drawn, but due to equipment problems during the blood collection and/or processing one or more of the Biorepository vials are

not available for testing. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

Blood component QNS (quantity not sufficient): Some or all of the Biorepository tubes were drawn during the blood draw procedure, however, one or more of the blood component quantities was not sufficient to fill the required vials to capacity. (Only the Laboratory Technologist may assign this reason.)

Vial(s) damaged, lost or destroyed: Some or all of the Biorepository tubes were obtained during the blood draw procedure and some or all of the Biorepository vials were filled, but one or more vials were subsequently damaged, lost, or destroyed and could not be shipped. (Only the Laboratory Technologist may assign this reason.)

Other (SPECIFY): Describe any other reason for inadequate in the space provided. (Either the Phlebotomist or the Laboratory Technologist may assign this reason.)

- 16. Comments:** If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., C.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF). Comments recorded in this box should pertain only to items related to the processing of the Biorepository vials or the shipment of the yellow top tubes. This includes Part C items C1a through C.15.
- 17. Lab Tech's Initials/ID#:** The Laboratory Technologist should sign his/her initials in the space provided, record his/her 4-digit staff ID number, and darken the circles corresponding to the four digits.

### **Forms Processing:**

The Forms Processing box is to be completed by the SC staff member.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicated the status of verbatim data entry. (Refer to Chapter 17 for

instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each OpScan form in the system, but is not required to mark the disposition on the hard copy form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional Forms Processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the OpScan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-11-1**

**A-11-1: Chest X-ray Screening Examination Form  
(XRY2)**

**Specifications for the Chest X-ray Screening Examination Form**



**PART B: CHEST X-RAY EXAMINATION FINDINGS (COMPLETED BY RADIOLOGIST)**

**1. Radiographic Abnormality Noted:**       No (GO TO PART C)       Yes

**2. Record Information for Each Abnormality:**

Abnormality #	LOCATION (MARK ALL THAT APPLY)		DESCRIPTION OF ABNORMALITY
	Right Hemithorax	Left Hemithorax	
	1 = Upper 1/3 2 = Middle 1/3 3 = Lower 1/3 4 = Diffuse 9 = NA	1 = Upper 1/3 2 = Middle 1/3 3 = Lower 1/3 4 = Diffuse 9 = NA	01 = Nodule (1 - 30 mm) 02 = Mass (> 30 mm) 07 = Pleural mass 08 = Granuloma(s) 13 = Right hilar/mediastinal lymph nodes (exclude calcified nodes) 14 = Left hilar/mediastinal lymph nodes (exclude calcified nodes) 15 = Major atelectasis/collapse 16 = Infiltrate (consolidation/alveolar opacity) 17 = Scarring/pulmonary fibrosis/honeycombing 18 = Pleural fibrosis/pleural plaque 19 = Pleural fluid 20 = Bone/soft tissue lesion 21 = Cardiac abnormality/cardiomegaly/congestive heart failure 22 = COPD/emphysema/bullae 88 = Other (SPECIFY)
1.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
2.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
3.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
4.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
5.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____

**PART C: CHEST X-RAY INTERPRETATION RESULTS (COMPLETED BY RADIOLOGIST)**

<b>1. Examination Result:</b>	<b>2. Reason for Inadequate Exam: (MARK ALL THAT APPLY)</b>	<b>3. Level of Referral:</b>
<input type="radio"/> Positive Screen - Referral Required (GO TO 3) <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3) <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3) <input type="radio"/> Inadequate	<input type="radio"/> Poor film quality <input type="radio"/> Films lost <input type="radio"/> Other (SPECIFY) _____ _____ _____	<input type="radio"/> 1 - Significant Abnormality, Referral <input type="radio"/> 2 - Moderate Abnormality, Referral <input type="radio"/> 3 - Slight Variation from Normal, No Referral <input type="radio"/> 4 - Normal/Result Not Available, No Referral

<b>4. Comments:</b>	<b>5. Radiologist ID:</b>																																								
<input type="radio"/> No <input type="radio"/> Yes (SPECIFY)	<table border="1"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9
0	0	0	0																																						
1	1	1	1																																						
2	2	2	2																																						
3	3	3	3																																						
4	4	4	4																																						
5	5	5	5																																						
6	6	6	6																																						
7	7	7	7																																						
8	8	8	8																																						
9	9	9	9																																						
<table border="1"> <tr> <th>Item#</th> <th>Comments</th> </tr> <tr><td> </td><td> </td></tr> </table>	Item#	Comments																			Signature _____																				
Item#	Comments																																								
<input type="radio"/> Continued																																									

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE CHEST X-RAY SCREENING**  
**EXAMINATION FORM (XRY2)**

This form is to be completed by an SC staff member and the Examiners (Technologist and Radiologist). The SC staff member will complete the top administrative section, the Technologist will complete Part A, and the Radiologist will complete Parts B and C of the form.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.

Correct Mark



Incorrect Marks



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

- 1. Date of Examination:** Enter the date of the examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
- 2. Satellite Center:** This field is optional. If the SC has elected to track satellite center activity and the examination is taking place at a satellite center, enter the 2-digit Satellite Center ID. If the examination is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank. Darken the circle corresponding to each number.
- 3. Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2, or T3 for the follow-up examinations.

4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete this examination in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the examination was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the chest X-ray examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. Refer to the Participant Control Record or the examination form from the previous visit for this information. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior film was of poor quality."*

This might be entered if the participant's prior film was of poor quality during the previous visit, but s/he was willing to return to the SC to for a repeat film. This information will alert the Examiner to explore the reasons for this problem.

*"Participant out of time. Unable to complete X-ray exam."*

This might be entered if the participant's schedule did not allow him to remain at the SC to complete the X-ray screening examination during a previous visit, and the examination was rescheduled.

**Note:** This information will not be entered into the Data Entry and Editing System.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Received into SMS:** This item is optional. Darken this circle after the form has been received into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are

"UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.

- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A: Chest X-Ray Examination Results:**

Part A is to be completed by the X-ray Technologist.

- 1. Number of Attempts:** Darken the circle corresponding to the number of attempts made to take the chest X-ray. No more than two attempts are permitted at one visit. Responses are explained below:

**None:** There is no attempt to take the chest X-ray. This might occur if the participant entered the dressing room to prepare for the exam, but for some reason there was no attempt to take the X-ray (participant became ill, could not wait, etc.). (Go to Item 2.)

If the participant never prepared for the exam in any way, the exam is considered "Not Done," and recorded as such on the Participant Control Record (PCR). The Chest X-ray Screening Examination Form would not be filled out in such cases.

**One:** The chest X-ray is attempted once, regardless of whether or not it is successfully completed.

**Two:** The chest X-ray is attempted twice, regardless of whether or not it is successfully completed.

- 2. Adequate Films Obtained:** Before the participant leaves the Screening Center, the Technologist will evaluate the X-ray for quality. Films judged to be adequate by the Technologist are then sent to the study Radiologist who will also judge their adequacy. A film will be considered adequate if the lung vessels are clearly visible, and the mediastinal structures are sufficiently penetrated to allow for adequate visualization. Responses are explained below:

**No:** The film is judged to be inadequate. (Go to Item 3 and complete Parts A and C of the examination form.) (\*Note: The XRY2 form is printed with an instruction to complete Part A only but the technologist should also complete Part C to document the Inadequate exam.)

**Yes:** The film is judged to be adequate. (Go to Item 4).

- 3. Reason for Inadequate Films:** This item is completed only if the answer to Item 2 is "No." Darken one or more circles to indicate the reason(s) for the inadequate films. An explanation of each reason for inadequate films is given below:

Participant Refusal: The participant is unwilling to cooperate, i.e., stand in the proper position, hold breath, etc.

Equipment Malfunction: There is a problem with the radiographic equipment which prevents the successful completion of the x-ray.

Poor Film Quality: A film was obtained, but it is not adequate for interpretation. Poor film quality may be due to excessive rotation, inadequate inspiration, motion or processing artifact, over or under penetration or if the entire lung and mediastinal structures are not included on the film.

Other (SPECIFY): Describe any other situation in which adequate films could not be obtained in the space provided.

- 4. Comments:** The comments box may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there no are additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item in Part A of the form, use the item number for the comments section itself (A.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued" and record additional comments on a Comments Continuation Form (CCF).

- 5. Technologist Identification:** Sign the form in the space provided, enter your 4 digit staff ID number, and darken the circles corresponding to the four digits.

### **Part B: Chest X-Ray Examination Findings:**

Part B is to be completed by the interpreting Radiologist. At some SCs, the SC staff will complete this section using the interpreting Radiologist's written report. If the result of the examination (Item C.1) is "Inadequate" Part B should be left blank.

- 1. Radiographic Abnormality Noted:**

**No:** No radiographic abnormality was seen. (Go to Part C.)

**Yes:** A radiographic abnormality (either suspicious for lung cancer or abnormal for any other reason) was seen.

- 2. Record Information for Each Abnormality:** Complete this item for up to five radiographic abnormalities. Complete the chart by darkening the circle corresponding to the correct response in each column and row. Enter information about the first abnormality in the row labeled "1", the second abnormality in the row labeled "2", etc.

**Location:** If an abnormality is seen in both the right and left hemithorax or in more than one section of a hemithorax (e.g., a nodule or mass seen in more than one hemithorax) darken the circles for all locations that apply. In the case of abnormalities which may be widespread (e.g., fibrosis or chronic obstructive pulmonary disease (COPD)) the location "diffuse" may be applicable. If an abnormality is seen in only one hemithorax, darken the circle for NA for the other hemithorax.

Right Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the right hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the right hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the right hemithorax.

Diffuse: The abnormality was spread throughout the right hemithorax. If diffuse is marked, no other location in the right hemithorax should be marked.

NA: The abnormality was not in the right hemithorax.

Left Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the left hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the left hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the left hemithorax.

Diffuse: The abnormality was spread throughout the left hemithorax. If diffuse is marked, no other location in the left hemithorax should be marked.

NA: The abnormality was not in the left hemithorax.

The only instances where it is appropriate for the examiner to code NA for both the left and the right hemithorax is for the following abnormalities:

#20: Bone/soft tissue lesion;

#21: Cardiac abnormality/cardiomegaly/congestive heart failure; and

#88: Other

**Description of Abnormality:** Darken one circle corresponding to the description of the abnormality. Please note that codes 01, 02, 07, and codes 13 through 16 (in bold) are considered to be a positive screen for lung cancer (i.e., for these abnormalities, the examination result in Part C.1. must be coded "Positive Screen - Referral Required"). The abnormalities are listed below:

01 =Nodule (1 - 30 mm)

02 =Mass (> 30 mm)

07 =Pleural mass

08 =Granuloma

13 =Right hilar/mediastinal lymph nodes (exclude calcified nodes)

14 =Left hilar mediastinal lymph nodes (exclude calcified nodes)

15 =Major atelectasis/collapse

16 =Infiltrate (consolidation/alveolar opacity)

17 =Scarring/pulmonary fibrosis/honeycombing

18 =Pleural fibrosis/pleural plaque

19 =Pleural fluid

20 =Bone/soft tissue lesion

21 =Cardiac abnormality/cardiomegaly/congestive heart failure

22 =COPD/emphysema/bullae

88 =Other (SPECIFY): The abnormality is other than those listed above. Specify the abnormality on the line provided in the "Description of Abnormality" column.

## **Part C: Chest X-Ray Interpretation Results**

Part C is to be completed by the interpreting Radiologist. At some SCs, the SC staff will complete this section using the interpreting Radiologist's written report. In cases where an adequate film was not obtained (A.2 = No), Part C should be completed by the technologist to document the result of the examination as "Inadequate."

- 1. Examination Results:** Darken the circle corresponding to the result of the examination. Definitions of examination results are given below:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Cancer): Evaluation reveals any of the following pulmonary abnormalities:

- nodule (a circular opacity less than or equal to 3.0 cm in diameter)
- mass (any discrete opacity greater than 3.0 in diameter without regard to contour, homogeneity or border characteristics)
- hilar or mediastinal lymph node enlargement (exclude calcified nodes)
- major atelectasis/lobar collapse
- infiltrate/consolidation/alveolar opacity
- pleural mass

Negative Screen - No Abnormalities (formerly Negative): Evaluation reveals mid-line structure and heart to be of normal size and not displaced or enlarged. Pulmonary parenchyma reveals no suspicious abnormality for cancer.

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Cancer): Evaluation reveals any of the following pulmonary abnormalities:

- pneumonia (particularly TB)
- marked cardiac enlargement
- pulmonary edema
- congestive heart failure (CHF)
- pericardial effusion
- pleural effusion
- valvular heart disease
- shunt vascularity
- thoracic aortic aneurysm, dissection
- pneumothorax
- pneumomediastinum
- unexplained foreign body (catheter fragment in heart, etc.)
- granuloma
- rib/spine/shoulder girdle metastases
- plasmocytomas
- acute fractures
- hepatomegaly
- splenomegaly

- old rib fractures
- compression fractures of the spine
- shoulder fractures
- scoliosis
- pleural calcification, pleural thickening, plaques
- previous mastectomies, breast implants
- COPD, emphysema, bullae
- old granulomatous disease, parenchymal calcification, calcified nodes
- pneumoconiosis
- mild to moderate cardiac enlargement
- pulmonary vascular congestion
- interstitial fibrosis, honeycombing, small scars
- pulmonary fibrosis with hilar retraction,
- radiation fibrosis
- previous lung surgery
- biopsy sites
- changes related to old trauma, retained shrapnel, etc.
- previous cardiac surgery (CABG, valve replacements)
- vascular anomalies (right aortic arch, etc.)
- vascular calcification
- bronchiectasis
- hiatal hernia, gallstones
- linear or plate atelectasis
- enlarging tracheal nodule

Some of these abnormalities are indicative of serious medical problems and will require referral. If the Examiner feels that a referral is necessary, Level 1 or Level 2 should be marked in Item C.3 (Level of Referral).

Inadequate: The X-Ray films were inadequate and sufficient information could not be obtained to determine whether the examination result was negative screen - no abnormalities, negative screen - other abnormalities or positive screen - referral required. Record the reason(s) for an inadequate examination in Item C.2 below.

If there is an abnormality which is indicative of a positive screen and one which is indicative of a negative screen - other abnormalities, only "Positive Screen - Referral Required" should be marked.

**2. Reason for Inadequate Exam:** Darken one or more circles to indicate the reason for an inadequate exam. If the exam was inadequate for reasons other than or in addition to poor film quality and/or films lost, darken the circle for "Other" and specify the reason(s) on the lines provided.

**3. Level of Referral:** Darken the circle corresponding to the level of referral.

- 1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate" and an abnormality considered to be significant and requiring referral was found.
  - 2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.
  - 3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.
  - 4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.
- 4. Comments:** The comments box should be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item in parts B or C of the form, use the item number for the comments section itself (C.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

- 5. Radiologist Identification:** (This item should be completed by the Radiologist. In the case where an adequate film was not obtained, the Technologist will complete this item.)

Sign the form in the space provided, enter your 4-digit ID number, and darken the circles corresponding to the four digits. If this section was completed by a member of the SC staff using the Radiologist's written report, the SC staff member should enter the Radiologist's name and staff ID, then sign his/her own name below the name of the Radiologist. If adequate films were not obtained and the Technologist assigned the examination result of "Inadequate", the Technologist should record his/her name and ID in the space provided.

## **A-11-2**

A-11-2: Chest X-ray Screening Examination Form for  
Quality Assurance (XRQ2)

Specifications for the Chest X-ray Screening Exami-  
nation Form for Quality Assurance

Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

# CHEST X-RAY SCREENING EXAMINATION QUALITY ASSURANCE (XRQ2)

<b>1. Date of Examination:</b> MO. DAY YR. [0-9] [0-9] [0-9] [0-9] [0-9] [0-9]			<b>2. Satellite Center:</b> [0-9] [0-9]		<b>3. Study Year:</b> <input type="radio"/> T <sub>0</sub> <input type="radio"/> T <sub>1</sub> <input type="radio"/> T <sub>2</sub> <input type="radio"/> T <sub>3</sub>		<b>4. Visit Number:</b> <input type="radio"/> One <input type="radio"/> Two <input type="radio"/> Three		<b>5. Reason for Repeat Visit:</b> _____ _____ _____ _____		
--	--	--	--	--	---	--	--	--	--	--	--

**For Office Use Only**

**6. Forms Processing (DARKEN CIRCLES AS STEPS ARE COMPLETED)**

Form Received into SMS <input type="radio"/>	<b>Data Retrieval:</b>
Manual Review Completed <input type="radio"/>	Attempted <input type="radio"/> OR None Required <input type="radio"/>
<b>Data Entry of Non-Scannable Items:</b>	<b>Final Disposition:</b>
Completed <input type="radio"/> OR None Required <input type="radio"/>	Final Complete (FCM) <input type="radio"/> OR Final Incomplete (FIC) <input type="radio"/>

▪ DO NOT FOLD, STAPLE, OR TEAR THIS FORM.  
 ▪ USE A NO. 2 PENCIL TO COMPLETE THIS FORM.

**PART A: CHEST X-RAY EXAMINATION FINDINGS (COMPLETED BY TECHNOLOGIST)**

<b>1. Number of Attempts:</b> <input type="radio"/> None (GO TO 2) <input type="radio"/> One <input type="radio"/> Two		<b>2. Adequate Films Obtained:</b> <input type="radio"/> No <input type="radio"/> Yes (GO TO 4)		<b>3. Reason for Inadequate Films: (MARK ALL THAT APPLY)</b> <input type="radio"/> Participant Refusal <input type="radio"/> Equipment Malfunction <input type="radio"/> Poor Film Quality <input type="radio"/> Other (SPECIFY) _____		<b>4. Comments:</b> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY) Item #      Comments _____ _____ _____ _____ _____ <input type="radio"/> Continued		<b>5. Tech. ID:</b> [0-9] [0-9] [0-9] [0-9] _____ Signature	
---	--	---	--	--	--	---	--	---	--

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

Version Date: 10/99

Expiration Date: 7/05

Form Approved OMB No.: 0925-0407

PLEASE DO NOT WRITE IN THIS AREA



021340

**PART B: CHEST X-RAY EXAMINATION FINDINGS (COMPLETED BY RADIOLOGIST)**

**1. Radiographic Abnormality Noted:**       No (GO TO PART C)       Yes

**2. Record Information for Each Abnormality:**

Abnormality #	LOCATION (MARK ALL THAT APPLY)		DESCRIPTION OF ABNORMALITY
	Right Hemithorax	Left Hemithorax	
	1 = Upper 1/3 2 = Middle 1/3 3 = Lower 1/3 4 = Diffuse 9 = NA	1 = Upper 1/3 2 = Middle 1/3 3 = Lower 1/3 4 = Diffuse 9 = NA	01 = Nodule (1 - 30 mm) 02 = Mass (> 30 mm) 07 = Pleural mass 08 = Granuloma(s) 13 = Right hilar/mediastinal lymph nodes (exclude calcified nodes) 14 = Left hilar/mediastinal lymph nodes (exclude calcified nodes) 15 = Major atelectasis/collapse 16 = Infiltrate (consolidation/alveolar opacity) 17 = Scarring/pulmonary fibrosis/honeycombing 18 = Pleural fibrosis/pleural plaque 19 = Pleural fluid 20 = Bone/soft tissue lesion 21 = Cardiac abnormality/cardiomegaly/congestive heart failure 22 = COPD/emphysema/bullae 88 = Other (SPECIFY)
1.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
2.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
3.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
4.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____
5.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 9	<input type="radio"/> 01 <input type="radio"/> 02 <input type="radio"/> 07 <input type="radio"/> 08 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 88 _____

**PART C: CHEST X-RAY INTERPRETATION RESULTS (COMPLETED BY RADIOLOGIST)**

<p><b>1. Examination Result:</b></p> <p><input type="radio"/> Positive Screen - Referral Required (GO TO 3)  <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3)  <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3)  <input type="radio"/> Inadequate</p>	<p><b>2. Reason for Inadequate Exam: (MARK ALL THAT APPLY)</b></p> <p><input type="radio"/> Poor film quality  <input type="radio"/> Films lost  <input type="radio"/> Other (SPECIFY)</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p><b>3. Level of Referral:</b></p> <p><input type="radio"/> 1 - Significant Abnormality, Referral  <input type="radio"/> 2 - Moderate Abnormality, Referral  <input type="radio"/> 3 - Slight Variation from Normal, No Referral  <input type="radio"/> 4 - Normal/Result Not Available, No Referral</p>
--	---	---

<p><b>4. Comments:</b></p> <p><input type="radio"/> No      <input type="radio"/> Yes (SPECIFY)</p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Item#</th> <th>Comments</th> </tr> </thead> <tbody> <tr><td> </td><td> </td></tr> </tbody> </table> <p align="center"><input type="radio"/> Continued</p>	Item#	Comments																					<p><b>5. Radiologist ID:</b></p> <table border="1" style="width: 100%; text-align: center;"> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table> <p>Signature _____</p>					0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9
Item#	Comments																																																																		
0	0	0	0																																																																
1	1	1	1																																																																
2	2	2	2																																																																
3	3	3	3																																																																
4	4	4	4																																																																
5	5	5	5																																																																
6	6	6	6																																																																
7	7	7	7																																																																
8	8	8	8																																																																
9	9	9	9																																																																

PLCO Cancer Screening Trial

**SPECIFICATIONS FOR COMPLETION OF THE CHEST X-RAY SCREENING EXAMINATION QUALITY ASSURANCE FORM (XRQ2)**

This form is to be completed by a SC staff member and the QA Examiner for the chest x-ray examination. The QA Examiner is defined as the radiologist who re-interprets the chest x-ray film for QA purposes. The QA Examiner must be blinded to the results of the original chest x-ray examination.

The SC staff member will complete the top administrative section and the QA Radiologist will complete Parts B and C of the form. Part A of the form (Chest X-Ray Examination Results) will be left blank. The completed form will then be receipted into the SMS and scanned into the DEES.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.

Correct Mark



Incorrect Marks



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the review of the chest X-ray film for quality assurance. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Satellite Center:** This field is optional. If the SC has elected to track satellite center activity and the original X-ray examination took place at a satellite center, enter the 2-digit Satellite Center ID. If the original X-ray examination did not take place at a

satellite center, or the SC has elected not to track satellite center activity, this item should be left blank. Darken the circle corresponding to each number.

3. **Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2, or T3 for the follow-up examinations.
4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the original chest x-ray examination. Copy this information from the XRY form which contains the original results.
5. **Reason for Repeat Visit:** If the chest x-ray was completed at a repeat visit (visit number 2 or 3), copy the reason for the repeat visit from the Participant Control Record on the original XRY form.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Received into SMS:** This item is optional. Darken this circle after the form has been received into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;

- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

**Part A: Chest X-Ray Examination Results:**

This part of the form should be left blank.

**Part B: Chest X-Ray Examination Findings:**

Part B is to be completed by the QA Radiologist. At some SCs, the SC staff will complete this section using the QA Radiologist's written report. If the result of the examination (Item C.1) is "Inadequate," Part B should be left blank.

**1. Radiographic Abnormality Noted:**

**No:** No radiographic abnormality was seen. (Go to Part C.)

**Yes:** A radiographic abnormality (either suspicious for lung cancer or abnormal for any other reason) was seen.

- 2. Record Information for Each Abnormality:** Complete this item for up to five radiographic abnormalities. Complete the chart by darkening the circle corresponding to the correct response in each column and row. Enter information about the first abnormality in the row labeled "1", the second abnormality in the row labeled "2", etc.

**Location:** If an abnormality is seen in both the right and left hemithorax or in more than one section of a hemithorax (e.g., a nodule or mass seen in more than one hemithorax) darken the circles for all locations that apply. In the case of abnormalities which may be widespread (e.g., fibrosis or chronic obstructive pulmonary disease (COPD)) the location "diffuse" may be applicable. If an abnormality is seen in only one hemithorax, darken the circle for NA for the other hemithorax.

Right Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the right hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the right hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the right hemithorax.

Diffuse: The abnormality was spread throughout the right hemithorax. If diffuse is marked, no other location in the right hemithorax should be marked.

NA: The abnormality was not in the right hemithorax.

Left Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the left hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the left hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the left hemithorax.

Diffuse: The abnormality was spread throughout the left hemithorax. If diffuse is marked, no other location in the left hemithorax should be marked.

NA: The abnormality was not in the left hemithorax.

The only instances where it is appropriate for the examiner to code NA for both the left and the right hemithorax is for the following abnormalities:

#20: Bone/soft tissue lesion;

#21: Cardiac abnormality/cardiomegaly/congestive heart failure; and

#88: Other

**Description of Abnormality:** Darken one circle corresponding to the description of the abnormality. Please note that codes 01, 02, 07, and codes 13 through 16 (in bold) are considered to be a positive screen for lung cancer (i.e., for these abnormalities, the examination result in Part C.1. must be coded "Positive Screen - Referral Required"). The abnormalities are listed below:

01 =Nodule (1 - 30 mm)

02 =Mass (> 30 mm)

07 =Pleural mass

08 =Granuloma

13 =Right hilar/mediastinal lymph nodes (exclude calcified nodes)

14 =Left hilar mediastinal lymph nodes (exclude calcified nodes)

15 =Major atelectasis/collapse

16 =Infiltrate (consolidation/alveolar opacity)

17 =Scarring/pulmonary fibrosis/honeycombing

18 =Pleural fibrosis/pleural plaque

19 =Pleural fluid

20 =Bone/soft tissue lesion

21 =Cardiac abnormality/cardiomegaly/congestive heart failure

22 =COPD/emphysema/bullae

88 =Other (SPECIFY): The abnormality is other than those listed above. Specify the abnormality on the line provided in the "Description of Abnormality" column.

### **Part C: Chest X-Ray Interpretation Results**

Part C is to be completed by the QA Radiologist. At some SCs, the SC staff will complete this section using the QA Radiologist's written report.

- 1. Examination Results:** Darken the circle corresponding to the result of the examination. Definitions of examination results are given below:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Cancer): Evaluation reveals any of the following pulmonary abnormalities:

- nodule (a circular opacity less than or equal to 3.0 cm in diameter)
- mass (any discrete opacity greater than 3.0 cm in diameter without regard to contour, homogeneity or border characteristics)
- hilar or mediastinal lymph node enlargement (exclude calcified nodes)
- major atelectasis/lobar collapse
- infiltrate/consolidation/alveolar opacity
- pleural mass

A referral to the participant's physician of choice for evaluation of these results is necessary, unless s/he was already referred for follow-up of the results of the original interpretation of the chest x-ray film.

Negative Screen - No Abnormalities (formerly Negative): Evaluation reveals mid-line structure and heart to be of normal size and not displaced or enlarged. Pulmonary parenchyma reveals no suspicious abnormality for cancer.

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Cancer): Evaluation reveals any of the following pulmonary abnormalities:

- pneumonia (particularly TB)
- marked cardiac enlargement
- pulmonary edema
- congestive heart failure (CHF)
- pericardial effusion
- pleural effusion
- valvular heart disease
- shunt vascularity
- thoracic aortic aneurysm, dissection
- pneumothorax
- pneumomediastinum
- unexplained foreign body (catheter fragment in heart, etc.)
- granuloma
- rib/spine/shoulder girdle metastases
- plasmocytomas
- acute fractures
- hepatomegaly
- splenomegaly
- old rib fractures
- compression fractures of the spine
- shoulder fractures
- scoliosis
- pleural calcification, pleural thickening, plaques
- previous mastectomies, breast implants
- COPD, emphysema, bullae
- old granulomatous disease, parenchymal calcification, calcified nodes
- pneumoconiosis
- mild to moderate cardiac enlargement
- pulmonary vascular congestion
- interstitial fibrosis, honeycombing, small scars

- pulmonary fibrosis with hilar retraction,
- radiation fibrosis
- previous lung surgery
- biopsy sites
- changes related to old trauma, retained shrapnel, etc.
- previous cardiac surgery (CABG, valve replacements)
- vascular anomalies (right aortic arch, etc.)
- vascular calcification
- bronchiectasis
- hiatal hernia, gallstones
- linear or plate atelectasis
- enlarging tracheal nodule

Some of these abnormalities are indicative of serious medical problems and will require referral. If the Examiner feels that a referral is necessary, Level 1 or Level 2 should be marked in Item C.3 (Level of Referral).

Inadequate: The x-ray films were inadequate and sufficient information could not be obtained to determine whether the examination result was negative screen - no abnormalities, negative screen - other abnormalities or positive screen - referral required. Record the reason(s) for an inadequate examination in Item C.2 below. A QA examination that is inadequate will not count toward the total number of QA examinations performed.

If there is an abnormality which is indicative of a positive screen and one which is indicative of a negative screen - other abnormalities, only "Positive Screen - Referral Required" should be marked.

**2. Reason for Inadequate Exam:** Darken one or more circles to indicate the reason for an inadequate exam. If the exam was inadequate for reasons other than or in addition to poor film quality and/or films lost, darken the circle for "Other" and specify the reason(s) on the lines provided.

**3. Level of Referral:** Darken the circle corresponding to the level of referral.

1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate" and an abnormality considered to be significant and requiring referral was found.

2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.

4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

4. **Comments:** The comments box should be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item on the form, use the item number for the comments section itself (C.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

5. **Radiologist Identification:** (This item should be completed by the QA Radiologist.)

Sign the form in the space provided, enter your 4-digit ID number, and darken the circles corresponding to the four digits. If this section was completed by a member of the SC staff using the QA Radiologist's written report, the SC staff member should enter the QA Radiologist's name and staff ID, then sign his/her own name below the name of the QA Radiologist.

## **A-12-1**

**A-12-1: Digital Rectal Screening Examination of the Prostate Form (DRE2)**

**Specifications for the Digital Rectal Screening Examination of the Prostate Form**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version Date: 10/99

Expiration Date: 7/05

Form Approved OMB No.: 0925-0407

## DIGITAL RECTAL SCREENING EXAMINATION OF THE PROSTATE (DRE2)

1.	Date of Examination:			2.	Screening Center:	3.	Satellite Center:	4.	Study Year:	5.	Visit Number:
	MO.	DAY	YEAR								
	0	0	0	0		0	0		<input type="radio"/> T <sub>0</sub>		<input type="radio"/> One
	1	1	1	1		1	1		<input type="radio"/> T <sub>1</sub>		<input type="radio"/> Two
	2	2	2	2		2	2		<input type="radio"/> T <sub>2</sub>		<input type="radio"/> Three
	3	3	3	3		3	3				
	4	4	4	4		4	4				
	5	5	5	5		5	5				
	6	6	6	6		6	6				
	7	7	7	7		7	7				
	8	8	8	8		8	8				
	9	9	9	9		9	9				

• DO NOT FOLD, STAPLE OR TEAR THIS FORM.  
• USE A NO. 2 PENCIL TO COMPLETE THIS FORM.

6. Reason for Repeat Visit:

---



---



---



---

**For Office Use Only**

**7. Form Processing**  
(DARKEN CIRCLES AS STEPS ARE COMPLETED)

Form Received into SMS

Manual Review Completed

**Data Entry of Non-Scannable Items:**  
Completed  OR None Required

**Data Retrieval:**  
Attempted  OR None Required

**Final Disposition:**  
Final Complete (FCM)  OR Final Incomplete (FIC)

### PART A: PROSTATE EXAMINATION FINDINGS

1.	Participant Position:	Transverse in cm.	Sagittal in cm.	4.	Prostate Symmetry:
	<input type="radio"/> Bent at waist over end of examination table <input type="radio"/> Kneeling, knees to chest <input type="radio"/> Lateral decubitus position with knees pulled up to chest				<input type="radio"/> Symmetrical <input type="radio"/> Asymmetrical
2.	Prostate Palpable:	3.	Approximate Size of Gland:	5.	Consistency of Gland:
	<input type="radio"/> No (GO TO PART B) <input type="radio"/> Yes				<input type="radio"/> Normal (GO TO 8) <input type="radio"/> Boggy, with No Induration (GO TO 8) <input type="radio"/> Boggy, with Induration/Nodular <input type="radio"/> Induration/Nodular
		MARK SIZES IN THE FOLLOWING GRIDS		6.	
				Areas of Induration:	
				<input type="radio"/> One <input type="radio"/> Three <input type="radio"/> Two <input type="radio"/> Four or more	

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

**PART A CONTINUED...**

<b>7. RECORD INFORMATION FOR THREE LARGEST AREAS OF INDURATION</b>	<b>Area of Induration</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>DIAGRAM</b>	<b>LOCATION:</b> DARKEN CIRCLES FOR ALL NUMBERS FROM THE DIAGRAM THAT APPLY (1-8)	1 2 3 4 5 6 7 8	1 2 3 4 5 6 7 8	1 2 3 4 5 6 7 8
	<b>APPROXIMATE SIZE:</b> 1 = Less than 1.5 cm 2 = 1.5 cm to 2.0 cm 3 = 2.1 cm to 3.0 cm 4 = 3.1 cm to 4.0 cm 5 = Greater than 4.0 cm	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
	<b>TYPE:</b> 1 = Focal (Non-nodular) 2 = Diffuse 3 = Nodular	1 2 3	1 2 3	1 2 3
<b>LOCATION</b>	<b>GRADE:</b> 1 = Firm 2 = Firmer 3 = Hard	1 2 3	1 2 3	1 2 3
1 = Left apex 2 = Right apex 3 = Left lateral lobe 4 = Right lateral lobe 5 = Left base 6 = Right base 7 = Left seminal vesicle 8 = Right seminal vesicle	<b>EXTENT:</b> 1 = Confined to Prostate 2 = Beyond Capsule (Not into Seminal Vesicles and Not Fixed) 3 = Beyond Capsule—Into Seminal Vesicles 4 = Beyond Capsule—Extensive (Fixed)	1 2 3 4	1 2 3 4	1 2 3 4

**8. Additional Findings: (MARK ALL THAT APPLY)**

None (GO TO PART B)     Other (SPECIFY) \_\_\_\_\_  
 Enlargement \_\_\_\_\_  
 Tenderness \_\_\_\_\_

**PART B: PROSTATE EXAMINATION RESULTS**

<b>1. Examination Results:</b>	<b>2. Reason for Inadequate Exam:</b> (MARK ALL THAT APPLY)	<b>3. Level of Referral:</b>	<b>4. Medical Complications of Exam:</b>
<input type="radio"/> Positive Screen - Referral Required (GO TO 3) <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3) <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3) <input type="radio"/> Inadequate	<input type="radio"/> Participant Discomfort <input type="radio"/> Participant Refusal <input type="radio"/> Participant Obesity <input type="radio"/> Other (SPECIFY) _____	<input type="radio"/> 1 - Significant Abnormality, Referral <input type="radio"/> 2 - Moderate Abnormality, Referral <input type="radio"/> 3 - Slight Variation from Normal, No Referral <input type="radio"/> 4 - Normal/Result Not Available, No Referral	<input type="radio"/> No <input type="radio"/> Yes (SPECIFY) _____ _____ _____

<b>5. Comments:</b>	<b>6. Examiner ID:</b>	<b>7. Consultant ID:</b>	
<input type="radio"/> No <input type="radio"/> Yes (SPECIFY) Item #      Comments	_____ Signature	<input type="radio"/> No <input type="radio"/> Yes (SPECIFY) _____ Signature	
<input type="radio"/> Continued	0 0 0 0 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4 5 5 5 5 6 6 6 6 7 7 7 7 8 8 8 8 9 9 9 9	0 0 0 0 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4 5 5 5 5 6 6 6 6 7 7 7 7 8 8 8 8 9 9 9 9	

## PLCO Cancer Screening Trial

# SPECIFICATIONS FOR COMPLETION OF THE DIGITAL RECTAL EXAMINATION OF THE PROSTATE FORM - VERSION 2 (DRE2)

This form is to be completed by an SC staff member and the Examiner. The SC staff member will complete the top administrative section and the Examiner will complete Parts A and B of the form. A physician consultant should be called if the Examiner is unable to complete the examination and requires assistance. If a physician consultant participates in an examination, the physician's results, not the Examiner's, should be recorded on the form.

Specifications for completing each item of the form are given below:

---

### General instructions for the completion of forms to be scanned by an Optical Mark Reader:

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.

Correct Mark



Incorrect Marks



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

### Administrative Section:

**Participant ID:** Affix a Participant ID label to the space provided in the upper right-hand corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Screening Center:** This item is optional. If this item is completed, enter the 2-digit SC ID and darken the circle corresponding to each number.
3. **Satellite Center:** This item is optional. If the SC has elected to track satellite center activity and the examination is taking place at a satellite center, enter the 2-digit Satellite Center ID. Darken the circle corresponding to each number. If the examination

is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank.

4. **Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2, or T3 for the follow-up examinations.
5. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete this examination in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the examination was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the digital rectal examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
6. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior DRE terminated due to rectal pain."*

This might be entered if the participant's digital rectal examination was stopped due to rectal pain in the previous visit, but he was willing to return to the SC to attempt the examination again. This information will alert the Examiner to the participant's physical/mental condition.

*"Participant out of time. Unable to complete DRE."*

This might be entered if the participant's schedule did not allow him to remain at the SC to complete the digital rectal examination during a previous visit, and the examination was rescheduled.

7. **Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (See documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional forms processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A - Prostate Examination Findings:**

Complete Items 1-8 below. If the result of the examination (Item B1) is "Inadequate," Part A may be left blank. The examiner should record any information that is available and leave the remaining items blank.

- 1. Participant Position:** Darken the circle corresponding to the participant's position during the examination. There are three acceptable positions:

Bent at waist over end of examination table: The participant is standing, bent forward at the waist, with his elbows resting on the examination table;

Kneeling, knees to chest: The participant is kneeling on the examination table, with his chest lowered toward his knees; and

Lateral decubitus position with knees pulled up to chest: The participant is lying on his side on the examination table, with his knees pulled up to his chest.

If more than one position is used, record the first position attempted in this item and record any additional positions in Comments, Item B.5.

- 2. Prostate Palpable:** Darken a circle to indicate whether the prostate is palpable. If the prostate is completely or partially palpable, darken the circle for "Yes." If the prostate is not palpable at all, darken the circle next to "No" and go to part B to record the exam result.
- 3. Approximate Size of Gland:** Enter the transverse and sagittal dimensions of the prostate in centimeters, and darken the circles corresponding to the numbers. Round all measurements to the nearest half-centimeter. Zero-fill measurements that are less than 10 cm. (e.g., 02.0, 05.5, etc.).

The transverse dimension refers to the width of the prostate (left to right), and the sagittal dimension refers to the length of the prostate (from bladder to membranous urethra).

- 4. Prostate Symmetry:** Darken a circle to indicate whether the left and right lobes of the prostate are symmetrical or asymmetrical in shape.

5. **Overall Consistency of Gland:** Darken a circle to indicate the overall consistency of the prostate gland. Definitions are as follows:

Normal: Smooth, rubbery and firm (like the base of thumb).

Boggy with No Induration: Fleshy consistency (like the cheek of face) with no abnormally hard areas.

Boggy with Induration/Nodular: Fleshy consistency (like the cheek of face) with one or more abnormally hard areas.

Induration/Nodular: An abnormally hard spot or area.

6. **Areas of Induration:** Darken the circle corresponding to the number of distinct areas of induration (i.e., One, Two, Three, Four or more). If the entire prostate is indurated, darken the circle for "One."

7. **Record Information for Three Largest Areas of Induration:** Complete the chart by darkening the circle corresponding to the correct response in each column. Enter information about the largest area of induration in the column labeled "1", the second largest area of induration in the column labeled "2" and the third largest area of induration in the column labeled "3."

Definitions of chart items are given below:

**Location:**

Refer to the diagram of the prostate on the examination form and document the location of each area of induration by drawing it on the diagram and by darkening one or more circles in the chart to indicate the location. The locations are defined below:

- 1 = Left apex;
- 2 = Right apex;
- 3 = Left lateral lobe;
- 4 = Right lateral lobe;
- 5 = Left base;
- 6 = Right base;
- 7 = Left seminal vesicle;
- 8 = Right seminal vesicle.

If an area of induration extends across one or more locations, darken the circles for all locations which contain the induration.

**Approximate Size:**

Darken the circle indicating the size range that includes the size of the induration. For example, if the induration is approximately 3.5 centimeters, darken the circle next to "3.1 cm to 4.0 cm."

The ranges are as follows:

- 1 = Less than 1.5 cm;
- 2 = 1.5 to 2.0 cm;
- 3 = 2.1 to 3.0 cm;
- 4 = 3.1 to 4.0 cm;
- 5 = Greater than 4.0 cm.

**Type:**

- 1 = Focal (Non-nodular): The induration is focused in one area, but does not protrude from the surface of the prostate.
- 2 = Diffuse: The induration is widely distributed, without a distinct margin.
- 3 = Nodular: The induration is focal with a distinct nodule, and causes a protrusion from the surface of the prostate.

**Grade:**

- 1 = Firm: Consistency of a tennis ball.
- 2 = Firmer: Consistency of a softball.
- 3 = Hard: Consistency of a marble.

**Extent:**

- 1 = Confined to Prostate: Within the capsule of the prostate.
- 2 = Beyond Capsule (Not into Seminal Vesicles and Not Fixed): Outside the capsule of the prostate, but not extending into the seminal vesicles, and not extensive to the point of fixation of the prostate to the surrounding structures such as the bladder, rectum, or pelvic side walls. (See Figure 1., left side.)
- 3 = Beyond Capsule - Into Seminal Vesicles: Beyond the capsule of the prostate, extending into the seminal vesicles which are superior and lateral to the prostate. (See Figure 1., right side.)
- 4 = Beyond Capsule - Extensive (Fixed): Beyond the capsule of the prostate, extending into and fixed to the surrounding structures (such as bladder and rectum). (See Figure 2.)

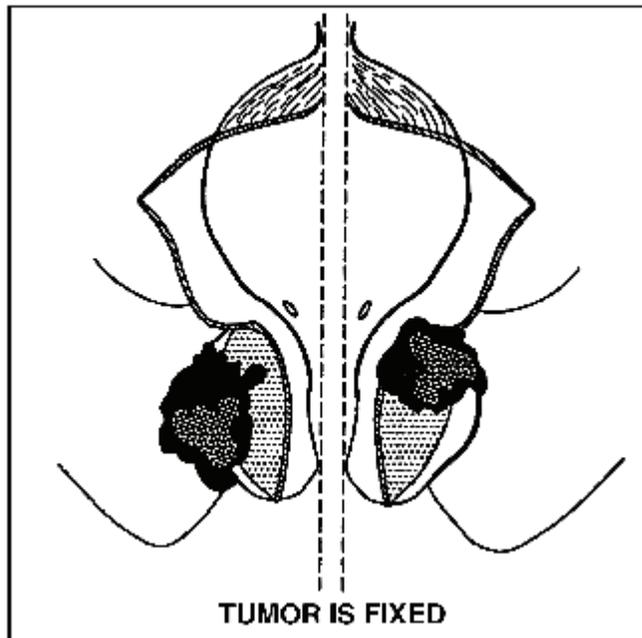


Figure 1

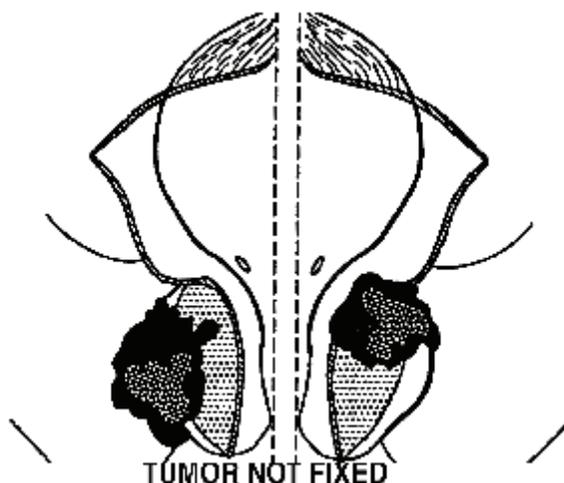


Figure 2

**8. Additional Findings:** Darken one or more circles to indicate any additional findings. Additional findings are described below:

None: No additional abnormalities noted. (Note: If this circle is darkened, no other circle may be darkened; continue with Part B.)

Enlargement: The prostate is enlarged in the opinion of the Examiner.

Tenderness: The participant experiences abnormal sensitivity to touch or pressure on the prostate.

Other (SPECIFY): Describe any other abnormalities noted during the examination in the space provided.

**Part B - Prostate Examination Results:**

**1. Examination Results:** Darken the circle corresponding to the result of the examination. Definitions of examination results are given below:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Prostate Cancer (Referral Needed): The prostate examination shows:

- nodularity or induration of the prostate; or
- the examiner judges the prostate to be suspicious for cancer in the absence of nodularity or induration.

In the event that the examiner judges the prostate to be suspicious for cancer in the absence of nodularity or induration, the examiner is required to describe the basis of this judgement in the comments section.

A referral to the participant's physician of choice for evaluation of these results is necessary.

Negative Screen - No Abnormalities (formerly Negative): The prostate examination reveals:

- a symmetric, soft, non-nodular prostate.

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Prostate Cancer): The prostate examination reveals:

- Enlargement;
- Tenderness;
- Bogginess with no other abnormal findings;
- Asymmetry in a prostate of normal consistency and of normal size or slightly enlarged;
- Prostate has been previously removed and abnormalities not indicative of a positive screen are identified.

If the Examiner feels that a referral is necessary, this information should be recorded in Item B.3 (Level of Referral).

- Inadequate: The prostate examination is incomplete, i.e., sufficient information could not be obtained to determine a result due to one or more of the following reasons:
  - the participant is unwilling to allow the examination;
  - the participant is unable to tolerate the discomfort of the examination;
  - the examiner is unable to palpate the prostate due to participant obesity;
  - the examiner is unable to palpate the apex, base and lateral lobes of the prostate, and seminal vesicles, and no abnormality suspicious for cancer is found in the area palpated; or
  - the prostate has been previously removed and no abnormalities are identified.

Record the reason(s) for the inadequate examination in Item B.2 below.

If there is an abnormality that is indicative of a positive screen, and one that is not indicative of a positive screen, only "Positive Screen - Referral Required" should be marked.

- 2. Reason for Inadequate Examination:** Darken one or more circles to indicate the reason(s) for the inadequate examination. An explanation of each reason for an inadequate examination is given below:

Participant Discomfort: The participant is unable to tolerate the discomfort of the examination and the examination is terminated prematurely, without collection of sufficient information to determine a result.

Participant Refusal: The participant is unwilling to allow the completion of the examination and a result could not be determined due to insufficient information.

Participant Obesity: The participant is so obese that the Examiner is unable to palpate the prostate at all.

Other (SPECIFY): Describe any other situation in which a result could not be determined due to insufficient information.

- 3. Level of Referral:** Darken the circle corresponding to the level of referral.

1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate", and an abnormality considered to be significant and requiring referral was found.

2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.

4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen, or the result of the examination is not available.

- 4. Medical Complications of Exam:** If the participant did not experience any complications of the examination prior to leaving the SC, darken the circle next to "No." If the participant experienced immediate medical complications (prior to leaving the SC), darken the circle next to "Yes" and briefly describe the complication(s) in the space provided.

**Note:** An Adverse Experience Report (AER) should be completed if the participant experiences a medical complication before arriving at or after leaving the SC or if he receives medical care for a complication experienced during the screening visit.

- 5. Comments:** The comments section may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item in Parts A or B of the form, use the item number for the comments section itself (B.5). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

- 6. Examiner ID:** (This item should be completed by the Examiner even if a physician was consulted during the examination.)

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

- 7. Consultant ID:** (This item should be completed by the physician consultant. If a physician was not consulted during the examination, the Examiner should darken the circle next to "No," and the signature should be left blank. Note that this item should not be completed for QA Examiners; QA Examiners must complete a separate examination form for QA.)

Darken the circle next to "Yes," and sign the form in the space provided. Enter your 4-digit staff ID number and darken the circles corresponding to the four digits.

## **A-12-2**

**A-12-2: Digital Rectal Screening Examination of the Prostate Form for Quality Assurance (DRQ2)**

**Specifications for the Digital Rectal Screening Examination of the Prostate Form for Quality Assurance**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

Version Date: 10/99

Expiration Date: 7/05

Form Approved OMB No.: 0925-0407

## DIGITAL RECTAL SCREENING EXAMINATION OF THE PROSTATE QUALITY ASSURANCE (DRQ2)

1.	Date of Examination:			2.	Screening Center:		3.	Satellite Center:		4.	Study Year:	5.	Visit Number:
	MO.	DAY	YEAR										
	0	0	0	0		0	0		0	0		<input type="radio"/> T0	<input type="radio"/> One
	1	1	1	1		1	1		1	1		<input type="radio"/> T1	<input type="radio"/> Two
	2	2	2	2		2	2		2	2		<input type="radio"/> T2	<input type="radio"/> Three
	3	3	3	3		3	3		3	3			
	4	4	4	4		4	4		4	4			
	5	5	5	5		5	5		5	5			
	6	6	6	6		6	6		6	6			
	7	7	7	7		7	7		7	7			
	8	8	8	8		8	8		8	8			
	9	9	9	9		9	9		9	9			

• DO NOT FOLD, STAPLE OR TEAR THIS FORM.  
• USE A NO. 2 PENCIL TO COMPLETE THIS FORM.

6. Reason for Repeat Visit:

---



---



---



---

**For Office Use Only**

**7. Form Processing**  
(DARKEN CIRCLES AS STEPS ARE COMPLETED)

Form Received into SMS <input type="radio"/>	<b>Data Retrieval:</b>
Manual Review Completed <input type="radio"/>	Attempted <input type="radio"/> OR None Required <input type="radio"/>
<b>Data Entry of Non-Scannable Items:</b>	<b>Final Disposition:</b>
Completed <input type="radio"/> OR None Required <input type="radio"/>	Final Complete (FCM) <input type="radio"/> OR Final Incomplete (FIC) <input type="radio"/>

### PART A: PROSTATE EXAMINATION FINDINGS

1. Participant Position:	<input type="radio"/> Bent at waist over end of examination table <input type="radio"/> Kneeling, knees to chest <input type="radio"/> Lateral decubitus position with knees pulled up to chest	Transverse in cm. 	Sagittal in cm. 	4. Prostate Symmetry:
				<input type="radio"/> Symmetrical <input type="radio"/> Asymmetrical
2. Prostate Palpable:	<input type="radio"/> No (GO TO PART B) <input type="radio"/> Yes			5. Consistency of Gland:
3. Approximate Size of Gland:				<input type="radio"/> Normal (GO TO 8) <input type="radio"/> Boggy, with No Induration (GO TO 8) <input type="radio"/> Boggy, with Induration/Nodular <input type="radio"/> Induration/Nodular
				6. Areas of Induration:
				<input type="radio"/> One <input type="radio"/> Two <input type="radio"/> Three <input type="radio"/> Four or more

MARK SIZES IN THE FOLLOWING GRIDS

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

PLEASE DO NOT WRITE IN THIS AREA



013011

**PART A CONTINUED...**

<b>7.</b> RECORD INFORMATION FOR THREE LARGEST AREAS OF INDURATION	<b>Area of Induration</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>DIAGRAM</b>	<b>LOCATION:</b> DARKEN CIRCLES FOR ALL NUMBERS FROM THE DIAGRAM THAT APPLY (1-8)	1 2 3 4 5 6 7 8	1 2 3 4 5 6 7 8	1 2 3 4 5 6 7 8
<p><b>DIAGRAM</b></p> <p>7 8 Seminal Vesicles</p> <p>Base</p> <p>5 6</p> <p>L 3 4 R</p> <p>1 2</p> <p>Apex</p>	<b>APPROXIMATE SIZE:</b> 1 = Less than 1.5 cm 2 = 1.5 cm to 2.0 cm 3 = 2.1 cm to 3.0 cm 4 = 3.1 cm to 4.0 cm 5 = Greater than 4.0 cm	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
	<b>TYPE:</b> 1 = Focal (Non-nodular) 2 = Diffuse 3 = Nodular	1 2 3	1 2 3	1 2 3
<b>LOCATION</b>	<b>GRADE:</b> 1 = Firm 2 = Firmer 3 = Hard	1 2 3	1 2 3	1 2 3
1 = Left apex 2 = Right apex 3 = Left lateral lobe 4 = Right lateral lobe 5 = Left base 6 = Right base 7 = Left seminal vesicle 8 = Right seminal vesicle	<b>EXTENT:</b> 1 = Confined to Prostate 2 = Beyond Capsule (Not into Seminal Vesicles and Not Fixed) 3 = Beyond Capsule—into Seminal Vesicles 4 = Beyond Capsule—Extensive (Fixed)	1 2 3 4	1 2 3 4	1 2 3 4

**8. Additional Findings: (MARK ALL THAT APPLY)**

- None (GO TO PART B)     Other (SPECIFY) \_\_\_\_\_  
 Enlargement \_\_\_\_\_  
 Tenderness \_\_\_\_\_

**PART B: PROSTATE EXAMINATION RESULTS**

<b>1. Examination Results:</b>	<b>2. Reason for Inadequate Exam:</b> (MARK ALL THAT APPLY)	<b>3. Level of Referral:</b>	<b>4. Medical Complications of Exam:</b>
<input type="radio"/> Positive Screen - Referral Required (GO TO 3) <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3) <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3) <input type="radio"/> Inadequate	<input type="radio"/> Participant Discomfort <input type="radio"/> Participant Refusal <input type="radio"/> Participant Obesity <input type="radio"/> Other (SPECIFY) _____	<input type="radio"/> 1 - Significant Abnormality, Referral <input type="radio"/> 2 - Moderate Abnormality, Referral <input type="radio"/> 3 - Slight Variation from Normal, No Referral <input type="radio"/> 4 - Normal/Result Not Available, No Referral	<input type="radio"/> No <input type="radio"/> Yes (SPECIFY) _____ _____ _____
<b>5. Comments:</b>	<b>6. Examiner ID:</b>	<b>7. Consultant ID:</b>	
<input type="radio"/> No <input type="radio"/> Yes (SPECIFY) Item #      Comments	_____ Signature	<input type="radio"/> No <input type="radio"/> Yes (SPECIFY) _____ Signature	
<input type="radio"/> Continued	0 0 0 0 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4 5 5 5 5 6 6 6 6 7 7 7 7 8 8 8 8 9 9 9 9	0 0 0 0 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4 5 5 5 5 6 6 6 6 7 7 7 7 8 8 8 8 9 9 9 9	

## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE DIGITAL RECTAL EXAMINATION OF THE PROSTATE QUALITY ASSURANCE FORM - VERSION 2 (DRQ2)

This form is to be completed by a SC staff member and the QA Examiner for the digital rectal examination. The QA Examiner is defined as the examiner who repeats the digital rectal examination for QA purposes.

The SC staff member will complete the top administrative section and the QA Examiner will complete Parts A and B of the form. The completed form will then be receipted into the SMS and scanned into the DEES.

Since the quality assurance for the digital rectal examination will involve a repeat examination, all items of this form must be completed. Specifications for completing each item of the form are given below:

---

#### General instructions for the completion of forms to be scanned by an Optical Mark Reader:

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.

Correct Mark



Incorrect Marks



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

#### Administrative Section:

**Participant ID:** Affix a Participant ID label to the space provided in the upper right-hand corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the QA examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Screening Center:** This item is optional. If this item is completed, enter the 2-digit SC ID and darken the circle corresponding to each number.

3. **Satellite Center:** This item is optional. If the SC has elected to track satellite center activity and the QA examination is taking place at a satellite center, enter the 2-digit Satellite Center ID. Darken the circle corresponding to each number. If the QA examination is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank.
4. **Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2, or T3 for the follow-up examinations.
5. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the digital rectal examination, including the QA examination, in the current study year. For example, if the QA examination is completed on the participant's first visit to the SC, darken the circle next to "One." If the participant was required to return to the SC a second time to complete the QA examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
6. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. If the repeat visit is specifically for the purpose of performing the QA examination, record "QA Examination" in the space provided. If the main purpose of the repeat visit is to complete the original digital rectal examination, record the reason for the repeat visit. The purpose of this item is to provide important information to the QA Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior DRE terminated due to rectal pain."*

This might be entered if the participant's digital rectal examination was stopped due to rectal pain in the previous visit, but he was willing to return to the SC to attempt the examination again. This information will alert the QA Examiner to the participant's physical/mental condition.

*"Participant out of time. Unable to complete exam."*

This might be entered if the participant's schedule did not allow him to remain at the SC to complete the digital rectal examination during a previous visit, and the examination was rescheduled.

7. **Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the

circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A - Prostate Examination Findings:**

Complete Items 1-8 below. If the result of the QA examination (Item B1) is "Inadequate," Part A may be left blank. The QA Examiner should record any information that is available and leave the remaining items blank.

- 1. Participant Position:** Darken the circle corresponding to the participant's position during the examination. There are three acceptable positions:
  - Bent at waist over end of examination table: The participant is standing, bent forward at the waist, with his elbows resting on the examination table;
  - Kneeling, knees to chest: The participant is kneeling on the examination table, with his chest lowered toward his knees; and
  - Lateral decubitus position with knees pulled up to chest: The participant is lying on his side on the examination table, with his knees pulled up to his chest.If more than one position is used, record the first position attempted in this item and record any additional positions in Comments, Item B.5.
- 2. Prostate Palpable:** Darken a circle to indicate whether the prostate is palpable. If the prostate is completely or partially palpable, darken the circle for "Yes." If the prostate is not palpable at all, darken the circle next to "No" and go to part B to record the exam result.
- 3. Approximate Size of Gland:** Enter the transverse and sagittal dimensions of the prostate in centimeters, and darken the circles corresponding to the numbers. Round all measurements to the nearest half-centimeter. Zero-fill measurements that are less than 10 cm. (e.g., 02.0, 05.5, etc.).

The transverse dimension refers to the width of the prostate (left to right), and the sagittal dimension refers to the length of the prostate (from bladder to membranous urethra).

4. **Prostate Symmetry:** Darken a circle to indicate whether the left and right lobes of the prostate are symmetrical or asymmetrical in shape.
5. **Overall Consistency of Gland:** Darken a circle to indicate the overall consistency of the prostate gland. Definitions are as follows:

Normal: Smooth, rubbery and firm (like the base of thumb).

Boggy with No Induration: Fleshy consistency (like the cheek of face) with no abnormally hard areas.

Boggy with Induration/Nodular: Fleshy consistency (like the cheek of face) with one or more abnormally hard areas.

Induration/Nodular: An abnormally hard spot or area.

6. **Areas of Induration:** Darken the circle corresponding to the number of distinct areas of induration (i.e., One, Two, Three, Four or more). If the entire prostate is indurated, darken the circle for "One."
7. **Record Information for Three Largest Areas of Induration:** Complete the chart by darkening the circle corresponding to the correct response in each column. Enter information about the largest area of induration in the column labeled "1", the second largest area of induration in the column labeled "2" and the third largest area of induration in the column labeled "3."

Definitions of chart items are given below:

**Location:**

Refer to the diagram of the prostate on the examination form and document the location of each area of induration by drawing it on the diagram and by darkening one or more circles in the chart to indicate the location. The locations are defined below:

- 1 = Left apex;
- 2 = Right apex;
- 3 = Left lateral lobe;
- 4 = Right lateral lobe;
- 5 = Left base;
- 6 = Right base;
- 7 = Left seminal vesicle;
- 8 = Right seminal vesicle.

If an area of induration extends across one or more locations, darken the circles for all locations which contain the induration.

**Approximate Size:**

Darken the circle indicating the size range that includes the size of the induration. For example, if the induration is approximately 3.5 centimeters, darken the circle next to "3.1 cm to 4.0 cm."

The ranges are as follows:

- 1 = Less than 1.5 cm;
- 2 = 1.5 to 2.0 cm;
- 3 = 2.1 to 3.0 cm;
- 4 = 3.1 to 4.0 cm;
- 5 = Greater than 4.0 cm.

**Type:**

- 1 = Focal (Non-nodular): The induration is focused in one area, but does not protrude from the surface of the prostate.
- 2 = Diffuse: The induration is widely distributed, without a distinct margin.
- 3 = Nodular: The induration is focal with a distinct nodule, and causes a protrusion from the surface of the prostate.

**Grade:**

- 1 = Firm: Consistency of a tennis ball.
- 2 = Firmer: Consistency of a softball.
- 3 = Hard: Consistency of a marble.

**Extent:**

- 1 = Confined to Prostate: Within the capsule of the prostate.
- 2 = Beyond Capsule (Not into Seminal Vesicles and Not Fixed): Outside the capsule of the prostate, but not extending into the seminal vesicles, and not extensive to the point of fixation of the prostate to the surrounding structures such as the bladder, rectum, or pelvic side walls. (See Figure 1., left side.)
- 3 = Beyond Capsule - Into Seminal Vesicles: Beyond the capsule of the prostate, extending into the seminal vesicles which are superior and lateral to the prostate. (See Figure 1., right side.)
- 4 = Beyond Capsule - Extensive (Fixed): Beyond the capsule of the prostate, extending into and fixed to the surrounding structures (such as bladder and rectum). (See Figure 2.)

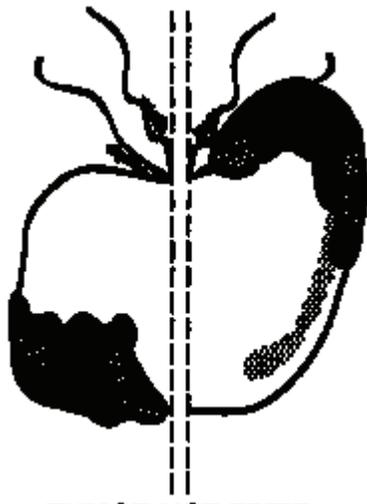
**8. Additional Findings:** Darken one or more circles to indicate any additional findings. Additional findings are described below:

None: No additional abnormalities noted. (Note: If this circle is darkened, no other circle may be darkened; continue with Part B.)

Enlargement: The prostate is enlarged in the opinion of the QA Examiner.

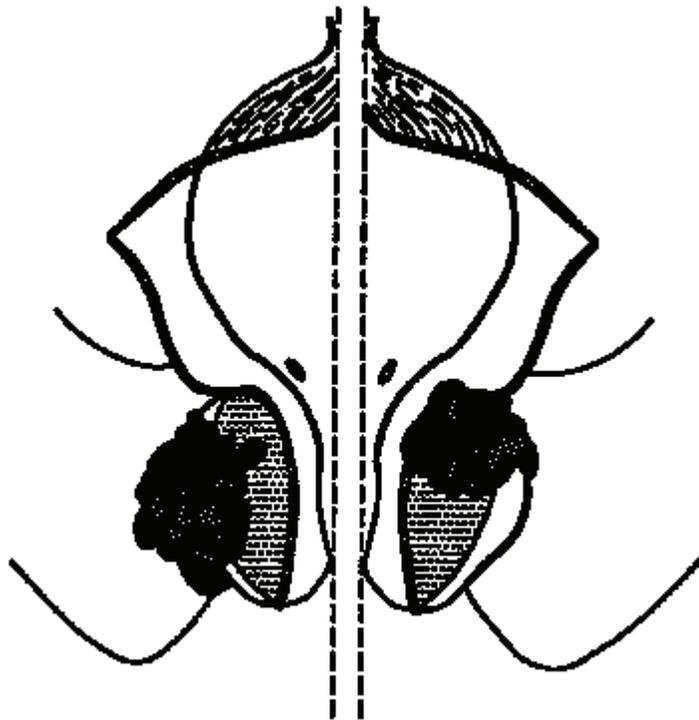
Tenderness: The participant experiences abnormal sensitivity to touch or pressure on the prostate.

Other (SPECIFY): Describe any other abnormalities noted during the examination in the space provided.



**TUMOR NOT FIXED**

Figure 1



**TUMOR IS FIXED**

Figure 2

## **Part B - Prostate Examination Results:**

- 1. Examination Results:** Darken the circle corresponding to the result of the examination. Definitions of examination results are given below:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Prostate Cancer (Referral Needed): The prostate examination shows:

- nodularity or induration of the prostate or
- the examiner judges the prostate to be suspicious for cancer in the absence of nodularity or induration.

In the event that the examiner judges the prostate to be suspicious for cancer in the absence of nodularity or induration, the examiner is required to describe the basis of this judgement in the comments section.

A referral to the participant's physician of choice for evaluation of these results is necessary.

Negative Screen - No Abnormalities (formerly Negative): The prostate examination reveals:

- a symmetric, soft, non-nodular prostate.

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Prostate Cancer): The prostate examination reveals:

- Enlargement;
- Tenderness;
- Bogginess with no other abnormal findings;
- Asymmetry in a prostate of normal consistency and of normal size or slightly enlarged;
- Prostate is removed and abnormalities not indicative of a positive screen are identified.

If the QA Examiner feels that a referral is necessary, this information should be recorded in Item B.3 (Level of Referral).

Inadequate: The prostate examination is incomplete, i.e., sufficient information could not be obtained to determine a result due to one or more of the following reasons:

- the participant is unwilling to allow the examination;
- the participant is unable to tolerate the discomfort of the examination;
- the QA Examiner is unable to palpate the prostate due to participant obesity;
- the QA Examiner is unable to palpate the apex, base and lateral lobes of the prostate, and seminal vesicles, and no abnormality suspicious for cancer is found in the area palpated; or
- the prostate is removed and no abnormalities are identified.

Record the reason(s) for the inadequate examination in Item B.2 below. A QA examination that is inadequate will not count toward the total number of QA examinations performed.

If there is an abnormality that is indicative of a positive screen, and one that is not indicative of a positive screen, only "Positive Screen - Referral Required" should be marked.

- 2. Reason for Inadequate Examination:** Darken one or more circles to indicate the reason(s) for the inadequate examination. An explanation of each reason for an inadequate examination is given below:

Participant Discomfort: The participant is unable to tolerate the discomfort of the examination and the examination is terminated prematurely, without collection of sufficient information to determine a result.

Participant Refusal: The participant is unwilling to allow the completion of the examination and a result could not be determined due to insufficient information.

Participant Obesity: The participant is so obese that the QA Examiner is unable to palpate the prostate at all.

Other (SPECIFY): Describe any other situation in which a result could not be determined due to insufficient information.

- 3. Level of Referral: Darken the circle corresponding to the level of referral.**

1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was a "Negative Screen - Other Abnormalities" or "Inadequate" screen for prostate cancer, and an abnormality considered to be significant and requiring referral was found.

2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.

4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

- 4. Medical Complications of Exam:** If the participant did not experience any complications of the examination prior to leaving the SC, darken the circle next to "No." If the participant experienced immediate medical complications (prior to leaving the SC), darken the circle next to "Yes" and briefly describe the complication(s) in the space provided.

**Note:** An Adverse Experience Report (AER) should be completed if the participant experiences a medical complication before arriving at or after leaving the SC or if he receives medical care for a complication experienced during the screening visit.

- 5. Comments:** The comments section may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item in Parts A or B of the form, use the item number for the comments section itself (B.5). Then enter the comments in the space provided to the right of the item number. If more

space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

**6. Examiner ID:** (This item should be completed by the QA Examiner.)

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

**7. Consultant ID:** (This item should be completed by any physician with whom the QA examiner consults regarding the QA examination.)

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

## **A-13-1**

**A-13-1: Flexible Sigmoidoscopy Screening Examination Form (FSG2)**

**Specifications for the Flexible Sigmoidoscopy Screening Examination Form**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

## FLEXIBLE SIGMOIDOSCOPY SCREENING EXAMINATION (FSG2)

1.	Date of Examination:			2.	Screening Center:	3.	Satellite Center:	4.	Study Year:	5.	Visit Number:
	MO.	DAY	YEAR								
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>							
	0 0 0 0	0 0 0 0	0 0 0 0	0 0	0 0	0 0	0 0	<input type="radio"/> T <sub>0</sub>	<input type="radio"/> One		
	1 1 1 1	1 1 1 1	1 1 1 1	1 1	1 1	1 1	1 1	<input type="radio"/> T <sub>5</sub>	<input type="radio"/> Two		
	2 2 2 2	2 2 2 2	2 2 2 2	2	2	2	2		<input type="radio"/> Three		
	3 3 3 3	3 3 3 3	3 3 3 3	3	3	3	3				
	4 4 4 4	4 4 4 4	4 4 4 4	4	4	4	4				
	5 5 5 5	5 5 5 5	5 5 5 5	5	5	5	5				
	6 6 6 6	6 6 6 6	6 6 6 6	6	6	6	6				
	7 7 7 7	7 7 7 7	7 7 7 7	7	7	7	7				
	8 8 8 8	8 8 8 8	8 8 8 8	8	8	8	8				
	9 9 9 9	9 9 9 9	9 9 9 9	9	9	9	9				

• DO NOT FOLD, STAPLE OR TEAR THIS FORM.  
• USE A NO. 2 PENCIL TO COMPLETE THIS FORM.

6. Reason for Repeat Visit:

---



---



---



---



---

**For Office Use Only**

**7. Form Processing**  
(DARKEN CIRCLES AS STEPS ARE COMPLETED)

Form Received into SMS

Manual Review Completed

**Data Entry of Non-Scannable Items:**  
Completed  OR None Required

**Data Retrieval:**  
Attempted  OR None Required

**Final Disposition:**  
Final Complete (FCM)  OR Final Incomplete (FIC)

**PART A: RECTAL EXAMINATION FINDINGS**

1. Rectal Examination Findings:  
(MARK ALL THAT APPLY)

None (GO TO PART B)

External hemorrhoids

Tenderness

Masses, Polyps, or Nodules

Blood

Stricture

Fistula or Fissures

Other (SPECIFY) \_\_\_\_\_

**PART B: FLEXIBLE SIGMOIDOSCOPY FINDINGS**

1.	Number of Attempts:	2.	Reason for Repeat Exam: (MARK ALL THAT APPLY)	3.	Depth of Sigmoidoscope Insertion:	4.	Number of Lesions Seen: (INCLUDES POLYPS AND MASSES)
	<input type="radio"/> One (GO TO 3)		<input type="radio"/> Participant Discomfort		<input type="text"/>		<input type="radio"/> None (GO TO 5)
	<input type="radio"/> Two		<input type="radio"/> Participant Refusal		<input type="text"/>		<input type="radio"/> One
			<input type="radio"/> Equipment Malfunction		<input type="text"/>		<input type="radio"/> Two
			<input type="radio"/> Inadequate Preparation		<input type="text"/>		<input type="radio"/> Three
			<input type="radio"/> Vasovagal Response		<input type="text"/>		<input type="radio"/> Four or More
			<input type="radio"/> Other (SPECIFY) _____		<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		
					<input type="text"/>		

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

PLEASE DO NOT WRITE IN THIS AREA



137130

**PART B CONTINUED...**

DIAGRAM	5. RECORD INFORMATION FOR LARGEST FOUR LESIONS:																																																																																				
<p>1 = Rectum 2 = Sigmoid colon 3 = Descending colon 4 = Splenic flexure</p>	LESION 1	LESION 2	LESION 3	LESION 4																																																																																	
	<b>TYPE</b> 1 = Polyp 2 = Mass	① ②	① ②	① ②	① ②																																																																																
	<b>LOCATION</b> (RECORD A NUMBER, 1-4, FROM THE DIAGRAM)	① ② ③ ④	① ② ③ ④	① ② ③ ④	① ② ③ ④																																																																																
	<b>SIZE</b> (LARGEST DIMENSION IN CM)	<table border="1"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<table border="1"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<table border="1"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<table border="1"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9
	0	0																																																																																			
	1	1																																																																																			
	2	2																																																																																			
3	3																																																																																				
4	4																																																																																				
5	5																																																																																				
6	6																																																																																				
7	7																																																																																				
8	8																																																																																				
9	9																																																																																				
0	0																																																																																				
1	1																																																																																				
2	2																																																																																				
3	3																																																																																				
4	4																																																																																				
5	5																																																																																				
6	6																																																																																				
7	7																																																																																				
8	8																																																																																				
9	9																																																																																				
0	0																																																																																				
1	1																																																																																				
2	2																																																																																				
3	3																																																																																				
4	4																																																																																				
5	5																																																																																				
6	6																																																																																				
7	7																																																																																				
8	8																																																																																				
9	9																																																																																				
0	0																																																																																				
1	1																																																																																				
2	2																																																																																				
3	3																																																																																				
4	4																																																																																				
5	5																																																																																				
6	6																																																																																				
7	7																																																																																				
8	8																																																																																				
9	9																																																																																				
<b>SHAPE</b> 1 = Sessile 2 = Pedunculated 8 = Other (SPECIFY)	① ② ⑧	① ② ⑧	① ② ⑧	① ② ⑧																																																																																	
<b>BIOPSY PERFORMED</b>	<input type="radio"/> NO <input type="radio"/> YES	<input type="radio"/> NO <input type="radio"/> YES	<input type="radio"/> NO <input type="radio"/> YES	<input type="radio"/> NO <input type="radio"/> YES																																																																																	
<b>VIDEO/PHOTO DOCUMENTATION</b>	<input type="radio"/> NO <input type="radio"/> YES	<input type="radio"/> NO <input type="radio"/> YES	<input type="radio"/> NO <input type="radio"/> YES	<input type="radio"/> NO <input type="radio"/> YES																																																																																	

**6. Other Irregular Findings: (MARK ALL THAT APPLY)**

<input type="radio"/> None (GO TO PART C)	<input type="radio"/> Vascular Lesions	<input type="radio"/> Stricture	<input type="radio"/> Anal Warts
<input type="radio"/> Diverticulosis	<input type="radio"/> Ulcers	<input type="radio"/> Fissures	<input type="radio"/> Other (SPECIFY) _____
<input type="radio"/> Diverticulitis	<input type="radio"/> Melanosis Coli	<input type="radio"/> Internal Hemorrhoids	
<input type="radio"/> Colitis	<input type="radio"/> Blood		

**PART C: EXAMINATION RESULTS**

<p><b>1. Examination Results:</b></p> <input type="radio"/> Positive Screen - Referral Required (GO TO 3) <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3) <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3) <input type="radio"/> Inadequate (Less than 90% mucosa is visible, or insertion of flexible sigmoidoscope to less than 50 cm, with no obstructing lesions and no abnormalities suspicious for cancer in the region visualized.)	<p><b>2. Reason for Inadequate Exam: (MARK ALL THAT APPLY)</b></p> <input type="radio"/> Participant Discomfort <input type="radio"/> Participant Refusal <input type="radio"/> Equipment Malfunction <input type="radio"/> Inadequate Preparation with Unclear Lumen <input type="radio"/> Vasovagal Response <input type="radio"/> Palpitations With Tachycardia <input type="radio"/> Severe Diverticulosis With Unclear Lumen <input type="radio"/> Severe Ulcerative Colitis <input type="radio"/> Other (SPECIFY) _____	<p><b>3. Level of Referral:</b></p> <input type="radio"/> 1 - Significant Abnormality, Referral <input type="radio"/> 2 - Moderate Abnormality, Referral <input type="radio"/> 3 - Slight Variation from Normal, No Referral <input type="radio"/> 4 - Normal/Result Not Available, No Referral	<p><b>4. Medical Complications of Procedure: (MARK ALL THAT APPLY)</b></p> <input type="radio"/> None (GO TO 5) <input type="radio"/> Fainting <input type="radio"/> Perforation <input type="radio"/> Bleeding <input type="radio"/> Other (SPECIFY) _____
---	---	--	---

<p><b>5. Comments:</b></p> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY)	<p><b>6. Examiner ID:</b></p> <p>Signature _____</p> <table border="1"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<p><b>7. Consultant ID:</b></p> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY)	<p>Signature _____</p> <table border="1"> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9
0	0	0	0																																																																																
1	1	1	1																																																																																
2	2	2	2																																																																																
3	3	3	3																																																																																
4	4	4	4																																																																																
5	5	5	5																																																																																
6	6	6	6																																																																																
7	7	7	7																																																																																
8	8	8	8																																																																																
9	9	9	9																																																																																
0	0	0	0																																																																																
1	1	1	1																																																																																
2	2	2	2																																																																																
3	3	3	3																																																																																
4	4	4	4																																																																																
5	5	5	5																																																																																
6	6	6	6																																																																																
7	7	7	7																																																																																
8	8	8	8																																																																																
9	9	9	9																																																																																

## PLCO Cancer Screening Trial

### SPECIFICATIONS FOR COMPLETION OF THE FLEXIBLE SIGMOIDOSCOPY SCREENING EXAMINATION FORM - VERSION 2 (FSG2)

This form is to be completed by an SC staff member and the Examiner. The SC staff member will complete the top administrative section and the Examiner will complete Parts A, B, and C of the form. A physician consultant should be called if the Examiner is unable to complete the examination and requires assistance. If a physician consultant participates in an examination, the physician's results, not the Examiner's, should be recorded on the form.

Specifications for completing each item of the form are given below:

---

#### General instructions for the completion of forms to be scanned by an Optical Mark Reader:

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

#### Administrative Section:

**Participant ID:** Affix a Participant ID label to the space provided in the upper right-hand corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Screening Center:** This item is optional. If this item is completed, enter the 2-digit SC ID and darken the circle corresponding to each number.
3. **Satellite Center:** This item is optional. If the SC has elected to track satellite center activity and the examination is taking place at a satellite center, enter the 2-digit Satellite Center ID. Darken the circle corresponding to each number. If the exami-

nation is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank.

4. **Study Year:** Darken the circle corresponding to the study year. The flexible sigmoidoscopy is performed in the T0 and T5 study years only. Darken the circle next to T0 for the baseline examination, or T5 for the follow-up examination.
5. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete this examination in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the examination was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the flexible sigmoidoscopy examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
6. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior flex. sig. terminated due to participant discomfort."*

This might be entered if, in the previous visit, the participant's flexible sigmoidoscopy examination was stopped due to pain, but s/he was willing to return to the SC to attempt the examination again. This information will alert the Examiner to the participant's physical/mental condition.

*"Participant out of time. Unable to complete flex. sig."*

This might be entered if the participant's schedule did not allow him/her to remain at the SC to complete the flexible sigmoidoscopy examination during a previous visit, and the examination was rescheduled.

7. **Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Receipted into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A - Rectal Examination Findings:**

Complete Item 1. If the result of the examination (Item C1) is "Inadequate," Item A.1 may be left blank.

- 1. Rectal Examination Findings:** The flexible sigmoidoscopy examination should begin with a rectal examination to exclude rectal lesions and to determine the path of the rectum. Darken one or more circles to indicate rectal examination findings. Descriptions of findings are given below:

Negative: The rectal examination reveals no abnormalities. (Note: If this circle is darkened, no other circle may be darkened; continue with Part B.)

External Hemorrhoids: Varicose dilatation of a vein of the inferior hemorrhoidal plexus, situated distal to the pectinate line and covered with modified anal skin.

Tenderness: Participant experiences abnormal sensitivity to physical examination of the rectum.

Masses, Polyps, or Nodules: One or more of the following is palpated in the rectum:

- Mass: An accumulation of cells or cohesive tissue.
- Polyp: A protruding growth from a mucous membrane.
- Nodule: A hard, stony area.

Blood: The participant experiences bleeding from the rectum at any time during the examination, or blood is present on the glove of the examining hand after the examination.

Stricture: A narrowing of the rectal canal due to cicatricial contraction or the deposition of abnormal tissue.

Fistula or Fissures:

- Fistula: An abnormal passage or communication between two internal organs or leading from an internal organ to the surface of the body. For example, an anal

fistula is an opening on the cutaneous surface near the anus, which may or may not communicate with the rectum.

- Fissure: A cleft or groove. For example, an anal fissure is a painful linear ulcer at the margin of the anus.

Other (SPECIFY): Describe any other findings in the space provided.

### **Part B - Flexible Sigmoidoscopy Findings:**

Complete Items 1-6. If the result of the examination (Item C.1) is "Inadequate," Part B may be left blank. The examiner should record any information that is available and leave the remaining items blank.

- 1. Number of Attempts:** This is the number of times the flexible sigmoidoscopy examination was attempted during this visit. For example, if the Examiner determined that the participant's colon was not prepared adequately for the examination, s/he might repeat the preparation and make a second attempt to perform the examination. In such a case, the circle next to "Two" should be darkened. The flexible sigmoidoscopy should not be attempted more than twice in one visit.
- 2. Reason for Repeat Exam:** Darken one or more circles to indicate the reason the flexible sigmoidoscopy was repeated during the visit.

Participant Discomfort: The participant was unable to tolerate the discomfort during the first examination and the examination was terminated prematurely.

Participant Refusal: The participant was unwilling to allow the completion of the first examination.

Equipment Malfunction: There was a problem with the flexible sigmoidoscope or the light which prevented the successful completion of the first examination.

Inadequate Preparation: The preparation of the colon (with one or more enemas) was not sufficient to clear all residual stool from the colon.

Vasovagal Response: The participant experienced a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure during the first examination.

Other (SPECIFY): Describe any other situation in which the examination was repeated during the same visit.

- 3. Depth of Sigmoidoscope Insertion:** Enter the number of centimeters the sigmoidoscope was inserted into the participant's colon (including the rectum). In cases where two attempts were made to successfully complete the examination, enter the depth for the attempt which was successful. If neither attempt was successful, enter the attempt with the greatest depth of insertion. In the rare case that a colonoscope is used instead of a flexible sigmoidoscope, the instrument should not be inserted beyond 60 cm. The use of the colonoscope should be documented in Item C.5 (Comments).

Enter whole centimeters only; do not enter fractions. Darken the circles corresponding to the numbers.

- 4. Number of Lesions Seen (INCLUDES POLYPS AND MASSES):** Darken the circle which corresponds to the number of lesions visualized. This includes polyps (protruding growths from a mucous membrane), and masses (accumulations of cells or cohesive tissue). This also includes "diminutive" polyps. If no lesions are visualized, go to Item 6.

5. **Record Information for Largest Four Lesions:** Complete the chart by darkening the circle corresponding to the correct response in each row. Enter information about the largest lesion in the column labeled "Lesion 1", the second largest lesion in the column labeled "Lesion 2", the third largest lesion in the line column labeled "Lesion 3," and the fourth largest lesion in the column labeled "Lesion 4." The following information should be recorded for each lesion:

**Type:**

Darken a circle corresponding to the type of lesion as follows:

1 = Polyp

2 = Mass

**Location:**

Mark the lesion on the diagram on the examination form, then darken a circle to indicate the location of the lesion in the colon or rectum. The diagram shows the division of the colon/rectum into the locations listed below:

1 = Rectum

2 = Sigmoid Colon

3 = Descending Colon

4 = Splenic Flexure

If a lesion extends across more than one location in the colon, enter the location which holds the greatest area of the lesion in it.

**Size:**

Largest dimension in cm: Enter the largest dimension of the lesion in centimeters. Zero fill the decimal place if there is no fraction of a centimeter (e.g. 3 cm. should be entered as "3.0"). Darken the circles corresponding to the numbers.

For example, if the lesion is 3.5 cm. in height and 1 cm. in width, enter "3.5" and darken the circles corresponding to these numbers.

If a lesion is reported as "diminutive" and an exact size is not given, if it is greater than 9.9 cm or if it is circumferential, its size should be documented as 0.0. If the lesion is greater than 9.9 cm, the exact size should be documented in Item C.5 (Comments). If the lesion is circumferential or diminutive, this should be documented in Item C.5 (Comments).

**Shape:**

1 = Sessile: The lesion is attached to normal tissue by a base, not a stalk (a stem-like connecting part).

2 = Pedunculated: The lesion has a stalk (a stemlike connecting part) by which it is attached to normal tissue.

8 = Other (SPECIFY): The lesion is neither sessile or pedunculated, or is mixed (both sessile and pedunculated). Identify the predominating shape in the space provided. If the predominating shape cannot be identified, briefly describe the shape of the lesion in the space provided.

**Biopsy Performed:**

If no biopsy was performed on this lesion, darken the circle next to "No." If a biopsy was performed on this lesion, darken the circle next to "Yes."

### **Video/Photo Documentation:**

If no video or photograph was taken of this lesion, darken the circle next to "No." If this lesion was recorded on video or photographed (with a still camera), darken the circle next to "Yes."

### **6. Other Irregular Findings: Darken one or more circles to indicate other irregular findings.**

None: There are no additional abnormalities noted during the examination. (Note: If this circle is darkened, no other circle may be darkened; continue with Part C).

Diverticulosis: The presence of colonic diverticula (acquired herniations of the mucosa of the colon through the muscular layers of the bowel wall), in the absence of inflammation.

Diverticulitis: Inflammation of colonic diverticula.

Colitis: Inflammation of the colon.

Vascular Lesions: Pathological or traumatic discontinuity of one or more blood vessels in the colon or rectum.

Ulcers: Local defects or excavations of the surface of an organ or tissue, which are produced by the sloughing of inflammatory necrotic tissue.

Melanosis Coli: A condition in which the mucous membrane of the colon is black or dark brown due to the presence of pigment-laden macrophages within the lamina propria.

Blood: The participant experiences bleeding from the colon or rectum at any time during the examination, or blood is present on the sigmoidoscope after examination.

Stricture: A narrowing of the colonic passage due to cicatricial contraction or the deposition of abnormal tissue.

Fissures: Abnormal passages communicating with the colon and the cutaneous surface of the body (external colonic fissures), or with the colon and another hollow organ (internal colonic fissures).

Internal Hemorrhoids: Varicose dilatation of a vein or the superior hemorrhoidal plexus, originating above the pectinate line, and covered by a mucous membrane.

Anal Warts: Papillomas with a central core of connective tissue in a treelike structure covered with epithelium, usually occurring on the mucous membrane or skin of the external genitals or of the perianal region.

Other (SPECIFY): Describe any other abnormalities in the space provided. Use the comments section (Item C.5), if necessary.

### **Part C - Flexible Sigmoidoscopy Examination Results:**

#### **1. Examination Results:** Darken the circle corresponding to the examination result. Definitions are as follows:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Colorectal Cancer (Referral Needed): There is visible or palpable evidence of a mucosal abnormality:

- rectal nodule(s);
- rectal and colon mass(es); and

- rectal and colon polyp(s).

A referral to the participant's physician of choice for evaluation of these results is necessary.

Negative Screen - No Abnormalities (formerly Negative): The Examiner is able to advance the scope to the full or desired length and give a description of negative findings (i.e., no abnormalities are detected).

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Colorectal Cancer): The examination reveals one of the following conditions (see definitions in B.6 above):

- External hemorrhoids;
- Rectal tenderness;
- Blood;
- Stricture;
- Fistulas;
- Fissures;
- Diverticulosis;
- Diverticulitis;
- Colitis;
- Vascular lesions;
- Ulcers;
- Melanosis coli;
- Internal hemorrhoids; and
- Anal warts.

If the Examiner feels that a referral is necessary, this information should be recorded in Item C.3 (Level of Referral).

**Inadequate:** An examination in which less than 90 percent of mucosa is visible, the flexible sigmoidoscopy is inserted to less than 50 cm. with no obstructing lesion and no abnormalities suspicious for cancer in the region visualized, or any other situation in which a result could not be determined due to insufficient information. (See definitions in Item 2 below).

If there is an abnormality that is indicative of a positive screen, and one that is not indicative of a positive screen, only "Positive Screen - Referral Required" should be marked.

**2. Reason for Inadequate Exam:** Darken one or more circles corresponding to the reason(s) for the inadequate examination. Definitions are as follows:

Participant Discomfort: The participant is unable to tolerate the discomfort of the examination and the examination is terminated prematurely, without collection of sufficient information to determine a result.

Participant Refusal: The participant is unwilling to allow the completion of the examination and a result could not be determined due to insufficient information.

Equipment Malfunction: There is a problem with the flexible sigmoidoscope or the light which prevents the successful completion of the examination. In Screening

Centers using video equipment, the examination may be inadequate due to a problem with the video equipment. In such cases, if a fiberoptic sigmoidoscope is available, it may be substituted in order to complete the exam adequately.

Inadequate Preparation with Unclear Lumen: The channel within the colon is not clear due to residual stool in the colon, even after preparation for sigmoidoscopy (with enema) and sufficient information could not be collected to determine a result.

Vasovagal Response: The participant experiences a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure, leading to the premature termination of the procedure and lack of sufficient information to determine a result.

Palpitations with Tachycardia: The participant experiences the sensation of a rapid or irregular heart beat, and the examination is terminated prematurely, without collection of sufficient information to determine a result.

Severe Diverticulosis with Unclear Lumen: The channel within the colon is not clear due to the presence of colonic diverticula (acquired herniations of the mucosa of the colon through the muscular layers of the bowel wall), in the absence of inflammation, and the examination is terminated prematurely, without collection of sufficient information to determine a result.

Severe Ulcerative Colitis: The participant has a severe, chronic, recurrent ulceration in the colon, chiefly of the mucosa and submucosa, and this condition caused the examination to be terminated prematurely, without collection of sufficient information to determine a result.

Other (SPECIFY): Describe any other situation in which a result could not be determined due to insufficient information.

**3. Level of Referral:** Darken the circle corresponding to the level of referral.

1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate" and an abnormality considered to be significant and requiring referral was found.

2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.

4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

**4. Medical Complications of Exam:** Darken one or more circles corresponding to any medical complications of the examination that the participant experiences prior to leaving the SC.

Complications are described below:

None: There were no medical complications of the examination. (Note: If this circle is darkened, no other circle may be darkened; continue with Item B.5.)

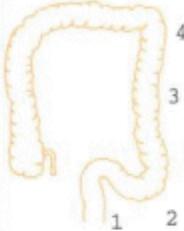
## **A-13-2**

**A-13-2: Flexible Sigmoidoscopy Screening Examination Form for Quality Assurance (FSQ2)**

**Specifications for the Flexible Sigmoidoscopy Screening Examination Form for Quality Assurance**



**PART B CONTINUED...**

DIAGRAM	5. RECORD INFORMATION FOR LARGEST FOUR LESIONS:																																																																																																																																																																																																																																																																																																																																																																												
	LESION 1	LESION 2	LESION 3	LESION 4																																																																																																																																																																																																																																																																																																																																																																									
 <p><b>LOCATION</b></p> <p>1 = Rectum 2 = Sigmoid colon 3 = Descending colon 4 = Splenic flexure</p>	<p><b>TYPE</b> 1 = Polyp 2 = Mass</p> <p>1 2</p>	<p>1 2</p>	<p>1 2</p>	<p>1 2</p>																																																																																																																																																																																																																																																																																																																																																																									
	<p><b>LOCATION</b> (RECORD A NUMBER, 1-4, FROM THE DIAGRAM)</p> <p>1 2 3 4</p>	<p>1 2 3 4</p>	<p>1 2 3 4</p>	<p>1 2 3 4</p>																																																																																																																																																																																																																																																																																																																																																																									
	<p><b>SIZE</b> (LARGEST DIMENSION IN CM)</p>	<table border="1"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	<table border="1"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	<table border="1"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	<table border="1"> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																			
	0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																			
	0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																			
	0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																			
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
0	1	2	3	4	5	6	7	8	9																																																																																																																																																																																																																																																																																																																																																																				
<p><b>SHAPE</b> 1 = Sessile 2 = Pedunculated 8 = Other (SPECIFY)</p> <p>1 2 8</p>	<p>1 2 8</p>	<p>1 2 8</p>	<p>1 2 8</p>																																																																																																																																																																																																																																																																																																																																																																										
<p><b>BIOPSY PERFORMED</b></p> <p><input type="radio"/> NO <input type="radio"/> YES</p>	<p><input type="radio"/> NO <input type="radio"/> YES</p>	<p><input type="radio"/> NO <input type="radio"/> YES</p>	<p><input type="radio"/> NO <input type="radio"/> YES</p>																																																																																																																																																																																																																																																																																																																																																																										
<p><b>VIDEO/PHOTO DOCUMENTATION</b></p> <p><input type="radio"/> NO <input type="radio"/> YES</p>	<p><input type="radio"/> NO <input type="radio"/> YES</p>	<p><input type="radio"/> NO <input type="radio"/> YES</p>	<p><input type="radio"/> NO <input type="radio"/> YES</p>																																																																																																																																																																																																																																																																																																																																																																										

**6. Other Irregular Findings: (MARK ALL THAT APPLY)**

<input type="radio"/> None (GO TO PART C)	<input type="radio"/> Vascular Lesions	<input type="radio"/> Stricture	<input type="radio"/> Anal Warts
<input type="radio"/> Diverticulosis	<input type="radio"/> Ulcers	<input type="radio"/> Fissures	<input type="radio"/> Other (SPECIFY) _____
<input type="radio"/> Diverticulitis	<input type="radio"/> Melanosis Coli	<input type="radio"/> Internal Hemorrhoids	
<input type="radio"/> Colitis	<input type="radio"/> Blood		

**PART C: EXAMINATION RESULTS**

<p><b>1. Examination Results:</b></p> <p><input type="radio"/> Positive Screen - Referral Required (GO TO 3)  <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3)  <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3)  <input type="radio"/> Inadequate (Less than 90% mucosa is visible, or insertion of flexible sigmoidoscope to less than 50 cm. with no obstructing lesions and no abnormalities suspicious for cancer in the region visualized.)</p>	<p><b>2. Reason for Inadequate Exam: (MARK ALL THAT APPLY)</b></p> <p><input type="radio"/> Participant Discomfort  <input type="radio"/> Participant Refusal  <input type="radio"/> Equipment Malfunction  <input type="radio"/> Inadequate Preparation with Unclear Lumen  <input type="radio"/> Vasovagal Response  <input type="radio"/> Palpitations With Tachycardia  <input type="radio"/> Severe Diverticulosis With Unclear Lumen  <input type="radio"/> Severe Ulcerative Colitis  <input type="radio"/> Other (SPECIFY) _____</p>	<p><b>3. Level of Referral:</b></p> <p><input type="radio"/> 1 - Significant Abnormality, Referral  <input type="radio"/> 2 - Moderate Abnormality, Referral  <input type="radio"/> 3 - Slight Variation from Normal, No Referral  <input type="radio"/> 4 - Normal/Result Not Available, No Referral</p>	<p><b>4. Medical Complications of Procedure: (MARK ALL THAT APPLY)</b></p> <p><input type="radio"/> None (GO TO 5)  <input type="radio"/> Fainting  <input type="radio"/> Perforation  <input type="radio"/> Bleeding  <input type="radio"/> Other (SPECIFY) _____</p>																																																																																																																																			
<p><b>5. Comments:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes (SPECIFY)</p> <table border="1"> <tr><th>Item #</th><th>Comments</th></tr> <tr><td> </td><td> </td></tr> </table> <p><input type="radio"/> Continued</p>	Item #	Comments																					<p><b>6. Examiner ID:</b></p> <table border="1"> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </table> <p>Signature _____</p>																																																								<p><b>7. Consultant ID:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes (SPECIFY)</p> <table border="1"> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </table> <p>Signature _____</p>																																																							
Item #	Comments																																																																																																																																					

PLCO Cancer Screening Trial

**SPECIFICATIONS FOR COMPLETION OF THE FLEXIBLE SIGMOIDOSCOPY SCREENING EXAMINATION QUALITY ASSURANCE FORM - VERSION 2 (FSQ2)**

This form is to be completed by a SC staff member and the QA Examiner for the flexible sigmoidoscopy examination. The QA Examiner is defined as the examiner who repeats or observes the flexible sigmoidoscopy examination, or reviews a videotape or photographs of the flexible sigmoidoscopy examination for QA purposes.

The SC staff member will complete the top administrative section and the QA Examiner will complete all or portions of Parts A, B, and C of the form, depending on the method of quality assurance.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the upper right-hand corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the QA examination or the date the videotape/photograph was reviewed. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digit need to be filled. Darken the circles corresponding to the month, day, and all four digits of the year.
2. **Screening Center:** This item is optional. If this item is completed, enter the 2-digit SC ID and darken the circle corresponding to each number.

3. **3.Satellite Center:** This item is optional. If the SC has elected to track satellite center activity and the QA examination is taking place at a satellite center, enter the 2-digit Satellite Center ID. Darken the circle corresponding to each number. If the QA examination is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank.
4. **4.Study Year:** Darken the circle corresponding to the study year. The flexible sigmoidoscopy is performed in the T0 and T5 study years only. Darken the circle next to T0 for the baseline examination, or T5 for the follow-up examination.
5. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete the flexible sigmoidoscopy examination, including the QA examination, in the current study year. For example, if the QA examination is completed on the participant's first visit to the SC, darken the circle next to "One." If the participant was required to return to the SC a second time to complete the QA examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year. If the QA examination does not involve a visit to the SC (as with a review of films), this item should be copied from the most recent FSG form completed for the participant.
6. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. If the repeat visit is specifically for the purpose of performing the QA examination, record "QA Examination" in the space provided. If the main purpose of the repeat visit is to complete the original flexible sigmoidoscopy examination, record the reason for the repeat visit. The purpose of this item is to provide important information to the QA Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior flex. sig. terminated due to participant discomfort."*

This might be entered if, in the previous visit, the participant's flexible sigmoidoscopy examination was stopped due to pain, but s/he was willing to return to the SC to attempt the examination again. This information will alert the Examiner to the participant's physical/mental condition.

*"Participant out of time. Unable to complete flex. sig."*

This might be entered if the participant's schedule did not allow him/her to remain at the SC to complete the flexible sigmoidoscopy examination during a previous visit, and the examination was rescheduled.

7. **Method of QA:** Darken a circle to indicate the method of quality assurance. QA for the flexible sigmoidoscopy may be done in four ways: 1) repeat examination, 2) observation of examination, 3) review of videotaped examination, and 4) review of photographs of examination. Depending on the method of QA, items on the form should be skipped as follows:

<u>Method of QA:</u>	<u>Items that should be skipped:</u>
Repeat examination	None
Direct observation of examination	A.1
Review of videotape	A.1, B.1, B.2, B.3, B.5 (Biopsy section only), C.4
Review of photographs	A.1, B.1, B.2, B.3, B.5 (Biopsy section only), C.4

8. **Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly

into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Received into SMS:** This item is optional. Darken this circle after the form has been received into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- **Final Complete (FCM):** This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC, or errors on the optional form processing items.
- **Final Incomplete (FIC):** This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

### **Part A - Rectal Examination Findings:**

This section should be completed only if the method of QA is repeat examination. For all other methods of QA, leave this section blank. If the result of the examination (Item C1) is "Inadequate," and rectal examination findings could not be determined, Item A.1 may be left blank.

1. **Rectal Examination Findings:** The flexible sigmoidoscopy examination should begin with a rectal examination to exclude rectal lesions and to determine the path of the rectum. Darken one or more circles to indicate rectal examination findings. Descriptions of findings are given below:

Negative: The rectal examination reveals no abnormalities. (Note: If this circle is darkened, no other circle may be darkened; continue with Part B.)

External Hemorrhoids: Varicose dilatation of a vein of the inferior hemorrhoidal plexus, situated distal to the pectinate line and covered with modified anal skin.

Tenderness: Participant experiences abnormal sensitivity to physical examination of the rectum.

Masses, Polyps, or Nodules: One or more of the following is palpated in the rectum:

- Mass: An accumulation of cells or cohesive tissue.
- Polyp: A protruding growth from a mucous membrane.
- Nodule: A hard, stony area.

Blood: The participant experiences bleeding from the rectum at any time during the examination, or blood is present on the glove of the examining hand after the examination.

Stricture: A narrowing of the rectal canal due to cicatricial contraction or the deposition of abnormal tissue.

Fistula or Fissures:

- Fistula: An abnormal passage or communication between two internal organs or leading from an internal organ to the surface of the body. For example, an anal fistula is an opening on the cutaneous surface near the anus, which may or may not communicate with the rectum.
- Fissure: A cleft or groove. For example, an anal fissure is a painful linear ulcer at the margin of the anus.

Other (SPECIFY): Describe any other findings in the space provided.

### **Part B - Flexible Sigmoidoscopy Findings:**

Complete all items below if the method of QA is repeat examination. For all other methods of QA, complete Items 4, 5, and 6 only. If the result of the examination (Item C.1) is "Inadequate," Part B may be left blank. The examiner should record any information that is available and leave the remaining items blank.

- 1. Number of Attempts:** This is the number of times the flexible sigmoidoscopy examination was attempted *during this visit*. For example, if the QA Examiner determined that the participant's colon was not prepared adequately for the examination, s/he might repeat the preparation and make a second attempt to perform the examination. In such a case, the circle next to "Two" should be darkened. The flexible sigmoidoscopy should not be attempted more than twice in one visit.
- 2. Reason for Repeat Exam:** Darken one or more circles to indicate the reason the flexible sigmoidoscopy was repeated during the visit.

Participant Discomfort: The participant was unable to tolerate the discomfort during the first examination and the examination was terminated prematurely.

Participant Refusal: The participant was unwilling to allow the completion of the first examination.

Equipment Malfunction: There was a problem with the flexible sigmoidoscope or the light which prevented the successful completion of the first examination.

Inadequate Preparation: The preparation of the colon (with one or more enemas) was not sufficient to clear all residual stool from the colon.

Vasovagal Response: The participant experienced a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure during the first examination.

Other (SPECIFY): Describe any other situation in which the examination was repeated during the same visit.

3. **Depth of Sigmoidoscope Insertion**: Enter the number of centimeters the sigmoidoscope was inserted into the participant's colon (including the rectum). In cases where two attempts were made to successfully complete the examination, enter the depth for the attempt which was successful. If neither attempt was successful, enter the attempt with the greatest depth of insertion. In the rare case that a colonoscope is used instead of a flexible sigmoidoscope, the instrument should not be inserted beyond 60 cm. The use of the colonoscope should be documented in Item C.5 (Comments).

Enter whole centimeters only; do not enter fractions. Darken the circles corresponding to the numbers.

4. **Number of Lesions Seen (INCLUDES POLYPS AND MASSES)**: Darken the circle which corresponds to the number of lesions visualized. This includes polyps (protruding growths from a mucous membrane), and masses (accumulations of cells or cohesive tissue). This also includes "diminutive" polyps. If no lesions are visualized, go to Item 6.
5. **Record Information for Largest Four Lesions**: Complete the chart by darkening the circle corresponding to the correct response in each row. Enter information about the largest lesion in the column labeled "Lesion 1", the second largest lesion in the column labeled "Lesion 2", the third largest lesion in the line column labeled "Lesion 3," and the fourth largest lesion in the column labeled "Lesion 4." The following information should be recorded for each lesion:

**Type:**

Darken a circle corresponding to the type of lesion as follows:

1=Polyp

2=Mass

**Location:**

Mark the lesion on the diagram on the examination form, then darken a circle to indicate the location of the lesion in the colon or rectum. The diagram shows the division of the colon/rectum into the locations listed below:

1 = Rectum

2 = Sigmoid Colon

3 = Descending Colon

4 = Splenic Flexure

If a lesion extends across more than one location in the colon, enter the location which holds the greatest area of the lesion in it.

**Size:**

Largest dimension in cm: Enter the largest dimension of the lesion in centimeters. Zero fill the decimal place if there is no fraction of a centimeter (e.g. 3 cm. should be entered as "3.0"). Darken the circles corresponding to the numbers.

For example, if the lesion is 3.5 cm. in height and 1 cm. in width, enter "3.5" and darken the circles corresponding to these numbers.

If a lesion is reported as "diminutive" and an exact size is not given, if it is greater than 9.9 cm or if it is circumferential, its size should be documented as 0.0. If the lesion is greater than 9.9 cm, the exact size should be documented in Item C.5 (Comments). If the lesion is circumferential or diminutive, this should be documented in Item C.5 (Comments).

**Shape:**

1 = Sessile: The lesion is attached to normal tissue by a base, not a stalk (a stem-like connecting part).

2 = Pedunculated: The lesion has a stalk (a stemlike connecting part) by which it is attached to normal tissue.

8 = Other (SPECIFY): The lesion is neither sessile or pedunculated, or is mixed (both sessile and pedunculated). Identify the predominating shape in the space provided. If the predominating shape cannot be identified, briefly describe the shape of the lesion in the space provided.

**Biopsy Performed:**

If the method of QA is repeat examination or observation of examination, complete this item. For all other methods of QA, leave this item blank.

If no biopsy was performed on this lesion, darken the circle next to "No." If a biopsy was performed on this lesion, darken the circle next to "Yes."

**Video/Photo Documentation:**

If the method of QA is repeat examination or observation of examination, complete this item as follows:

If no video or photograph was taken of this lesion, darken the circle next to "No." If this lesion was recorded on video or photographed (with a still camera), darken the circle next to "Yes."

If the method of QA is review of videotape or photographs, darken the circle next to "Yes."

**6. Other Irregular Findings:** Darken one or more circles to indicate other irregular findings.

None: There are no additional abnormalities noted during the examination. (Note: If this circle is darkened, no other circle may be darkened; continue with Part C).

Diverticulosis: The presence of colonic diverticula (acquired herniations of the mucosa of the colon through the muscular layers of the bowel wall), in the absence of inflammation.

Diverticulitis: Inflammation of colonic diverticula.

Colitis: Inflammation of the colon.

Vascular Lesions: Pathological or traumatic discontinuity of one or more blood vessels in the colon or rectum.

Ulcers: Local defects or excavations of the surface of an organ or tissue, which are produced by the sloughing of inflammatory necrotic tissue.

Melanosis Coli: A condition in which the mucous membrane of the colon is black or dark brown due to the presence of pigment-laden macrophages within the lamina propria.

Blood: The participant experiences bleeding from the colon or rectum at any time during the examination, or blood is present on the sigmoidoscope after examination.

Stricture: A narrowing of the colonic passage due to cicatricial contraction or the deposition of abnormal tissue.

Fissures: Abnormal passages communicating with the colon and the cutaneous surface of the body (external colonic fissures), or with the colon and another hollow organ (internal colonic fissures).

Internal Hemorrhoids: Varicose dilatation of a vein or the superior hemorrhoidal plexus, originating above the pectinate line, and covered by a mucous membrane.

Anal Warts: Papillomas with a central core of connective tissue in a treelike structure covered with epithelium, usually occurring on the mucous membrane or skin of the external genitals or of the perianal region. Note: This may not be able to be determined from a videotape or photograph of the examination.

Other (SPECIFY): Describe any other abnormalities in the space provided. Use the comments section (Item C.5), if necessary.

### **Part C - Flexible Sigmoidoscopy Examination Results:**

Complete all items below if the method of QA is repeat examination or direct observation of examination. For all other methods of QA, complete Items 1, 2, 4, 5, and 6 only.

- 1. Examination Results:** Darken the circle corresponding to the examination result. Definitions are as follows:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Colorectal Cancer (Referral Needed): There is visible or palpable evidence of a mucosal abnormality:

- rectal nodule(s);
- rectal and colon mass(es); and
- rectal and colon polyp(s).

A referral to the participant's physician of choice for evaluation of these results is necessary.

Negative Screen - No Abnormalities (formerly Negative): The QA Examiner is able to advance the scope to the full or desired length and give a description of negative findings (i.e., no abnormalities are detected).

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Colorectal Cancer): The examination reveals one of the following conditions (see definitions in B.6 above):

- External hemorrhoids;
- Rectal tenderness;
- Blood;
- Stricture;
- Fistulas;

- Fissures;
- Diverticulosis;
- Diverticulitis;
- Colitis;
- Vascular lesions;
- Ulcers;
- Melanosis coli;
- Internal hemorrhoids; and
- Anal warts.

If the QA Examiner feels that a referral is necessary, this information should be recorded in Item C.3 (Level of Referral).

Inadequate: An examination in which less than 90 percent of mucosa is visible, the flexible sigmoidoscopy is inserted to less than 50 cm. with no obstructing lesion and no abnormalities suspicious for cancer in the region visualized, or any other situation in which a result could not be determined due to insufficient information. (See definitions in Item 2 below). A QA examination that is inadequate will not count toward the total number of QA examinations performed.

If there is an abnormality that is indicative of a positive screen, and one that is not indicative of a positive screen, only "Positive Screen - Referral Required" should be marked.

2. **Reason for Inadequate Exam:** Darken one or more circles corresponding to the reason(s) for the inadequate examination. If the method of QA is a review of a videotape or photographs, it is likely that the reason(s) noted will be among the starred responses only. Definitions are as follows:

Participant Discomfort: The participant is unable to tolerate the discomfort of the examination and the examination is terminated prematurely, without collection of sufficient information to determine a result.

Participant Refusal: The participant is unwilling to allow the completion of the examination and a result could not be determined due to insufficient information.

Equipment Malfunction: There is a problem with the flexible sigmoidoscope or the light which prevents the successful completion of the examination. In Screening Centers using video equipment, the examination may be inadequate due to a problem with the video equipment. In such cases, if a fiberoptic sigmoidoscope is available, it may be substituted in order to complete the exam adequately.

\*Inadequate Preparation with Unclear Lumen: The channel within the colon is not clear due to residual stool in the colon, even after preparation for sigmoidoscopy (with enema) and sufficient information could not be collected to determine a result.

Vasovagal Response: The participant experiences a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure, leading to the premature termination of the procedure and lack of sufficient information to determine a result.

Palpitations with Tachycardia: The participant experiences the sensation of a rapid or irregular heart beat, and the examination is terminated prematurely, without collection of sufficient information to determine a result.

\*Severe Diverticulosis with Unclear Lumen: The channel within the colon is not clear due to the presence of colonic diverticula (acquired herniations of the mucosa of the colon through the muscular layers of the bowel wall), in the absence of inflammation, and the examination is terminated prematurely, without collection of sufficient information to determine a result.

\*Severe Ulcerative Colitis: The participant has a severe, chronic, recurrent ulceration in the colon, chiefly of the mucosa and submucosa, and this condition caused the examination to be terminated prematurely, without collection of sufficient information to determine a result.

\*Other (SPECIFY): Describe any other situation in which a result could not be determined due to insufficient information.

**3. Level of Referral:** Darken the circle corresponding to the level of referral.

1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate", and an abnormality considered to be significant and requiring referral was found.

2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.

4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

**4. Medical Complications of Exam:** Darken one or more circles corresponding to any medical complications of the examination that the participant experiences prior to leaving the SC.

Complications are described below:

None: There were no medical complications of the examination. (Note: If this circle is darkened, no other circle may be darkened; continue with Item B.5.)

Fainting: The participant experienced a temporary loss of consciousness. Feeling faint or dizzy is not considered fainting.

Perforation: The participant's bowel was perforated (a hole was made in the bowel). This applies to microperforations as well as perforations requiring surgical repair.

Bleeding: The participant experienced bleeding from the rectum after the examination.

Other (SPECIFY): Describe any other medical complications in the space provided.

Note: An Adverse Experience Report (AER) should be completed if the participant experiences a medical complication before arriving at or after leaving the SC or if s/he receives medical care for a complication experienced during the screening visit.

**5. Comments:** The comments section may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "continued" and record additional comments on a Comments Continuation Form (CCF).

**6. Examiner ID:** (This item should be completed by the QA Examiner.)

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

**7. Consultant ID:** (This item should be completed by any physician with whom the QA Examiner consults regarding the QA Examination.)

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

## **A-14-1**

### **A-14-1: Ovarian Palpation Screening Examination Form (OVR)**

**Specifications for the Ovarian Palpation Screening  
Examination Form**

## **A-14-2**

**A-14-2: Ovarian Palpation Screening Examination  
Form for Quality Assurance (OVQ)**

**Specifications for the Ovarian Palpation Screening  
Examination Form for Quality Assurance**

## **A-15-1**

**A-15-1: Transvaginal Ultrasound Screening Examination Form (TVU2)**

**Specifications for the Transvaginal Ultrasound Screening Examination Form**

Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

TRANSVAGINAL ULTRASOUND SCREENING EXAMINATION (TVU2)

<b>1. Date of Examination:</b> MO. DAY YR. 0 0 0 0 0 0 0 1 1 1 1 1 1 1 2 2 2 2 2 2 2 3 3 3 3 3 3 3 4 4 4 4 4 4 4 5 5 5 5 5 5 5 6 6 6 6 6 6 6 7 7 7 7 7 7 7 8 8 8 8 8 8 8 9 9 9 9 9 9 9			<b>2. Satellite Center:</b> 0 0 1 1 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9		<b>3. Study Year:</b> <input type="radio"/> T <sub>0</sub> <input type="radio"/> T <sub>1</sub> <input type="radio"/> T <sub>2</sub> <input type="radio"/> T <sub>3</sub>		<b>4. Visit Number:</b> <input type="radio"/> One <input type="radio"/> Two <input type="radio"/> Three		<b>5. Reason for Repeat Visit:</b> _____ _____ _____ _____ _____	
---	--	--	---	--	---	--	--	--	---	--

DO NOT FOLD, STAPLE, OR TEAR THIS FORM. USE A NO. 2 PENCIL TO COMPLETE THIS FORM.

PART A: TRANSVAGINAL ULTRASOUND EXAMINATION FINDINGS

QUESTION	RIGHT	LEFT																																																																																								
1. Sonographically Detectable Ovary	<input type="radio"/> No (GO TO 3) <input type="radio"/> Yes	<input type="radio"/> No (GO TO 3) <input type="radio"/> Yes																																																																																								
2. Ovary Size (CALCULATE VOLUME: WIDTH X HEIGHT X THICKNESS X 0.523)	<table border="1"> <tr> <th>Longitudinal diameter (cm)</th> <th>Transverse diameter (cm)</th> <th>Antero-posterior diameter (cm)</th> <th>Volume (cc)</th> </tr> <tr> <td>0 0 0</td> <td>0 0 0</td> <td>0 0 0</td> <td>0 0 0 0 0</td> </tr> <tr> <td>1 1 1</td> <td>1 1 1</td> <td>1 1 1</td> <td>1 1 1 1 1</td> </tr> <tr> <td>2 2 2</td> <td>2 2 2</td> <td>2 2 2</td> <td>2 2 2 2 2</td> </tr> <tr> <td>3 3</td> <td>3 3</td> <td>3 3</td> <td>3 3 3 3 3</td> </tr> <tr> <td>4 4</td> <td>4 4</td> <td>4 4</td> <td>4 4 4 4 4</td> </tr> <tr> <td>5 5</td> <td>5 5</td> <td>5 5</td> <td>5 5 5 5 5</td> </tr> <tr> <td>6 6</td> <td>6 6</td> <td>6 6</td> <td>6 6 6 6 6</td> </tr> <tr> <td>7 7</td> <td>7 7</td> <td>7 7</td> <td>7 7 7 7 7</td> </tr> <tr> <td>8 8</td> <td>8 8</td> <td>8 8</td> <td>8 8 8 8 8</td> </tr> <tr> <td>9 9</td> <td>9 9</td> <td>9 9</td> <td>9 9 9 9 9</td> </tr> </table>	Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)	0 0 0	0 0 0	0 0 0	0 0 0 0 0	1 1 1	1 1 1	1 1 1	1 1 1 1 1	2 2 2	2 2 2	2 2 2	2 2 2 2 2	3 3	3 3	3 3	3 3 3 3 3	4 4	4 4	4 4	4 4 4 4 4	5 5	5 5	5 5	5 5 5 5 5	6 6	6 6	6 6	6 6 6 6 6	7 7	7 7	7 7	7 7 7 7 7	8 8	8 8	8 8	8 8 8 8 8	9 9	9 9	9 9	9 9 9 9 9	<table border="1"> <tr> <th>Longitudinal diameter (cm)</th> <th>Transverse diameter (cm)</th> <th>Antero-posterior diameter (cm)</th> <th>Volume (cc)</th> </tr> <tr> <td>0 0 0</td> <td>0 0 0</td> <td>0 0 0</td> <td>0 0 0 0 0</td> </tr> <tr> <td>1 1 1</td> <td>1 1 1</td> <td>1 1 1</td> <td>1 1 1 1 1</td> </tr> <tr> <td>2 2 2</td> <td>2 2 2</td> <td>5 2 2</td> <td>2 2 2 2 2</td> </tr> <tr> <td>3 3</td> <td>3 3</td> <td>3 3</td> <td>3 3 3 3 3</td> </tr> <tr> <td>4 4</td> <td>4 4</td> <td>4 4</td> <td>4 4 4 4 4</td> </tr> <tr> <td>5 5</td> <td>5 5</td> <td>5 5</td> <td>5 5 5 5 5</td> </tr> <tr> <td>6 6</td> <td>6 6</td> <td>6 6</td> <td>6 6 6 6 6</td> </tr> <tr> <td>7 7</td> <td>7 7</td> <td>7 7</td> <td>7 7 7 7 7</td> </tr> <tr> <td>8 8</td> <td>8 8</td> <td>8 8</td> <td>8 8 8 8 8</td> </tr> <tr> <td>9 9</td> <td>9 9</td> <td>9 9</td> <td>9 9 9 9 9</td> </tr> </table>	Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)	0 0 0	0 0 0	0 0 0	0 0 0 0 0	1 1 1	1 1 1	1 1 1	1 1 1 1 1	2 2 2	2 2 2	5 2 2	2 2 2 2 2	3 3	3 3	3 3	3 3 3 3 3	4 4	4 4	4 4	4 4 4 4 4	5 5	5 5	5 5	5 5 5 5 5	6 6	6 6	6 6	6 6 6 6 6	7 7	7 7	7 7	7 7 7 7 7	8 8	8 8	8 8	8 8 8 8 8	9 9	9 9	9 9	9 9 9 9 9
Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)																																																																																							
0 0 0	0 0 0	0 0 0	0 0 0 0 0																																																																																							
1 1 1	1 1 1	1 1 1	1 1 1 1 1																																																																																							
2 2 2	2 2 2	2 2 2	2 2 2 2 2																																																																																							
3 3	3 3	3 3	3 3 3 3 3																																																																																							
4 4	4 4	4 4	4 4 4 4 4																																																																																							
5 5	5 5	5 5	5 5 5 5 5																																																																																							
6 6	6 6	6 6	6 6 6 6 6																																																																																							
7 7	7 7	7 7	7 7 7 7 7																																																																																							
8 8	8 8	8 8	8 8 8 8 8																																																																																							
9 9	9 9	9 9	9 9 9 9 9																																																																																							
Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)																																																																																							
0 0 0	0 0 0	0 0 0	0 0 0 0 0																																																																																							
1 1 1	1 1 1	1 1 1	1 1 1 1 1																																																																																							
2 2 2	2 2 2	5 2 2	2 2 2 2 2																																																																																							
3 3	3 3	3 3	3 3 3 3 3																																																																																							
4 4	4 4	4 4	4 4 4 4 4																																																																																							
5 5	5 5	5 5	5 5 5 5 5																																																																																							
6 6	6 6	6 6	6 6 6 6 6																																																																																							
7 7	7 7	7 7	7 7 7 7 7																																																																																							
8 8	8 8	8 8	8 8 8 8 8																																																																																							
9 9	9 9	9 9	9 9 9 9 9																																																																																							
3. Number of Morphologic Abnormalities in Adnexal Area	<input type="radio"/> None (GO TO LEFT) <input type="radio"/> One <input type="radio"/> Two <input type="radio"/> Three or more	<input type="radio"/> None (GO TO 5) <input type="radio"/> One <input type="radio"/> Two <input type="radio"/> Three or more																																																																																								

4. Complete for Three Largest Discrete Cysts or Abnormalities :

	#1	#2	#3	#1	#2	#3
A. Maximum Diameter of Cyst or Abnormality (in cm.)	0 0 0 1 1 1 2 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9	0 0 0 1 1 1 2 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9	0 0 0 1 1 1 2 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9	0 0 0 1 1 1 2 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9	0 0 0 1 1 1 2 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9	0 0 0 1 1 1 2 2 2 3 3 4 4 5 5 6 6 7 7 8 8 9 9

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20832-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

PLEASE DO NOT WRITE IN THIS AREA

157176



**PLCO Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE TRANSVAGINAL ULTRASOUND SCREENING  
EXAMINATION FORM (TVU2)**

This form is to be completed by an SC staff member and the Examiner. The SC staff member will complete the top administrative section and the Examiner will complete Parts A and B of the form. A consultant should be called if the Examiner is unable to complete the examination and requires assistance. If a consultant participates in an examination, the consultant's results, not the Examiner's should be recorded on the form.

Specifications for completing each item of the form are given below:

---

**General instructions for the completion of forms to be scanned by an Optical Mark Reader:**

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

---

**Administrative Section:**

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Satellite Center:** This field is optional. If the SC has elected to track satellite center activity and the examination is taking place at a satellite center, enter the 2-digit Satellite Center ID. If the examination is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank. Darken the circle corresponding to each number.
3. **Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2, or T3 for the follow-up examinations.

4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete this examination in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the examination was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the transvaginal ultrasound examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. Refer to the Participant Control Record from the previous visit for this information. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior TVU terminated due to participant discomfort."*

This might be entered if the participant's previous transvaginal ultrasound examination was stopped due to discomfort, but she was willing to return to the SC to attempt the examination again. This information will alert the Examiner to the participant's physical condition.

*"Prior TVU terminated due to participant refusal."*

This might be entered if the participant previously refused the transvaginal ultrasound examination, but was willing to return to the SC to attempt the examination again.

#### **Part A: Transvaginal Ultrasound Findings:**

Complete Items 1 through 4 for both the right and left adnexal areas. Record information first for the right adnexal area then for the left adnexal area. If the result of the examination (Item B.1) is "Inadequate", Part A may be left blank. The examiner should record any information that is available and leave the remaining items blank.

1. **Sonographically Detectable Ovary:** If the ovary is detected via the transvaginal ultrasound, darken the circle for "Yes." If the ovary is not detected, darken the circle for "No."
2. **Ovary Size:** Measure the longitudinal diameter, the transverse diameter, and the anteroposterior diameter, in centimeters, for each ovary. Record the measurements and darken the circle corresponding to each number. Zero fill, including the decimal place if there is no fraction of a centimeter. (For example, 3 cm should be recorded as 03.0 cm.) Calculate and record the volume (in cubic centimeters) using the formula below, then darken the circle corresponding to each number.

Volume = width (transverse) x height (longitudinal) x thickness (anteroposterior) x 0.523

Note: When a measurement value includes a fraction, apply the following rules for rounding (Refer to the General Abstracting Techniques):

If the fraction is equal to .05 or more, round up. For example, 4.184 = 4.2

If the fraction is less than .05 round down. For example, 1.724 = 1.7

3. **Number of Morphologic Abnormalities in Adnexal Area:** Darken the circle corresponding to the number of morphologic abnormalities (regardless of size) visualized in each adnexal area. If an abnormality is detected in the adnexal area that is

clearly not related to the ovary (e.g., hydrosalpinx), do not record it in this item. It may be recorded in Item A.5 (Other Abnormalities).

If a large mass is detected but there is not enough definition on the image to determine whether it is one abnormality or several, it should be counted as one abnormality and described in the table in Item 4 as one abnormality.

If no abnormalities are found, darken the circle for "None" and complete the section for the left adnexal area.

4. **Complete for Three Largest Discrete Cysts or Abnormalities:** Complete 4A through 4G for each of the three largest cysts or abnormalities detected in both the right and left adnexal areas. As noted in Item 3 above, do not complete for abnormalities that are clearly not ovarian in nature. Complete the chart by darkening the circle corresponding to the correct response in each column.

**A. Maximum Diameter of Cyst or Abnormality:** Record the maximum diameter in centimeters. Zero fill the decimal place if there is no fraction of a centimeter. (For example, 5 cm. should be recorded as 05.0 cm.) Darken the circles corresponding to the numbers. (See Item A.2 for rounding rules or refer to General Abstracting Techniques.)

**B. Volume of Cyst or Abnormality:** Calculate and record the volume of the cyst or abnormality using the formula below, then darken the circle corresponding to each number.

$$\text{Volume} = (\text{maximum diameter})^3 \times 0.523$$

Zero-fill, including the decimal place if there is no fraction of a cubic centimeter (for example, 5 cc should be recorded as 0005.0 cc, since the field is a 5-digit field). (See Item A.2 for rounding rules, or refer to the General Abstracting Techniques.)

If the volume of the cyst or abnormality is greater than 4999.9, record "4999.9" and record the actual volume in comments.

If the volume of the cyst or abnormality is less than 0.0, record "0000.0" and record the actual volume in comments.

**C. Solid Area:**

0 = None: The cyst or abnormality is visualized with no solid areas.

1 = Mixed: The cyst or abnormality is visualized with some solid areas and some sonolucent areas.

2 = All solid: The cyst or abnormality is visualized as all solid. If the cyst or abnormality is all solid, darken the corresponding circle and go to 4G.

**D. Septal Structure:**

0 = No septae: No dividing wall or partition is visualized in the cyst or abnormality.

1 = Yes, thin (≤3 mm): A thin (≤3 mm) dividing wall or partition is visualized in the cyst or abnormality.

2 = Yes, thick (>3 mm): A thick (>3 mm) dividing wall or partition is visualized in the cyst or abnormality.

**E. Cyst Outline:**

1 = Smooth: The cyst or abnormality is visualized with a smooth outline.

- 2 = Irregularities: The cyst or abnormality is visualized with an irregular outline (irregular projections or bumpiness of  $\geq 3$  mm)
- 3 = Papillarities: The outline of the cyst or abnormality is visualized with small nipple shaped or finger-like projections or elevations ( $> 3$  mm).

**F. Cyst Wall Thickness:**

- 1 = Thin ( $\leq 3$  mm): The cyst or abnormality is visualized with a thin wall ( $\leq 3$  mm).
- 2 = Thick ( $> 3$  mm): The cyst or abnormality is visualized with a thick wall ( $> 3$  mm).

**G. Echogenicity:**

- 1 = Sonolucent: Ultrasound waves are passed without reflection.
- 2 = Low: A low level of reflection (echoes) of ultrasound waves.
- 3 = Low with an echogenic core: A low level of reflection (echoes) of ultrasound waves with central area of higher reflection.
- 4 = Mixed: High and low levels of reflection (echoes) of ultrasound waves.
- 5 = High: A high level of reflection (echoes) of ultrasound waves.

5. **Other Abnormalities Noted:** Use this area to record any non-ovarian abnormalities (e.g., thickening of endometrium) noted incidentally during the examination. If there are other abnormalities, darken the circle for "Yes" and describe the abnormalit(ies) in the space provided. If there are no other abnormalities, darken the circle for "No."

**Part B: Examination Results:**

In some SCs, a second Examiner, such as a radiologist or another sonographer will interpret the TVU films, so Part B will be completed by this second Examiner.

1. **Examination Results:** Darken the circle corresponding to the examination result. Definitions are as follows:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Cancer): An examination with one or more of the following features:

- Any ovary or cyst greater than 10 cubic centimeters in volume;
- Any solid area or papillary projection extending into the cavity of a cystic ovarian tumor of any size;
- Any mixed (solid/cystic) component within a cystic ovarian tumor.

A referral to the participant's physician of choice for evaluation of any of the above results is necessary.

Negative Screen - No Abnormalities (formerly Negative): An examination in which no abnormalities of any kind are found (regardless of whether or not the ovaries are visualized).

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Cancer): An examination which reveals one or more abnormalities that do not satisfy the criteria for a positive screening examination.

Inadequate: An examination which could not be adequately completed due to one of the reasons outlined in B.2 below.

2. **Reason for Inadequate Examination:** Darken one or more of the circles corresponding to the reason(s) for the inadequate examination. Definitions are as follows:

Participant Discomfort: The participant is unable to tolerate the discomfort of the examination and the examination is terminated prematurely, without collection of sufficient information to determine a result of positive or negative.

Participant Refusal: The participant is unwilling to allow the completion of the examination and a result of positive or negative could not be determined due to insufficient information.

Equipment Malfunction: There is a problem with the transvaginal ultrasound equipment which prevents the successful completion of the examination.

Inability to Insert Probe: The ultrasonographer is unable to insert the probe for the transvaginal ultrasound procedure and sufficient information could not be collected to determine a result of positive or negative.

Bowel Interference: Visualization of the bowel interfered with the Examiner's ability to visualize the adnexal area, and to collect sufficient information to determine a result of positive or negative.

Other (SPECIFY): Describe any other situation in which a result of positive or negative could not be determined due to insufficient information.

**Note:** If sufficient information can be gathered to determine a positive screen despite one or more of the above reasons for inadequate exam, then the examination results should be recorded as "Positive." For example, if an adnexal abnormality is noted that is sufficient to be considered positive, but the examiner is unable to obtain measurements on all three planes and therefore unable to calculate ovarian volume, then the final result of "Positive" should take precedent over an inadequate exam.

3. **Level of Referral:** Darken the circle corresponding to the level of referral.

1 - **Significant Abnormality, Referral:** The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be significant and requiring referral was found.

2 - **Moderate Abnormality, Referral:** The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3 - **Slight Variation from Normal, No Referral:** The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal not requiring referral was found.

4 - **Normal/Result Not Available, No Referral:** The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

4. **Photo Documentation:** A photograph or thermal printout must be obtained for documentation and retention as part of the permanent record. A photo document should be obtained regardless of whether or not the ovaries were visualized. The photo document must be of material that will allow for long term storage (at least 20 years). Darken the corresponding circle to indicate whether photo documentation is obtained.

If the result of the examination is "Inadequate" (especially if the participant refuses the exam or the examiner is unable to insert the probe), the examiner may not be able to obtain photo documentation. In such cases, darken the circle next to "No."

- 5. Medical Complications of Exam:** If there were no medical complications of the examination that the participant experienced prior to leaving the SC, darken the circle next to "No." If the participant experienced a medical complication prior to leaving the SC, darken the circle next to "Yes" and briefly describe the complication in the space provided.

**Note:** An Adverse Experience Report (AER) should be completed if the participant experiences a medical complication before arriving at or after leaving the SC or if she receives medical care for a complication experienced during the screening visit.

- 6. Comments:** The comments box may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed. If a large mass was detected but the Examiner could not determine whether it was one abnormality or several, record the following statement: "large mass-resolution not sufficient to rule out multiple abnormalities."

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item on the form, use the item number for the comments section itself (B.6). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

- 7. Examiner ID:** (This item should be completed by the Examiner, even if another examiner was consulted during the examination.)

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

- 8. Consultant ID:** (This item should be completed by the physician consultant or by a radiologist or other sonographer who interprets the transvaginal ultrasound. If a physician was not consulted during the examination, the Examiner should darken the circle next to "No," and the signature should be left blank. Note that this item should not be completed for QA Examiners; QA Examiners must complete a separate exam form for QA.)

If a consultant was used, the consultant should darken the circle next to "Yes," and sign the form in the space provided. S/he should enter his/her 4-digit staff ID number and darken the circles corresponding to the four digits.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Received into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-15-2**

**A-15-2: Transvaginal Ultrasound Screening Examination Form for Quality Assurance (TVQ2)**

**Specifications for the Transvaginal Ultrasound Screening Examination Form for Quality Assurance**

# Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

## TRANSVAGINAL ULTRASOUND SCREENING EXAMINATION QUALITY ASSURANCE (TVQ2)

<b>1. Date of Examination:</b> <table border="1" style="width: 100%; text-align: center;"> <tr> <th colspan="2">MO.</th> <th colspan="2">DAY</th> <th colspan="2">YR.</th> </tr> <tr> <td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td> </tr> <tr> <td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td> </tr> <tr> <td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td> </tr> <tr> <td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td> </tr> <tr> <td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td> </tr> <tr> <td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td> </tr> <tr> <td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td> </tr> <tr> <td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td> </tr> <tr> <td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td> </tr> <tr> <td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td> </tr> </table>	MO.		DAY		YR.		0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	8	8	8	8	8	8	9	9	9	9	9	9	<b>2. Satellite Center:</b> <table border="1" style="width: 100%; text-align: center;"> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td></tr> </table>	0	0	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	<b>3. Study Year:</b> <input type="radio"/> T <sub>0</sub> <input type="radio"/> T <sub>1</sub> <input type="radio"/> T <sub>2</sub> <input type="radio"/> T <sub>3</sub>	<b>4. Visit Number:</b> <input type="radio"/> One <input type="radio"/> Two <input type="radio"/> Three	<b>5. Reason for Repeat Visit:</b> <hr/> <hr/> <hr/>
MO.		DAY		YR.																																																																																						
0	0	0	0	0	0																																																																																					
1	1	1	1	1	1																																																																																					
2	2	2	2	2	2																																																																																					
3	3	3	3	3	3																																																																																					
4	4	4	4	4	4																																																																																					
5	5	5	5	5	5																																																																																					
6	6	6	6	6	6																																																																																					
7	7	7	7	7	7																																																																																					
8	8	8	8	8	8																																																																																					
9	9	9	9	9	9																																																																																					
0	0																																																																																									
1	1																																																																																									
2	2																																																																																									
3	3																																																																																									
4	4																																																																																									
5	5																																																																																									
6	6																																																																																									
7	7																																																																																									
8	8																																																																																									
9	9																																																																																									
<b>6. Method of QA:</b> <input type="radio"/> Repeat Examination - Complete all items <input type="radio"/> Observation of Examination - Complete all items <input type="radio"/> Review of films - Skip Item B.5					DO NOT FOLD, STAPLE, OR TEAR THIS FORM. USE A NO. 2 PENCIL TO COMPLETE THIS FORM.																																																																																					

### PART A: TRANSVAGINAL ULTRASOUND EXAMINATION FINDINGS

QUESTION	RIGHT	LEFT																																																																																								
<b>1. Sonographically Detectable Ovary</b>	<input type="radio"/> No (GO TO 3) <input type="radio"/> Yes	<input type="radio"/> No (GO TO 3) <input type="radio"/> Yes																																																																																								
<b>2. Ovary Size (CALCULATE VOLUME: WIDTH X HEIGHT X THICKNESS X 0.523)</b>	<table border="1" style="width: 100%; text-align: center;"> <tr> <th>Longitudinal diameter (cm)</th> <th>Transverse diameter (cm)</th> <th>Antero-posterior diameter (cm)</th> <th>Volume (cc)</th> </tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	<table border="1" style="width: 100%; text-align: center;"> <tr> <th>Longitudinal diameter (cm)</th> <th>Transverse diameter (cm)</th> <th>Antero-posterior diameter (cm)</th> <th>Volume (cc)</th> </tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>	Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)	0	0	0	0	1	1	1	1	2	2	2	2	3	3	3	3	4	4	4	4	5	5	5	5	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9
	Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)																																																																																						
0	0	0	0																																																																																							
1	1	1	1																																																																																							
2	2	2	2																																																																																							
3	3	3	3																																																																																							
4	4	4	4																																																																																							
5	5	5	5																																																																																							
6	6	6	6																																																																																							
7	7	7	7																																																																																							
8	8	8	8																																																																																							
9	9	9	9																																																																																							
Longitudinal diameter (cm)	Transverse diameter (cm)	Antero-posterior diameter (cm)	Volume (cc)																																																																																							
0	0	0	0																																																																																							
1	1	1	1																																																																																							
2	2	2	2																																																																																							
3	3	3	3																																																																																							
4	4	4	4																																																																																							
5	5	5	5																																																																																							
6	6	6	6																																																																																							
7	7	7	7																																																																																							
8	8	8	8																																																																																							
9	9	9	9																																																																																							
<b>3. Number of Morphologic Abnormalities in Adnexal Area</b>	<input type="radio"/> None (GO TO LEFT) <input type="radio"/> Two <input type="radio"/> One <input type="radio"/> Three or more	<input type="radio"/> None (GO TO 5) <input type="radio"/> Two <input type="radio"/> One <input type="radio"/> Three or more																																																																																								
<b>4. Complete for Three Largest Discrete Cysts or Abnormalities :</b>	<table border="1" style="width: 100%; text-align: center;"> <tr> <th>#1</th> <th>#2</th> <th>#3</th> <th>#1</th> <th>#2</th> <th>#3</th> </tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>		#1	#2	#3	#1	#2	#3	0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	8	8	8	8	8	8	9	9	9	9	9	9																						
#1	#2	#3	#1	#2	#3																																																																																					
0	0	0	0	0	0																																																																																					
1	1	1	1	1	1																																																																																					
2	2	2	2	2	2																																																																																					
3	3	3	3	3	3																																																																																					
4	4	4	4	4	4																																																																																					
5	5	5	5	5	5																																																																																					
6	6	6	6	6	6																																																																																					
7	7	7	7	7	7																																																																																					
8	8	8	8	8	8																																																																																					
9	9	9	9	9	9																																																																																					
<b>A. Maximum Diameter of Cyst or Abnormality (in cm.)</b>	<table border="1" style="width: 100%; text-align: center;"> <tr> <th>#1</th> <th>#2</th> <th>#3</th> <th>#1</th> <th>#2</th> <th>#3</th> </tr> <tr><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr> <tr><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td><td>2</td></tr> <tr><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr> <tr><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td><td>4</td></tr> <tr><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td><td>5</td></tr> <tr><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr> <tr><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td><td>7</td></tr> <tr><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td><td>8</td></tr> <tr><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td><td>9</td></tr> </table>		#1	#2	#3	#1	#2	#3	0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	4	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	8	8	8	8	8	8	9	9	9	9	9	9																						
#1	#2	#3	#1	#2	#3																																																																																					
0	0	0	0	0	0																																																																																					
1	1	1	1	1	1																																																																																					
2	2	2	2	2	2																																																																																					
3	3	3	3	3	3																																																																																					
4	4	4	4	4	4																																																																																					
5	5	5	5	5	5																																																																																					
6	6	6	6	6	6																																																																																					
7	7	7	7	7	7																																																																																					
8	8	8	8	8	8																																																																																					
9	9	9	9	9	9																																																																																					

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0407). Do not return the completed form to this address.

PLEASE DO NOT WRITE IN THIS AREA

017335

QUESTION	RIGHT									LEFT								
	#1			#2			#3			#1			#2			#3		
	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2
<b>B. Volume of Cyst or Abnormality (in cc.)</b>  CALCULATE VOLUME:  $[MAXIMUM DIAMETER]^3 \times 0.523$	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9

<b>C. Solid Area</b> 0 = None      2 = All solid (GO TO 4G) 1 = Mixed	0 1 2	0 1 2	0 1 2	0 1 2	0 1 2	0 1 2
<b>D. Septal Structure</b> 0 = No septae      2 = Yes, thick (>3 mm) 1 = Yes, thin (≤3mm)	0 1 2	0 1 2	0 1 2	0 1 2	0 1 2	0 1 2
<b>E. Cyst Outline</b> 1 = Smooth      3 = Papillarities 2 = Irregularities	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
<b>F. Cyst Wall Thickness</b> 1 = Thin (≤3mm)      2 = Thick (>3mm)	1 2	1 2	1 2	1 2	1 2	1 2
<b>G. Echogenicity</b> 1 = Sonolucent      4 = Mixed 2 = Low      5 = High 3 = Low with echogenic core	1 2 3 4 5					

5. Other Abnormalities Noted:  No  Yes (SPECIFY) \_\_\_\_\_

**PART B: EXAMINATION RESULTS**

<b>1. Examination Result:</b> <input type="radio"/> Positive Screen - Referral Required (GO TO 3) <input type="radio"/> Negative Screen - No Abnormalities (GO TO 3) <input type="radio"/> Negative Screen - Other Abnormalities (GO TO 3) <input type="radio"/> Inadequate	<b>2. Reason for Inadequate Exam: (MARK ALL THAT APPLY)</b> <input type="radio"/> Participant Discomfort <input type="radio"/> Participant Refusal <input type="radio"/> Equipment Malfunction <input type="radio"/> Inability to Insert Probe <input type="radio"/> Bowel Interference <input type="radio"/> Other (SPECIFY) _____	<b>3. Level of Referral:</b> <input type="radio"/> 1 - Significant Abnormality, Referral <input type="radio"/> 2 - Moderate Abnormality, Referral <input type="radio"/> 3 - Slight Variation from Normal, No Referral <input type="radio"/> 4 - Normal/Result Not Available, No Referral	<b>4. Photo Documentation:</b> <input type="radio"/> No <input type="radio"/> Yes
---	---	--	---

<b>5. Medical Complications of Examination:</b> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY)	<b>6. Comments:</b> <input type="radio"/> No <input type="radio"/> Yes (SPECIFY)	<b>7. Examiner ID:</b>	<b>8. Consultant ID:</b>																				
<input type="radio"/> No <input type="radio"/> Yes (SPECIFY)	<table border="1"> <thead> <tr> <th>Item #</th> <th>Comments</th> </tr> </thead> <tbody> <tr><td> </td><td> </td></tr> </tbody> </table>	Item #	Comments																			Signature _____	<input type="radio"/> No <input type="radio"/> Yes (SPECIFY)  Signature _____
Item #	Comments																						

**For Office Use Only**

<b>Forms Processing (DARKEN CIRCLES AS STEPS ARE COMPLETED)</b>		
<b>Data Retrieval:</b> Form Received into SMS <input type="checkbox"/> Manual Review Completed <input type="checkbox"/>	<b>Data Entry of Non-Scannable Items:</b> Attempted <input type="checkbox"/> OR None Required <input type="checkbox"/>	<b>Final Disposition:</b> Completed <input type="checkbox"/> OR None Required <input type="checkbox"/> Final Complete (FCM) <input type="checkbox"/> OR Final Incomplete (FIC) <input type="checkbox"/>

## PLCO Cancer Screening Trial

# SPECIFICATIONS FOR COMPLETION OF THE TRANSVAGINAL ULTRASOUND SCREENING EXAMINATION QUALITY ASSURANCE FORM (TVQ2)

This form is to be completed by a SC staff member and the QA Examiner for the transvaginal ultrasound examination. The QA Examiner is defined as the examiner who repeats or observes the transvaginal ultrasound examination, or reviews films of the transvaginal ultrasound examination for QA purposes.

The SC staff member will complete the top administrative section and the QA Examiner will complete all or portions of Parts A and B of the form, depending on the method of quality assurance. QA for the transvaginal ultrasound may be done in three ways: 1) repeat examination, 2) observation of examination, and 3) review of ultrasound images on film. In SCs where a second Examiner, such as a radiologist or another sonographer interprets the original TVU films, QA will be accomplished through a blinded review of the films by another radiologist or sonographer.

After the TVQ form is completed, it will be receipted into the SMS and scanned into the DEES. Specifications for completing each item of the form are given below:

---

### General instructions for the completion of forms to be scanned by an Optical Mark Reader:

- Use a No. 2 pencil to mark your answers. Do not use red ink or felt tip pens.
- Make heavy marks that fill the circle completely.



- If you need to change an answer, be sure to erase completely.
- Mark only one response for each question, unless the instructions tell you otherwise.
- Some questions also have additional instructions next to certain answers. These instructions may either ask you to skip questions that do not apply to you or ask you to provide additional information. First darken the appropriate circle, then follow the instructions as directed. Unless instructed otherwise, go to the next question.

### Administrative Section:

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled. Darken the circles corresponding to the month, day, and all four (4) digits of the year.
2. **Satellite Center:** This field is optional. If the SC has elected to track satellite center activity and the examination is taking place at a satellite center, enter the 2-digit

Satellite Center ID. If the examination is not taking place at a satellite center, or the SC has elected not to track satellite center activity, this item should be left blank. Darken the circle corresponding to each number.

3. **Study Year:** Darken the circle corresponding to the study year. Darken the circle next to T0 for the baseline examination, and T1, T2, or T3 for the follow-up examinations.
4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete this examination in the current study year. For example, if this is the first time the participant has come to the SC, darken the circle next to "One." If the examination was not completed for some reason in a previous visit and the participant returned to the SC a second time to complete the transvaginal ultrasound examination, darken the circle next to "Two." If this is the third visit, darken the circle next to "Three." There should be no more than three visits to the SC in any study year.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. If the repeat visit is specifically for the purpose of performing the QA examination, record "QA Examination" in the space provided. If the main purpose of the repeat visit is to complete the original transvaginal ultrasound examination, refer to the Participant Control Record or the TVU form from the previous visit for this information. The purpose of this item is to provide important information to the QA Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior TVU terminated due to participant discomfort."*

This might be entered if the participant's previous transvaginal ultrasound examination was stopped due to discomfort, but she was willing to return to the SC to attempt the examination again. This information will alert the Examiner to the participant's physical condition.

*"Prior TVU terminated due to participant refusal."*

This might be entered if the participant previously refused the transvaginal ultrasound examination, but was willing to return to the SC to attempt the examination again.

6. **Method of QA:** Darken a circle to indicate which method of QA was used. There are three possible methods of QA for the TVU examination.

Repeat Examination - The entire examination is repeated by the QA examiner. In this case, all items on the TVQ form should be completed.

Observation of Examination - The entire examination is observed by the QA Examiner. In this case, all items on the TVQ form should be completed.

Review of Films - The film records of the TVU examination are reviewed by the QA Examiner. In this case, all items except B.5 (Medical complications of exam) should be completed.

### **Part A: Transvaginal Ultrasound Findings:**

Complete Items 1 through 4 for both the right and left adnexal areas. Record information first for the right adnexal area then for the left adnexal area. If the result of the examination (Item B.1) is "Inadequate", Part A may be left blank. The QA examiner should record any information that is available and leave the remaining items blank.

1. **Sonographically Detectable Ovary:** If the ovary is detected via the transvaginal ultrasound, darken the circle for "Yes." If the ovary is not detected, darken the circle for "No."
2. **Ovary Size:** Measure the longitudinal diameter, the transverse diameter, and the anteroposterior diameter, in centimeters, for each ovary. Record the measurements and darken the circle corresponding to each number. Zero fill, including the decimal place if there is no fraction of a centimeter. (For example, 3 cm should be recorded as 03.0 cm.) Calculate and record the volume (in cubic centimeters) using the formula below, then darken the circle corresponding to each number.

$$\text{Volume} = \text{width (transverse)} \times \text{height (longitudinal)} \times \text{thickness (anteroposterior)} \times 0.523$$

**Note:** When a measurement value includes a fraction, apply the following rules for rounding (Refer to the General Abstracting Techniques):

If the fraction is equal to .05 or more, round up. For example, 4.184 = 4.2

If the fraction is less than .05 round down. For example, 1.724 = 1.7

3. **Number of Morphologic Abnormalities in Adnexal Area:** Darken the circle corresponding to the number of morphologic abnormalities (regardless of size) visualized in each adnexal area. If an abnormality is detected in the adnexal area that is clearly not related to the ovary (e.g., hydrosalpinx), do not record it in this item. It may be recorded in Item A.5 (Other Abnormalities).

If a large mass is detected but there is not enough definition on the image to determine whether it is one abnormality or several, it should be counted as one abnormality and described in the table in Item 4 as one abnormality.

If no abnormalities are found, darken the circle for "None" and complete the section for the left adnexal area.

4. **4.Complete for Three Largest Discrete Cysts or Abnormalities:** Complete 4A through 4G for each of the three largest cysts or abnormalities detected in both the right and left adnexal areas. As noted in Item 3 above, do not complete for abnormalities that are clearly not ovarian in nature. Complete the chart by darkening the circle corresponding to the correct response in each column.

**A. Maximum Diameter of Cyst or Abnormality:** Record the maximum diameter in centimeters. Zero fill the decimal place if there is no fraction of a centimeter. (For example, 5 cm. should be recorded as 05.0 cm.) Darken the circles corresponding to the numbers. (See Item A.2 for rounding rules or refer to General Abstracting Techniques.)

**B. Volume of Cyst or Abnormality:** Calculate and record the volume of the cyst or abnormality using the formula below, then darken the circle corresponding to each number.

$$\text{Volume} = (\text{maximum diameter})^3 \times 0.523$$

Zero-fill, including the decimal place if there is no fraction of a cubic centimeter (for example, 5 cc should be recorded as 0005.0 cc, since the field is a 5-digit field). (See Item A.2 for rounding rules, or refer to the General Abstracting Techniques.)

If the volume of the cyst or abnormality is greater than 4999.9, record "4999.9" and record the actual volume in comments.

If the volume of the cyst or abnormality is less than 0.0, record "0000.0" and record the actual volume in comments.

### C. Solid Area:

- 0 = None: The cyst or abnormality is visualized with no solid areas.
- 1 = Mixed: The cyst or abnormality is visualized with some solid areas and some sonolucent areas.
- 2 = All solid: The cyst or abnormality is visualized as all solid. If the cyst or abnormality is all solid, darken the corresponding circle and go to 4G.

### D. Septal Structure:

- 0 = No septae: No dividing wall or partition is visualized in the cyst or abnormality.
- 1 = Yes, thin (≤3 mm): A thin (≤3 mm) dividing wall or partition is visualized in the cyst or abnormality.
- 2 = Yes, thick (>3 mm): A thick (>3 mm) dividing wall or partition is visualized in the cyst or abnormality.

### E. Cyst Outline:

- 1 = Smooth: The cyst or abnormality is visualized with a smooth outline.
- 2 = Irregularities: The cyst or abnormality is visualized with an irregular outline (irregular projections or bumpiness of ≥3 mm)
- 3 = Papillarities: The outline of the cyst or abnormality is visualized with small nipple shaped or finger-like projections or elevations (>3 mm).

### F. Cyst Wall Thickness:

- 1 = Thin (≤3 mm): The cyst or abnormality is visualized with a thin wall (≤3 mm).
- 2 = Thick (>3 mm): The cyst or abnormality is visualized with a thick wall (>3 mm).

### G. Echogenicity:

- 1 = Sonolucent: Ultrasound waves are passed without reflection.
- 2 = Low: A low level of reflection (echoes) of ultrasound waves.
- 3 = Low with an echogenic core: A low level of reflection (echoes) of ultrasound waves with central area of higher reflection.
- 4 = Mixed: High and low levels of reflection (echoes) of ultrasound waves.
- 5 = High: A high level of reflection (echoes) of ultrasound waves.

5. **Other Abnormalities Noted:** Use this area to record any non-ovarian abnormalities (e.g., thickening of endometrium) noted incidentally during the examination. If there are other abnormalities, darken the circle for "Yes" and describe the abnormalit(ies) in the space provided. If there are no other abnormalities, darken the circle for "No."

## Part B: Examination Results:

In some SCs, a second Examiner, such as a radiologist or another sonographer will interpret the TVU films, so Part B will be completed by this second Examiner.

1. **Examination Results:** Darken the circle corresponding to the examination result. Definitions are as follows:

Positive Screen - Referral Required (formerly Abnormal, Suspicious for Cancer):

An examination with one or more of the following features:

- Any ovary or cyst greater than 10 cubic centimeters in volume;
- Any solid area or papillary projection extending into the cavity of a cystic ovarian tumor of any size;
- Any mixed (solid/cystic) component within a cystic ovarian tumor.

A referral to the participant's physician of choice for evaluation of any of the above results is necessary, regardless of the result of the original transvaginal ultrasound examination.

Negative Screen - No Abnormalities (formerly Negative): An examination in which no abnormalities of any kind are found (regardless of whether or not the ovaries are visualized).

Negative Screen - Other Abnormalities (formerly Abnormal, Not Suspicious for Cancer): An examination which reveals one or more abnormalities that do not satisfy the criteria for a positive screening examination.

Inadequate: An examination which could not be adequately completed due to one of the reasons outlined in B.2 below.

2. **Reason for Inadequate Examination:** Darken one or more of the circles corresponding to the reason(s) for the inadequate examination. Definitions are as follows:

Participant Discomfort: The participant is unable to tolerate the discomfort of the examination and the examination is terminated prematurely, without collection of sufficient information to determine a result of positive or negative.

Participant Refusal: The participant is unwilling to allow the completion of the examination and a result of positive or negative could not be determined due to insufficient information.

Equipment Malfunction: There is a problem with the transvaginal ultrasound equipment which prevents the successful completion of the examination.

Inability to Insert Probe: The ultrasonographer is unable to insert the probe for the transvaginal ultrasound procedure and sufficient information could not be collected to determine a result of positive or negative.

Bowel Interference: Visualization of the bowel interfered with the Examiner's ability to visualize the adnexal area, and to collect sufficient information to determine a result of positive or negative.

Other (SPECIFY): Describe any other situation in which a result of positive or negative could not be determined due to insufficient information.

3. **Level of Referral: Darken the circle corresponding to the level of referral.**

1. **Significant Abnormality, Referral:** The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be significant and requiring referral was found.
2. **Moderate Abnormality, Referral:** The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.

3. **Slight Variation from Normal, No Referral:** The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal not requiring referral was found.
4. **Normal/Result Not Available, No Referral:** The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.
4. **Photo Documentation:** A photograph or thermal printout must be obtained for documentation and retention as part of the permanent record. A photo document should be obtained regardless of whether or not the ovaries were visualized. The photo document must be of material that will allow for long term storage (at least 20 years). If the method of QA is repeat examination or observation of examination, darken the appropriate circle to indicate whether photo documentation is obtained. If the method of QA is review of films, darken the circle next to "Yes."

If the result of the examination is "Inadequate", (especially if the participant refuses the exam or the QA examiner is unable to insert the probe), the QA examiner may not be able to obtain photo documentation. In such cases, darken the circle next to "No."

5. **Medical Complications of Exam:** If there were no medical complications of the examination that the participant experienced prior to leaving the SC, darken the circle next to "No." If the participant experienced a medical complication prior to leaving the SC, darken the circle next to "Yes" and briefly describe the complication in the space provided.

**Note:** An Adverse Experience Report (AER) should be completed if the participant experiences a medical complication before arriving at or after leaving the SC or if she receives medical care for a complication experienced during the screening visit.

6. **Comments:** The comments box may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed. If a large mass was detected but the Examiner could not determine whether it was one abnormality or several, record the following statement: "large mass-resolution not sufficient to rule out multiple abnormalities."

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item on the form, use the item number for the comments section itself (B.6). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

7. **Examiner ID:** *(This item should be completed by the Examiner, even if another examiner was consulted during the examination.)*

Sign the form in the space provided, enter your 4-digit staff ID number, and darken the circles corresponding to the four digits.

8. **Consultant ID:** *(This item should be completed by the physician consultant or by a radiologist or other sonographer who interprets the transvaginal ultrasound. If a physician was not consulted during the examination, the Examiner should darken the circle next to "No," and the signature should be left blank. Note that this item*

*should not be completed for QA Examiners; QA Examiners must complete a separate exam form for QA.)*

If a consultant was used, the consultant should darken the circle next to "Yes," and sign the form in the space provided. S/he should enter his/her 4-digit staff ID number and darken the circles corresponding to the four digits.

**Form Processing:** These are the steps that should be completed in order to process the examination form. All of the items except "Final Disposition" are optional. "Final Disposition" is required and may be marked on the form or entered directly into DEES. Final Disposition may also be set automatically in DEES when the form is edited (see the documentation for DEES 2.03).

**Form Received into SMS:** This item is optional. Darken this circle after the form has been receipted into the SMS. (Refer to Chapter 17 for instructions on receipting forms.)

**Manual Review Completed:** This item is optional. Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate circles are darkened properly. (Refer to Chapter 17 for instructions on performing a manual review of forms.)

**Data Entry of Non-Scannable Items:** This item is optional. Complete this item to indicate the status of verbatim data entry. (Refer to Chapter 17 for instructions on data entry of non-scannable items.) When data entry is complete, darken the circle next to "Completed." If no data entry of non-scannable items is required, darken the circle next to "None Required."

**Data Retrieval:** This item is optional. Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each opscan form. There are two final dispositions:

- Final Complete (FCM): This disposition may be assigned when there are no errors reported on the DEES edit report or the only errors reported are "UNLIKELY" errors that have been investigated by the SC or errors on the optional forms processing items.
- Final Incomplete (FIC): This disposition may be assigned when there are errors reported on the DEES edit report (except UNLIKELY errors that have been investigated) which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

The final disposition may be assigned in three ways:

- by darkening the bubble on the opscan form and scanning it;
- by keying the final disposition into DEES;
- by allowing the computer to assign the final disposition for forms with no errors (FCM only).

## **A-17-1**

A-17-1: Missing Data Form (MDF)

Specifications for the Missing Data Form

**MISSING DATA FORM**

Screening Center .....|\_|\_|  
 Satellite Center .....|\_|\_|  
 Screening Center Staff ID: ....|\_|\_|\_|\_|  
 Date: ..... |\_|\_|-|\_|\_|-|\_|\_|\_|\_|



**MDF**

STUDY FORM		STUDY YEAR (T00-T13)	REASON CODE/SUB-CODES (IF SUB-CODE = 888, SPECIFY REASON)
1. Baseline Questionnaire (BQF/BQM)	_	T  0 0	_ / _ _
2. Baseline Locator Form (BLF)	_	T  0 0	_ / _ _
3. Etiologic Studies Consent (ESC)	_	T  _ _	_ / _ _
4. 1998 Protocol Change Consent (PCC)	_	T  _ _	_ / _ _
5. Buccal Cell Sample (BUC)	_	T  _ _	_ / _ _
6. Annual Study Update (ASU/ PSH)	_	T  _ _	_ / _ _
7. Followup Locator Form (FLF)	_	T  _ _	_ / _ _
8. Blood Collection Form (BCF/BFF/Vanguard)	_	T  _ _	_ / _ _
9. Chest X-Ray Screening Exam Form (XRY)	_	T  _ _	_ / _ _
10. Ovarian Palpation Screening Exam Form (OVR)	_	T  _ _	_ / _ _
11. Transvaginal Ultrasound Screening Exam Form(TVU) _	_	T  _ _	_ / _ _
12. Digital Rectal Screening Exam Form (DRE)	_	T  _ _	_ / _ _
13. Flex Sigmoidoscopy Screening Exam Form (FSG)	_	T  _ _	_ / _ _
14. Diagnostic Evaluation Form - Prostate (DEP)	_	T  _ _	_ / _ _
15. Diagnostic Evaluation Form - Colorectum (DEC)	_	T  _ _	_ / _ _
16. Diagnostic Evaluation Form - Lung (DEL)	_	T  _ _	_ / _ _
17. Diagnostic Evaluation Form - Ovary (DEO)	_	T  _ _	_ / _ _
18. Treatment Information Form - Prostate (TIP)	_	T  _ _	_ / _ _
19. Treatment Information Form - Colorectum (TIC)	_	T  _ _	_ / _ _
20. Treatment Information Form - Lung (TIL)	_	T  _ _	_ / _ _
21. Treatment Information Form - Ovary (TIO)	_	T  _ _	_ / _ _
22. Dietary Questionnaire (DQX)	_	T  0 0	_ / _ _
23. Diet History Questionnaire (DHQ)	_	T  _ _	_ / _ _
24. Health Status Questionnaire (HSW/HSM)	_	T  _ _	_ / _ _
25. Other Cancer Confirmation Form (OCF)	_	T  _ _	_ / _ _
			_ _  Cancer Code

**Reason Codes/Sub-Codes**

- |  |                          |                                      |
|--|--------------------------|--------------------------------------|
| 1 = Refused procedure/Activity               | 5 = Can't Locate/Contact | C = Reported PLCO Cancer*            |
| 1/112 Out of Area*                           | 6 = Out of Window*       | D = Deceased*                        |
| 1/113 = Participant Illness/Medical Problem* | 7 = PLCO Organ Removed*  | E = Erroneous Report of Cancer       |
| 1/114 = Family Problem*                      | 8 = Other (SPECIFY)      | F = Follow-up Colonoscopy Indicated* |
|  |                          | R = Records Could Not Be Obtained    |

\*These codes can NOT be used for DE/TI/OCF forms

## **MDF REASON CODES/SUB-CODES**

### **Code 1: Refused Study Activity (Procedure, Form, Follow-up)**

#### **Sub-Code(s):**

- 101= Participant will not sign consent form
- 102= Refused to schedule screening appointment
- 103= Failure to show up for scheduled appointments
- 104= Participant refused to go for follow-up (*exclusive for DE/OCF forms*)
- 105= Participant refused to obtain treatment for a confirmed cancer (*exclusive for TI form*)
- 106= Worried about health effects and/or side effects of medical test/procedures
- 107= Dissatisfied with study/staff
- 108= Transportation problems
- 109= Loss of interest
- 110= No insurance
- 111= Work demands
- 112= Participant out of area and therefore unable to complete study activity
- 113= Participant did not complete study activities due to other more critical illness
- 114= Participant did not complete study activities due to family responsibilities/obligations
- 115= Concerns about medical cost responsibility
- 116= Concerned about privacy
- 117= Failure to complete study activity after agreeing to do so
- 118= Received screening exam from PCP
- 888= Other (*Specify*)
- 999= No reason given

### **Code 2: Out of Area\***

Code 2 discontinued. Use Reason Code 1, Sub-code 112

### **Code 3: Participant Illness/Medical Problems\***

Code 3 discontinued. Use Reason Code 1, Sub-code 113

### **Code 4: Family Problem\***

Code 4 discontinued. Use Reason Code 1, Sub-code 114

### **Code 5: Can't Locate**

#### **Sub-Code(s):**

- 501= Phone calls not returned or no response to mailings-*correct address and telephone*
- 502= Cannot locate participant to complete procedures (screening exams, blood collection, buccal cell collection) or forms (questionnaires, consents)-*Incorrect address and telephone*
- 503= Cannot locate participant to determine whether or not they obtained follow-up to a positive screen (*exclusive for DE forms*)
- 504= SC unable to locate participant or family to obtain consent/authorization for release of medical records

### **Code 6: Out of Window\***

#### **Sub-Code(s):**

- 666= Out of window

### **Code 7: PLCO Organ Removed (*exclusive for screening exams*)\***

#### **Sub-Code(s):**

- 777= PLCO Organ removed

### **Code 8: Other (*SPECIFY*)**

#### **Sub-Code(s):**

- 801= Completed dietary questionnaires lost after shipment
- 802= DQX was mistakenly completed
- 803= Participant died before going for follow-up (*exclusive for DE/OCF forms*)
- 804= Participant received follow-up for a positive screen after the 12 month window
- 888= Other (*Specify*)

### **Code C: Reported PLCO Cancer\***

#### **Sub-Code(s):**

- CCC= Reported PLCO cancer

### **Code D: Deceased\***

#### **Sub-Code(s):**

- DDD= Deceased

### **Code E: Erroneous Report of Cancer**

#### **(*exclusive for DE/OCF forms*)**

#### **Sub-Code(s):**

- E01= Erroneous report of cancer
- E02= Cancer diagnosed prior to randomization
- E03= Cancer diagnosed after randomization
- E04= Erroneous report of cancer (confirmed in-situ) Does not apply to OCF forms.

### **Code F: Follow-up Colonoscopy**

#### **Indicated\* (*exclusive for FSG form*)**

#### **Sub-Code(s):**

- F01= No T5 FSG; Positive T0 FSG; T0 colonoscopy with adenoma
- F02= No T5 FSG; Positive T0 FSG with subsequent colonoscopy and no adenoma found
- F03= No T5 FSG; colonoscopy between T0-T1
- F04= No T5 FSG, colonoscopy after the T1 year
- F05= No T5 FSG; Scheduled colonoscopy
- F06= No T5 FSG; Plans colonoscopy

### **Code R: Records Could Not be Obtained (*exclusive for DE/TI/OCF forms*):**

#### **Sub-Code(s):**

- R01= Participant does not want to release medical records
- R02= Family refuses to release medical records
- R03= Primary care provider will not release information
- R04= Physician or institution does not respond to medical record inquiry
- R05= Records lost
- R06= SC not willing to contact family
- 888: Other (*Specify*)

\*These codes can NOT be used for DE/TI/OCF forms

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MISSING DATA FORM (MDF)**

A SC staff member should complete a Missing Data Form (MDF) to document the absence of a study data collection form. This MDF will cancel expectations for the noted missing form(s) and any other related expectations. This missing data may be due to a variety of reasons such as participant refusal, inability to locate the participant, suspected death of the participant, inability to obtain medical records, etc.

Specifications for completing each item of the form are given below:

**Administrative Section:**

**Barcode:** This is the three-character form identifier (MDF) in barcode format. The barcode may be read by a barcode reader (wand) during the receipt of the form into the SMS.

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form.

**Screening Center:** Record the 2-digit SC ID.

**Satellite Center:** If the participant is seen at a satellite center for the PLCO Trial, enter the 2-digit Satellite Center ID. If the participant is not seen at a satellite center, enter "00" or leave blank.

**Screening Center Staff ID:** Record your 4-digit staff ID number.

**Date:** Record the date the Missing Data Form was completed. Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1996).

**Missing Data Section:**

**Study Form:** Complete this item to document all data forms that are missing, i.e., all forms which will not be completed by or for the participant in the current study year, and therefore will not be receipted into the SMS before the end of the delinquency period. Check the box next to each form that is missing.

**Study Year:** Enter the number corresponding to the study year. Zero-fill study years from T0 to T13 (e.g., T00, T01, T02, etc.).

**Reason Codes/Sub-codes:** Complete this item to document the reason the data form is missing. Refer to the Reason Codes/Sub-codes for the list of possible reasons the data form is missing. Enter the code corresponding to the main reason a data form is missing in the first box under the Reason Code/Sub-code field and enter a three digit sub-code corresponding to a more detailed explanation, if available, in the three boxes to the right of the first box. When sub-code 888=Other (Specify) is used, specify the reason to the right of the sub-codes in the space provided. If the specific reason falls into one of the sub-codes, it should be coded appropriately. This includes but is not limited to the following examples:

1. If a participant refuses to sign the consent form and reason is not known, Code 1 and Sub-code 101 should be used.
2. If a participant refuses to sign the consent form due to transportation problems, Code 1, Sub-code 108 should be used.
3. If a participant refuses to sign a consent form because of a reason that isn't specified in the code list, use Code 1, Sub-code 888 and specify the reason.

4. If a participant refuses to schedule a screening exam and reason is not known, Code 1, Sub-code 102 should be used.
5. If a participant refuses to schedule a screening exam because they have no insurance Code 1, Sub-code 110 should be used.
6. If a participant refuses to return a buccal cell kit and/or a questionnaire and the reason is not known, Code 1, Sub-code 999 should be used.
7. If a participant refuses to return a buccal cell kit and/or questionnaire due to other more critical illnesses Code 1, Sub-code 113 should be used.

(Note: Medical record abstracting forms require a reason code of 1, 5, 8, E, or R only. Codes with an asterisk (\*) can NOT be used for DE/TI/OCF forms.) The reason codes and the three digit sub-codes are as follows:

**1 = Refused Study Activity (Procedure, Form, Follow-up):**

**Sub-codes:**

**101 = Participant will not sign consent form:** Participant has made contact with the SC concerning the study activity but will not sign the consent (PCC or ESC) and reason for refusal is not known.

**102 = Refused to schedule screening appointment:** Participant has made contact with the SC concerning the study activity but will not allow one or more screening examinations to be performed and reason for refusal is not known.

**103 = Failure to show up for scheduled appointments:** Repeatedly cancelled or did not show up for visits before the delinquency period closed.

**104 = Participant refused to go for follow-up (exclusive for DE/OCF forms):** When the SC determines that the participant will not ever be obtaining diagnostic follow-up for a positive screen. Also used if the participant states that s/he plans to go for follow-up but does not. In this case, an MDF should be completed after 12 months from the positive screen, or the next screening visit (whichever comes first).

**105 = Participant refused to obtain treatment for a confirmed cancer (exclusive for TI form):** When the SC determines that the health care provider recommends treatment but the participant decides not to obtain treatment for a confirmed cancer. In this case an MDF should be completed after 12 months.

**106 = Worried about health effects and/or side effects of medical test/procedures**

**107 = Dissatisfied with study/staff**

**108 = Transportation problems**

**109 = Loss of interest**

**110 = No insurance**

**111 = Work demands**

**112 = Participant out of area and therefore unable to complete study activities:** The participant has moved out of the area or will be out of the area temporarily, and is unwilling or unable to complete study activities (may include procedures, forms, and follow-up).

**113 = Participant did not complete study activities due to other more critical illness:** The participant has an illness or medical problem which precludes their ability to complete study activities.

**114 = Participant did not complete study activities due to family responsibilities/obligations:** The participant has a family problem, such as illness in a family member, or other family problem which prevents him/her from completing a study activity.

**115 = Concerns about medical cost responsibility**

**116 = Concerned about privacy**

**117 = Failure to complete study activity after agreeing to do so:** Participant agreed to complete study forms and/or activities once they have been contacted by SC but still fail to do so.

**118 = Received screening exam from PCP:** Participant received screening examination from his/her health care provider and therefore refuses study screen.

**888= Other (Specify)** \_\_\_\_\_

**999= No reason given:** Applies to all activities except consents and screening exams.

**5 = Can't Locate/Contact:**

**Sub-codes:**

**501 = Phone calls not returned or no response to mailings:** The participant does not respond to phone calls or to mailing conducted according to the appropriate follow-up protocol. (SC believes they have correct telephone number or address.)

**502 = Cannot locate participant to complete procedures (screening exams, blood collection, buccal cell collection) or forms (questionnaires, consents). (SC does not have correct telephone number or address).**

**503 = Cannot locate participant to determine whether or not they obtained follow-up to a positive screen (exclusive for DE forms)**

**504 = SC unable to locate participant or family to obtain consent/authorization for release of medical records**

**6 = Out of Window\*:**

**Sub-code:**

**666 = Out of window:** The activity window has passed. This code should be used when the participant was willing but the SC has a problem scheduling the participant on-time. The activity window for completion of all screening exams with the exception of the T5 FSG and CA-125 and PSA blood draws is from one month prior to six months past the participant's randomization anniversary date. The activity window for the T5 FSG and CA-125 and PSA blood draws is from one month prior to and 12 months post the T5 randomization anniversary date.

**7 = PLCO Organ Removed\* (exclusive for screening exams):**

**Sub-code:**

**777 = PLCO Organ removed:** The participant has had entire prostate, one lung, entire colon or both ovaries removed and the screening examination for that organ was not performed.

**8 = Other (Specify):**

**Sub-codes:**

**801 = Completed dietary questionnaires lost after shipment:** An MDF with reason code 8 and sub-code 801 should be receipted for each lost form.

**802 = DX was mistakenly completed: DHQ is no longer required:** An MDF with reason code 8 and sub-code 802 should be completed for the DHQ.

**803 = Participant died before going for follow-up (exclusive for DE/OCF forms):** If a participant dies before seeking follow-up for a positive PLCO screen or a report of cancer that had yet to be evaluated/ investigated before death.

**804 = Participant received follow-up for a positive screen after 12 month window:** The participant did not receive follow-up for a positive screen within 12 months but did receive it after the 12 month window.

**888 = Other (Specify) \_\_\_\_\_**

**C = Reported PLCO Cancer\*:**

**Sub-code:**

**CCC = Reported PLCO cancer:** After the reporting window for the current study year opened, the participant reported that s/he was diagnosed with a PLCO cancer. A MDF should be receipted with this reason code to "turn off" expectations for screening examination(s) associated with the cancer site for the current study year. If a Diagnostic Evaluation form confirming the cancer is not receipted before the study year begins, the expectation for the examination(s) associated with the cancer will be re-instated.

**D = Deceased\*:**

**Sub-code:**

**DDD = Deceased:** The participant's participation status became "presumed deceased" after the reporting window for the current study year opened. A MDF should be receipted with reason code D to "turn off" the expectations for study activities that require participant contact (such as exams and questionnaires) for the current study year.

**E = Erroneous Report of Cancer (exclusive for DE/OCF forms):**

**Sub-codes:**

**E01 = Erroneous report of cancer:** When the SC obtains records for a participant who reported an interval cancer (PLCO or non-PLCO) but the records do not substantiate the report of cancer diagnosis.

**E02 = Cancer diagnosed prior to randomization:** When the cancer reported by the participant is found to be a primary, or a recurrence, or a metastasis from a primary cancer that was diagnosed prior to randomization. If the primary cancer that was found to have been diagnosed before randomization is a PLCO cancer, an ATF should also be completed to document the participant as a randomized ineligible

**E03 = Cancer diagnosed after randomization:** When the cancer reported by the participant is found to be a recurrence or metastasis from a primary cancer diagnosed after randomization.

**E04 = Erroneous report of cancer (confirmed in-situ):** The original report of cancer was not confirmed; instead an in-situ cancer was confirmed by medical record. Applies only to DE forms since in situ is allowed on OCF forms.

**E = Follow-up Colonoscopy Indicated\*** (*exclusive for FSG form*):

**Note:** This reason code may only be used for the FSG exam (Item #13 on the list of study forms).

**Sub-codes\*:**

**F01 = No T5 FSG; Positive T0 FSG; T0 colonoscopy with adenoma:** The participant will not have a T5 FSG because she/he had a positive T0 FSG and a T0 adenoma and is now receiving periodic follow-up colonoscopy.

**F02 = No T5 FSG; Positive T0 FSG with subsequent colonoscopy and no adenoma found:** The participant had a positive T0 screen with a follow-up colonoscopy, but no adenoma was found and declines T5 FSG.

**F03 = No T5 FSG; Colonoscopy between T0-T1:** Participant declines T5 FSG (If adenoma, should be in surveillance; if no adenoma found at colonoscopy, T5 FSG is optional).

**F04 = No T5 FSG; colonoscopy after the T1 year:** The participant will not have a T5 FSG because she/he had a colonoscopy at any time after the T1 year.

**F05 = No T5 FSG; Scheduled colonoscopy:** The participant will not have a T5 FSG because although she/he has not had a colonoscopy between T0 and T5, she/he is scheduled to have a colonoscopy in the T5 year.

**F06 = No T5 FSG; Plans colonoscopy:** The participant will not have a T5 FSG because although she/he has not had a colonoscopy between T0 and T5, she/he plans to have a colonoscopy in the T5 year.

\*All sub-codes above also apply to T3 FSG.

**R = Records Could Not Be Obtained** (*exclusive for DE/TI/OCF forms*):

**Sub-codes:**

**R01 = Participant does not want to release medical records:** Participant refuses to sign consent/authorization form needed in order to obtain medical records to document cancer diagnostic/staging procedures or treatment info.

**R02 = Family refuses to release medical records:** Participant has died and the family is unwilling to consent/authorize release of medical records.

**R03 = Primary care provider will not release information:** When the participant sees a physician, but the physician or medical facility refuses to release info to SC regarding the details or outcome.

**R04 = Physician or institution does not respond to medical record inquiry:** When repeated attempts to obtain medical records from a health care provider or institution outside the screening network are unsuccessful. At least 5 attempts to obtain records should be made.

**R05 = Records lost:** The institution or clinic cannot find the record(s) requested.

**R06 = SC not willing to contact family:** When the participant may have sought follow-up attention but has since died, and the SC is unwilling to contact the participant's family for consent/authorization to obtain medical records.

**888 = Other (Specify):** \_\_\_\_\_

**Number 25: Other Cancer Confirmation Form (OCF):** In order to update expectations for cancer confirmation information, the OCF item requires more information than the others. If the OCF form is missing, the study year should be entered as well as a reason code and three-character sub-code. In addition, a cancer code should be entered.

Cancer Code: Enter a three-digit cancer code (from Appendix I of the MOOP) to indicate that only one of the open OCF records should be closed. This three-digit code must match a three-digit code for an open OCF record for the participant for the specified study year.

**After completing the form:**

- Receipt the form into the SMS.
- File the form in the participant's folder.

**Deleting a MDF:**

In situations where a MDF should be deleted from SMS (i.e., actual study form received or found or the MDF was complete in error), the SC should delete the MDF from SMS but keep the hardcopy MDF in the participant's file. SC staff should document on the MDF why the MDF was deleted from SMS and initial and date the form.

## **A-17-2**

A-17-2: Nonresponse Form (NRF)

Specifications for the Nonresponse Form

## Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

### NONRESPONSE FORM

Screening Center: .....|\_|\_|

Satellite Center: .....|\_|\_|

Screening Center Staff ID: .....|\_|\_|\_|\_|

Date: .....|\_|\_| - |\_|\_| - |\_|\_|\_|\_|  
MO DY YEAR



NRF

**Participant ID Label**

**INSTRUCTIONS:** This form is to be completed only when a participant will no longer be participating in any aspect of the study that involves participant contact.

#### Reasons for Non-Participation

(A) Medical Condition: (SPECIFY): \_\_\_\_\_  
 \_\_\_\_\_

Date of Last Contact:      |\_|\_| - |\_|\_| - |\_|\_|\_|\_|  
MO DY YEAR

(B) Refused further participation (SPECIFY): \_\_\_\_\_  
 \_\_\_\_\_

Level of Refusal (MARK ONE):

(1) No Active Contact with Participant

(2) No Active Contact or Passive Follow-Up with Participant

(3) Participant Withdraws Consent; Remove Information from PLCO Files

Date of Refusal:              |\_|\_| - |\_|\_| - |\_|\_|\_|\_|  
MO DY YEAR

(C) Lost Contact: (SPECIFY): \_\_\_\_\_  
 \_\_\_\_\_

Date Lost Contact:          |\_|\_| - |\_|\_| - |\_|\_|\_|\_|  
MO DY YEAR

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE NONRESPONSE FORM (NRF)**

This form is to be completed by SC staff member if a participant will no longer participate in any aspect of the trial that involves participant contact, such as screening visits and questionnaires.

Specifications for completing each item of the form are given below:

**Administrative Section:**

- **Barcode:** This is the three-character form identifier (NRF) in barcode format. The barcode may be read by a barcode reader (wand) during the receipt of the form into the SMS.
- **Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form.
- **Screening Center:** Record the 2-digit SC ID.
- **Satellite Center:** If the participant is seen at a satellite center for the PLCO Trial, enter the 2-digit Satellite Center ID. If the participant is not seen at a satellite center, enter "00."
- **Screening Center Staff ID:** Record your 4-digit staff ID number.
- **Date:** Record the date the Nonresponse Form was filled out. Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1996).

**Reasons for Non-Participation:**

- (A) Medical Condition:** The purpose of this item is to document any disease, illness, or related medical condition causing the participant to withdraw from all aspects of the trial involving participant contact. For example, this code would be used in the situation where a participant diagnosed with a PLCO or other cancer, decides to no longer participate actively in the trial. Check the box next to "Medical Condition," and specify the condition(s) on the line(s) provided.

**Date of Last Contact:** Record the date the SC last had contact with the participant. This date is defined as follows:

- The date the SC last had a contact with the participant in person, by mail, or by phone, in which s/he withdrew from the trial; or
- The date a relative/friend of the participant notified the SC (in person, by mail, or by phone) of the participant's withdrawal from the trial.

Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1996).

- (B) Refused Further Participation:** The purpose of this item is to document that the participant has refused to continue participation in the trial. Check the box next to "Refused further participation," and specify the reason(s) for refusal on the line(s) provided. Document the level of refusal as follows. Level 1: "No Active Contact with Participant" should be marked if the participant has refused to participate in all study activities involving participant contact. For example, this code would be used in the situation where a participant refuses to undergo any screening tests (if randomized to intervention group) or to complete questionnaires (both intervention and control). Level 2: "No Active Contact or Passive Follow-Up with Partici-

part" should be marked if the participant has requested that no person or organization be contacted to request information about him or her. Level 3: "Participant Withdraws Consent; Remove Information from PLCO Files" should be marked if the participant has demanded that all records of his or her participation be removed from the PLCO files.

**Date of Refusal:** Record the date the participant indicated his/her refusal. Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1996).

- (C) **Lost Contact:** The purpose of this item is to document participant nonresponse because the participant has been lost to follow-up. This category is used for participants who, despite tracing efforts, have been lost to follow-up, and will no longer be reporting to the SC. Do not complete this form if you plan to continue tracing efforts or if the participant has simply relocated and may be willing to return to the SC for annual visits or to complete questionnaires by mail.

If the participant has relocated to an area covered by another SC in the trial, contact the Coordinating Center for instructions.

Check the box next to "Lost Contact," and specify the reason(s) for lost contact, including efforts to trace the participant on the line(s) provided.

**Date Lost Contact:** Record the date that contact was lost with the participant. This date is defined as follows:

- Date the SC last had any contact with the participant in person, by phone, or by mail (contacts with others don't count here). If the mail contact was the receipt of a form at the SC, the date lost contact should be the date the participant completed the form, not the receipt date in the SMS.

Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1996).

**After completing the form:**

- Receipt the form into the SMS.
- If Level of Refusal = 3, send a copy of the NRF to the SC Coordinator at Westat. Refer to Decision Log 70(1) regarding the proper steps of Westat notification.
- File the form in the participant's folder.

**A-17-3**

A-17-3: Coding Decision Log

## **A-17-4**

A-17-4: Adverse Experience Report (AER)

Specifications for the Adverse Experience Report

# Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

## REPORT OF ADVERSE EVENTS FOR NIH-SPONSORED CLINICAL TRIALS

Screening Center: ..... |\_\_|\_\_|

Screening Center Staff ID: ..... |\_\_|\_\_|\_\_|\_\_|

Date Event Occurred: .... |\_\_|\_\_|\_|-|\_\_|\_\_|\_|-|\_\_|\_\_|\_\_|\_\_|  
MO DY YEAR

Date Reported to SC: .... |\_\_|\_\_|\_|-|\_\_|\_\_|\_|-|\_\_|\_\_|\_\_|\_\_|  
MO DY YEAR



Participant ID Label

**INSTRUCTIONS:** Please refer to the Specifications for Completion of the Report of Adverse Events for NIH- Sponsored Clinical Trials. (Please attach copies of any relevant exam forms, AE reports, or other documentation regarding the event)

1. Category of Event: (Check all that apply)

- Death
- Life-threatening event
- Inpatient hospitalization
- Persistent or significant disability/incapacity
- Medical or surgical intervention to prevent one of the above outcomes
- Other: \_\_\_\_\_

2. Description of participant who experienced the adverse event, such as gender, age, etc. (no identifiers):

---

---

---

3. Brief description of event:

---

---

---

4. Description of the outcome of the event:

---

---

---

5. Using your best judgement, do you believe that the adverse event was related to one of the screening examinations?

- Yes, study related
- Possibly study related
- Not study related
- Unknown

6. Do you feel revision to the informed consent document is necessary?

- Yes, revision of the informed consent form is necessary
- Possible revision of the informed consent form is necessary
- No revision of the informed consent form is necessary
- Unknown

Investigator's signature and date: \_\_\_\_\_

Investigator's Printed Last Name and Initial: \_\_\_\_\_

## **A-17-5**

**A-17-5: Record of Experience, Credentials and Training (ECT)**

**Specifications for the Record of Experience, Credentials and Training**



6. **CREDENTIALS:** (Mark all that apply. A photocopy of the document which qualifies the individual for a particular position must be included for each position marked in Item 4.)

- XRY:**  Radiologic Technician, ARRT (Attach copy of ARRT certification.)  
 ABR Board-certified Physician (Attach copy of board certification.)  
 ABR Board-eligible, Physician (Attach copy of physician's license.)  
 Other: \_\_\_\_\_ (Attach copy of qualifying documentation.)

- DRE:**  Board-certified Urologist (Attach copy of board certification.)  
 Board-eligible Urologist (Attach copy of physician's license.)  
 Physician (Attach copy of physician's license.)  
 Physician's Assistant (Attach copy of P.A. license.)  
 Registered Nurse (Attach copy of R.N.'s license.)  
 Other: \_\_\_\_\_ (Attach copy of qualifying documentation.)

- FSG:**  Board-certified Gastroenterologist (Attach copy of board certification.)  
 Board-eligible Gastroenterologist (Attach copy of physician's license.)  
 Physician (Attach copy of physician's license.)  
 Physician's Assistant (Attach copy of P.A. license.)  
 Registered Nurse (Attach copy of R.N.'s license.)  
 Other: \_\_\_\_\_ (Attach copy of qualifying documentation.)

- TVU:**  Board-certified Sonographer, ARDMS (Attach copy of certification.)  
 Board-certified radiologist (Attach copy of certification.)  
 Board-eligible radiologist (Attach copy of certification.)  
 Physician (Attach copy of license.)  
 Physician's Assistant (Attach copy of P.A. license.)  
 Registered Nurse (Attach copy of R.N.'s license.)  
 Other: \_\_\_\_\_ (Attach copy of qualifying documentation.)

- BLD:**  Medical Technician/Technologist, ASCP (Attach copy of registration.)  
 Medical Technician/Technologist, NCA (Attach copy of registration.)  
 Registered Nurse (Attach copy of R.N.'s license.)  
 Other: \_\_\_\_\_ (Attach copy of qualifying documentation.)

7. **TRAINING:** (Complete for all that apply. Required training on protocols and forms must be documented for each Examiner, Interpreter, Trainer/Supervisor and QA Examiner position marked in Item 4. Required training on PLCO procedures must be documented for each Examiner position marked in Item 4.)

- XRY:**  PLCO Protocol for Chest X-ray Exam  
 PLCO XRY Form

- DRE:**  PLCO Protocol for the Digital Rectal Exam  
 PLCO DRE Form  
 PLCO digital rectal exam procedures --> \_\_\_\_\_ number of training exams completed.

This Examiner has completed the required training exams and is qualified to perform PLCO digital rectal exams (of the prostate).

Supervisor/Trainer Signature: \_\_\_\_\_

Supervisor/Trainer Name (Please print): \_\_\_\_\_

Date: \_\_\_\_\_

- FSG:**  PLCO Protocol for the Flexible Sigmoidoscopy Exam  
 PLCO FSG Form  
 PLCO Flexible Sigmoidoscopy exam procedures --> \_\_\_\_\_ number of training exams completed.

This examiner has completed the required training exams and is qualified to perform PLCO Flexible Sigmoidoscopy exams.

Supervisor/Trainer Signature: \_\_\_\_\_

Supervisor/Trainer Name (Please print): \_\_\_\_\_

Date: \_\_\_\_\_

- TVU:**  PLCO Protocol for the Transvaginal Ultrasound Exams  
 PLCO TVU Form  
 PLCO Transvaginal Ultrasound exam procedures --> \_\_\_\_\_ number of training exams completed.

This examiner has completed the required training exams and is qualified to perform/interpret PLCO Transvaginal Ultrasound exams.

Supervisor/Trainer Signature: \_\_\_\_\_

Supervisor/Trainer Name (Please print): \_\_\_\_\_

Date: \_\_\_\_\_

- BLD:**  PLCO Protocol for Blood Collection and Processing (Chapter 10 PLCO MOOP)  
 PLCO Blood Collection Form  
 PLCO Phlebotomy procedures --> \_\_\_\_\_ number of phlebotomy procedures completed.  
 PLCO blood processing procedures --> \_\_\_\_\_ number of processing procedures completed.

This examiner has completed the required training exams and is qualified to perform PLCO phlebotomy/blood processing procedures.

Supervisor/Trainer Signature: \_\_\_\_\_

Supervisor/Trainer Name (Please print): \_\_\_\_\_

Date: \_\_\_\_\_

8. **REGISTRATION:** (To be completed by the NCI reviewer.)

This individual is qualified to perform as a PLCO: (Mark all that apply.)

- | <b>XRY</b>                                      | <b>DRE</b>                                      | <b>FSG</b>  | <b>TVU</b>                                      | <b>BLD</b>                                      |
|---|---|---|---|---|
| <input type="checkbox"/> Examiner               | <input type="checkbox"/> Examiner               | <input type="checkbox"/> Examiner <input type="checkbox"/> Examiner | <input type="checkbox"/> Phlebotomist           | <input type="checkbox"/> Processor              |
| <input type="checkbox"/> Interpreter            | <input type="checkbox"/> Interpreter            | <input type="checkbox"/> Interpreter                                | <input type="checkbox"/> Interpreter            | <input type="checkbox"/> Trainer/<br>Supervisor |
| <input type="checkbox"/> Trainer/<br>Supervisor | <input type="checkbox"/> Trainer/<br>Supervisor | <input type="checkbox"/> Trainer/<br>Supervisor                     | <input type="checkbox"/> Trainer/<br>Supervisor |   |
| <input type="checkbox"/> QA Examiner            | <input type="checkbox"/> QA Examiner            | <input type="checkbox"/> QA Examiner                                | <input type="checkbox"/> QA Examiner            |   |

Signature of NCI reviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Comments:

---

---

---

---

**STAFF ID# ASSIGNMENT:** (To be completed by the Screening Center **following NCI approval.**)

Staff ID#: |\_|\_|\_|\_|

Date: \_\_\_\_\_

**PLCO Cancer Screening Trial**

**SPECIFICATIONS FOR COMPLETION OF THE RECORD OF EXPERIENCE, CREDENTIALS AND TRAINING (EXAMINER/TRAINER/QUALITY ASSURANCE EXAMINER REGISTRATION FORM)**

This form is to be completed for all individuals who are to perform screening examinations for the PLCO Trial. One form should be completed for each individual. When the form is completed and approved by the NCI reviewer, it will be sent back to the Screening Center for assignment of a staff ID number. No individual may perform a screening examination for the PLCO study without a staff ID number.

**Items 1-7 are to be completed by SC staff. Specifications for completion of these items are given below.**

- 1. Screening Center ID:** Enter the 2-digit SC ID number.
- 2. Satellite Center ID:** If the staff member is to perform examinations at a satellite center, enter the 2-digit satellite center ID number. If the staff member is to perform examinations at more than one satellite center, record the ID of one satellite in the space provided and list additional satellite IDs in the margin.
- 3. Name of Staff Member to be Registered:** Enter the full (last, first, middle) name of the staff member to be registered.
- 4. Staff Position:** Place a check mark in the box next to each staff position which this individual will assume. Mark all staff positions which apply for this individual.
- 5. Experience:** For each position marked in Item 4, record the approximate total number of examinations/procedures performed or interpreted by the individual in his/her lifetime. In the case of blood processing, record the total number of years experience processing blood specimens.
- 6. Credentials:** For each position marked in Item 4, place a check mark next to the credential that qualifies the individual for this position. Attach a photocopy of the qualifying documentation requested (such as a license, board certification, etc.).

For each position, the minimum qualifications, as given in the current screening examination protocols, are listed below:

Exam	Position	Minimum Qualifications
XRY	Technician	- Certified by the ARRT
	Interpreter/QA Examiner	- ABR board certified or board eligible
DRE	Examiner	- R.N., Certified Physician's Assistant, Nurse Practitioner, Physician, or equivalent
	QA Examiner	- Licensed physician who is adequately trained and experienced in the digital rectal examination or a certified PLCO DRE examiner
	Trainer	- Board certified urologist

Exam	Position	Minimum Qualifications
FSG	Examiner	- R.N., Certified Physician's Assistant, Nurse Practitioner, Physician, or equivalent
	QA Examiner	- PLCO FSG trainer or a PLCO FSG examiner who has performed at least 240 PLCO FSG exams in the prior 12 months (average 20 per month) and achieved 50+cm insertion depth in at least 85% of cases with adequate bowel preparation
	Trainer	- Board certified gastroenterologist
OVR	As of December 1998, this exam has been discontinued	
TVU	Examiner	- Sonographer registered by the American Registry of Diagnostic Medical Sonographers (ARDMS) or certified by the ARRT, or Physician
	QA Examiner	- PLCO trainer or a PLCO TVU examiner who has performed at least 240 PLCO TVU exams in prior 12 months (average of 20 per month)
	Trainer	- Board certified radiologist with specific training in ultrasonography

If the individual is a nurse practitioner or a clinical nurse, check the box for "Registered Nurse" and attach a copy of his/her nursing license.

If the individual does not possess any of the credentials listed, but possesses some other credential which the SC feels qualifies the individual for this position, check the box next to "Other" and record the type of credential being submitted. Attach a photocopy of the documentation of this credential.

- 7. Training:** For each position marked in Item 4, place a check mark next to each training activity completed by the individual.

All Examiners, Interpreters, Trainer/Supervisors and QA Examiners must undergo training on the appropriate examination protocol and form completion. Therefore, the first two boxes of the appropriate exam type must be checked for all staff members.

In addition, training examinations must be completed by Examiners/Interpreters in accordance with the PLCO examination protocols. Check the box for the appropriate exam procedures and record the number of training exams completed.

For each examination type, the individuals required to complete training examinations and the number of required training examinations are listed below:

<u>Exam:</u>	<u>Individuals Requiring Training:</u>	<u>Required Number of Training Exams:</u>
XRY	—	None required.
DRE	all non-physician examiners	A minimum of 30 exams (including 10 on men with abnormal findings).
FSG	all examiners except board certified gastroenterologists and physicians with hospital privileges to perform flexible sigmoidoscopies or colonoscopies	A minimum of 10 procedures (observation only), a minimum of 10 procedures (withdrawal of scope only), and as many complete procedures (insertion and withdrawal) as deemed necessary by the Trainer.
TVU	all non-physician sonographers	A minimum of 50-100 prior exams (done as part of the PLCO training or elsewhere).

For individuals required to complete training examinations, the Supervisor/Trainer must attest to the fact that the training examinations were performed and that the individual is qualified to perform as a PLCO Examiner. For each position listed in Item 4, the Supervisor/Trainer should sign the statement, print his/her name and record the date of signature.

If the Principal Investigator feels that an individual's prior experience qualifies him/her to perform exams for PLCO without completing extra training examinations, s/he should attach a letter describing the prior experience and attesting to the individual's qualification to perform as a PLCO examiner.

**Item 8 is to be completed by the NCI reviewer. Specifications for completion of this item are given below.**

8. **Registration:** For each position marked in Item 4, review the experience (Item 5), credentials (Item 6), and training (Item 7) to determine whether or not the individual is qualified to perform in that position for PLCO. If so, place a check mark in the box for the appropriate position.

Sign the form and record the date of signature. In the Comments section, record any additional comments regarding this staff member.

**The following item is to be completed by the Screening Center following NCI approval. Specifications for completion of this item are given below.**

**Staff ID# Assignment:** Record the staff ID# and the date it was assigned in the space provided.

When the form is received by the SC, the Coordinator should enter the information regarding the staff member (i.e., full name, staff ID#, all positions held in the study) in the System Administration module of the SMS. Refer to the *SMS User's Guide* for information regarding the use of the System Administration module.

## **A-17-6**

A-17-6: Comments Continuation Form (CCF)

Specifications for the Comments Continuation Form



**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE**  
**COMMENTS CONTINUATION FORM (CCF)**

This form is to be completed by the Examiner when more space is needed to continue comments from an examination form, a medical record abstract form (MRA), or an Adverse Experience Report (AER).

Specifications for completing each item of the form are given below:

**Administrative Section:**

**Barcode:** This is the three-character form identifier (CCF) in barcode format. The barcode may be read by a barcode reader (wand) during the receipt of the form into the SMS.

**Participant ID:** Affix a Participant ID label to the space provided in the upper right corner of the form.

**Screening Center:** Enter the 2-digit SC ID.

**Satellite Center:** If the original form is associated with a specific satellite center, enter the 2-digit Satellite Center ID. If the original form is not associated with a specific satellite center, enter "00."

**Screening Center Staff ID:** Enter your 4-digit staff ID number.

**Study Year:** Enter the code corresponding to the study year.

**Visit Number:** Enter the visit number (1, 2, or 3). This information may be found in the administrative section of the examination form. If the CCF is not associated with an examination form, this item should be left blank.

**Date of Examination/MRA Completion/AER Completion:** Record the date the original form was completed.

- For examination forms, this is Item 1 in the administrative section, "Date of Examination."
- For MRA forms, this is Item 1 in the administrative section, "Date Abstracted."
- For AER forms, this is the first item in the administrative section, "Date Completed."

Month and day should be zero filled, and four digits should be recorded for the year (e.g., 02/07/1996).

**Comments Section:**

- Check a box to indicate the data collection form to which the comments are related.
- For examination and MRA forms: Enter the item number indicating the item on the data collection form to which the comments are related. Then enter the comments in the space provided to the right of the item number.
- For AER forms: Use this section to record the details of the adverse experience such as call logs, statements by the participant, details of diagnostic or treatment procedures, etc.

**After completing the form:**

- Keep the form together with the data collection form to which it is related.
- For examination and MRA forms: Receipt the form into the DEES after the data collection form has been scanned. File the form in the participant's folder.
- For AER forms: File the form in the participant's folder. Do not attempt to receipt the form into the DEES as there is no receipt capability in the DEES for a CCF associated with an Adverse Experience Report.

**A-17-7**

A-17-7: Protocol Violation Form

## SC Report of Protocol Violation

SC Name: \_\_\_\_\_

Reported By: \_\_\_\_\_

Today's Date: \_\_\_\_\_

**Please check the type of protocol violation below. Depending on the type of violation, please provide the information requested on all pages. Attach additional sheets as necessary.**

- \* **PLEASE COMPLETE A SEPARATE FORM FOR EACH PROTOCOL VIOLATION.**
- \* **PLEASE DO NOT INCLUDE ANY PARTICIPANT NAMES OR IDENTIFYING INFORMATION. USE PIDs OR INITIALS ONLY TO IDENTIFY PARTICIPANTS.**

### A. Randomization Violations

- **Duplicate Randomization**  
List the affected PIDs. For each PID, describe all actions that have been taken, including any forms completed, receipted, and scanned. Also describe all contact with the affected participant(s).
- **Participant Randomized with Incorrect Gender**  
List the affected PIDs. For each PID, indicate both the incorrect and the correct gender.
- **Participant Randomized with Incorrect Date of Birth**  
List the affected PIDs. For each PID, indicate both the incorrect and the correct date of birth.
- **Participant Randomized without Informed Consent**  
List the affected PIDs.

### Screening Violations

- **Participant Screened without SCF**  
List the affected PIDs.
- **Participant Screened without PCC**  
List the affected PIDs.
- **Screening of a Control Participant**  
List the affected PIDs. For each PID, indicate the study year, exam results, forms completed, receipted and scanned, referral information and any participant contact.
- **Inappropriate Screening of a Participant (i.e confirmed PLCO cancer or missing PLCO organ)**  
List the affected PIDs. For each PID, indicate the reason the screening was not appropriate, the study year, exam results, forms completed, receipted and scanned, referral information and any participant contact.
- **Screened Exam not Completed According to Protocol (e.g., performance of exam by non- PLCO examiner, lateral and PA Chest X-Ray, Colonoscope used instead of Flexible Sigmoidoscope)**  
List the affected PID. For each PID, indicate the study year and the exam type.

### Results Violations

- **Exam Result Miscoded, Incorrect Result Sent to Participant, Results Delayed or Never Sent to Participant, Recommendations for Specific Diagnostic Follow-up Procedures Given to Ppt**  
List the affected PIDs. For each PID, indicate the study year, form type, incorrect result, correct result, date STRR sent and any other contact with the participant.

- **Worst Case not Reported when QA Exam, Result Code Assigned Based on Comparison to Previous Results**

List the affected PIDs. For each PID, indicate the study year, form type, incorrect result, correct result, date STRR sent and any other contact with the participant

Forms Violations

- **Missing or Lost Forms**

List the affected PIDs. For each PID, indicate the study year, type of form(s), form receipted and scanned, referral information and any participant contact

- **Mislabeled Form (e.g. DHQ, HSQ, ASU, FLF—either wrong PID on form or incorrect participant information on form)**

List the affected PIDs. For each PID indicate the study year, type of form, form receipted and scanned, and any participant contact

Blood Violations

- **Outside Protocol for Blood Draw or Processing of Blood Samples**

List the affected PIDs and Sample IDs, study year, transmittal dates, and ship dates. Indicate whether or not test results were sent to the participant. Indicate whether the BCF has been receipted in SMS and scanned in DEES

- **Incorrect Labeling of BCF/Blood Vials, Incorrect Shipment**

List the affected PIDs and Sample IDs, study year, transmittal dates, and ship dates. Indicate whether or not test results were sent to the participant. Indicate whether the BCF has been receipted in SMS and scanned in DEES.

- **Biorepository blood drawn without an ESC**

List the affected PIDs.

Buccal Cell

- **Buccal cells collected without an ESC**

List the affected PIDs.

Not a PV

- **NPV**

PID mistakenly identified as PV when no violation has occurred.

Other

- **Other (This includes any error not listed above. Some examples are: screening a non-randomized individual, neglecting to screen an intervention participant due to SC error, mislabeling of exam forms other than the BCF), etc.)**

B. List the affected PIDs. For each PID, describe all actions that have been taken, including any forms completed, receipted, and scanned. Also describe all contact with the affected participant(s). If there are more than 5 PIDs or Sample IDs involved, then continue on another form.

<u>PID(s)</u>	<u>Rand Group (C or I)</u>	<u>Rand Date</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

C. Please record the information requested for the violation checked above.

---

---

---

---

---

---

---

---

D. Please describe how the error occurred and how you discovered it. If applicable, identify any system reports that led to the discovery.

---

---

---

---

---

---

---

---

---

---

E. Describe any corrective actions you have taken or plan to take. **[NOTE: Do not make any changes in SMS or DEES to correct the error unless directed to do so by Westat User Support]**

---

---

---

---

---

---

---

---

---

---

F. Is corrective action by Westat required? (CHECK ONE)    ● Yes            ● No            ● Don't Know

If Yes, please describe the Westat action you feel is required:

---

---

---

---

---

---

---

---

---

---



## **A-17-8**

A-17-8: Health Status Questionnaire for Male Participants (HSM)

Specifications for the Health Status Questionnaire for Male Participants

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE MEN'S HEALTH STATUS**  
**QUESTIONNAIRE (HSM)**

This form is designed for self-administration by all male participants selected for the contamination survey. However, if the participant has difficulty completing the form, an SC staff member may assist the participant (by telephone or in person). Furthermore, if the participant does not return a completed questionnaire within three weeks of the initial mailing, an SC staff member may administer the questionnaire by telephone or, in a rare situation, administer the questionnaire in person. The specifications include guidelines for the completion of each question on the form, whether it is completed by the participant or by some other person. All items on the questionnaire are considered critical and therefore, require data retrieval. Specifications for each item on the form are given below:

**Form Type:** This information will be pre-printed in barcode format. The letters "HSM" will also be pre-printed below the barcode. The barcode may be read by a barcode reader (wand) during receipt of the form into the SMS.

**Participant ID and Study Year:** The PID and study year will be printed on labels in both numeric format and in barcode format. The CC will affix the labels to each page of the HSM. If an SC uses an "unintelligent" version of the form, the SC must affix a PID label to each page of the HSM in the boxes provided. The barcodes may be read by a barcode reader (wand) during receipt of the form into the SMS.

1. **Date of Birth:** Instruct the participant to enter the month, day, and year he was born.

**PHYSICAL EXAMINATIONS:**

This section of the questionnaire is concerned with the participant's past physical examinations, when the examinations occurred, and the reason for the examinations. The participant should mark only one response for each question on this form.

- 2a. Have you ever had an eye examination for glaucoma or cataracts?

Glaucoma is a disease of the eye characterized by high pressure within the eyeball, damage to the optic disk, hardening of the eyeball, and partial or complete loss of vision. Cataracts involve opacity of the lens of the eye, causing partial or total blindness.

Mark the appropriate response. If "No" or "Don't Know", skip to 3a.

- 2b. When did you have your most recent eye examination for glaucoma or cataracts?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know".

- 2c. What was the main reason you had this eye examination for glaucoma or cataracts?

We are interested here in why the participant had an eye examination for glaucoma or cataracts. Mark the box for the appropriate reason. The possible reasons include the following:

*Because of a specific eye problem:* The participant had an eye exam for glaucoma or cataracts due to a particular eye problem, not as part of a regular or routine physical or eye exam and not as part of a follow-up exam for a pre-existing or past eye problem for which he has previously had an exam.

*Follow-up to a previous eye problem:* The participant had an eye exam for glaucoma or cataracts due to a previous eye problem and for follow-up purposes only. The exam was not due to a new eye problem or part of a regular or routine physical or eye exam.

*Part of a routine physical exam:* The participant had an eye exam for glaucoma or cataracts during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific eye problem or as a follow-up exam due to a specific eye problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

*Part of a routine eye exam:* The participant had an eye exam for glaucoma or cataracts as a regular and routine—usually annual—eye examination or check-up.

**3a.** Have you ever had a chest x-ray?

This does not include diagnostic procedures, such as a GI series or a CT scan.

Mark the appropriate response. If "No" or "Don't Know," skip to 4a.

**3b.** When did you have your most recent chest x-ray?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**3c.** What was the main reason you had this chest x-ray?

Mark the box for the appropriate reason for his chest x-ray. The possible reasons include the following:

*Because of a specific health problem:* The participant had a chest x-ray due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a chest x-ray due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a chest x-ray during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific chest problem or as a follow-up exam due to a specific chest problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**4a.** Have you ever had a digital rectal examination of the prostate?

During a DRE exam, a doctor or health care provider inserts a gloved finger into the rectum to feel for abnormalities of the prostate gland.

Mark the appropriate response. If "No" or "Don't Know," skip to 5a.

**4b.** When did you have your most recent digital rectal examination of the prostate?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**4c.** What was the main reason you had this digital rectal examination of the prostate?

Mark the box indicating the appropriate reason for his digital rectal examination. The possible reasons include the following:

*Because of a specific prostate problem:* The participant had a digital rectal examination of the prostate due to a particular prostate problem, not as part of a regular or

routine physical exam and not as part of a follow-up exam for a pre-existing or past prostate problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a digital rectal examination of the prostate due to a previous health problem and for follow-up purposes only. The exam was not due to a new prostate or health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a digital rectal examination of the prostate during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific prostate problem or as a follow-up exam due to a specific prostate problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**5a.** Have you ever had a barium enema to examine your colon and rectum?

A barium enema involves drinking a white, chalky liquid containing barium and taking x-rays of the colon and rectum.

Mark the appropriate response. If "No" or "Don't Know," skip to 6a.

**5b.** When did you have your most recent barium enema to examine your colon and rectum?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**5c.** What was the main reason you had this barium enema to examine your colon and rectum?

Mark the box indicating the appropriate reason for the barium enema. The possible reasons include the following:

*Because of a specific health problem:* The participant had a barium enema to examine the colon and rectum due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a barium enema to examine the colon and rectum due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a barium enema to examine the colon and rectum during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**6a.** Have you ever had a flexible sigmoidoscopy examination of your colon and rectum?

A flexible sigmoidoscopy examination involves the insertion of a thin, lighted viewing instrument into the rectum to look at the rectum and partial length of the colon.

Mark the appropriate response. If "No" or "Don't Know," skip to 7a.

**6b.** When did you have your most recent flexible sigmoidoscopy examination of your colon and rectum?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

- 6c.** What was the main reason you had this flexible sigmoidoscopy examination of your colon and rectum?

Mark the box indicating the appropriate reason for the flexible sigmoidoscopy examination. The possible reasons include the following:

*Because of a specific health problem:* The participant had a flexible sigmoidoscopy examination of the colon and rectum due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a flexible sigmoidoscopy examination of the colon and rectum due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a flexible sigmoidoscopy examination of the colon and rectum during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

- 7a.** Have you ever had a colonoscopic examination of your colon and rectum?

A colonoscopy is a procedure in which a doctor or health care provider inserts a long, flexible viewing tube into the rectum to inspect the rectum and the entire length of the colon.

Mark the appropriate response. If "No" or "Don't Know," skip to 8a.

- 7b.** When did you have your most recent colonoscopic examination of your colon and rectum?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

- 7c.** What was the main reason you had this colonoscopic examination of your colon and rectum?

Mark the box indicating the appropriate reason for the colonoscopic examination. The possible reasons include the following:

*Because of a specific health problem:* The participant had a colonoscopic examination of the colon and rectum due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a colonoscopic examination of the colon and rectum due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a colonoscopic examination of the colon and rectum during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the

participant's regular office visit. An insurance physical is considered a routine physical exam.

**8a.** Have you ever had your blood pressure checked?

Mark the appropriate response. If "No" or "Don't Know," skip to 9a.

**8b.** When did you have your most recent blood pressure check?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**8c.** What was the main reason you had this blood pressure check?

Mark the box indicating the appropriate reason for the blood pressure check. The possible reasons include the following:

*Because of a specific health problem:* The participant had his blood pressure checked due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had his blood pressure checked due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had his blood pressure checked during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

### **BLOOD TESTS:**

This section of the questionnaire is concerned with blood tests the participant may have had, when he had the tests, and the reason for the tests. Again, the participant should mark only one response for each question.

**9a.** Have you ever had a test to check your blood cholesterol level?

Mark the appropriate response. If "No" or "Don't Know," skip to 10a.

**9b.** When did you have your most recent test to check your blood cholesterol level?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**9c.** What was the main reason you had this test to check your blood cholesterol level?

Mark the box indicating the appropriate reason for the blood cholesterol test. The possible reasons include the following:

*Because of a specific health problem:* The participant had a blood cholesterol test due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a blood cholesterol test due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a blood cholesterol test during the course of and as part of a regular physical exam. The exam was not performed as

a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**10a.** Have you ever had a test to check your blood glucose (sugar) level?

Mark the appropriate response. If "No" or "Don't Know," skip to 11a.

**10b.** When did you have your most recent test to check your blood glucose (sugar) level?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**10c.** What was the main reason you had this test to check your blood glucose (sugar) level?

Mark the box indicating the appropriate reason for the blood glucose level test. The possible reasons include the following:

*Because of a specific health problem:* The participant had a test to check his blood glucose level due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a test to check his blood glucose level due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a test to check his blood glucose level during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**11a.** Have you ever had a PSA blood test for prostate cancer?

This blood test for prostate cancer measures the amount of prostate-specific antigens in the blood.

Mark the appropriate response. If "No" or "Don't Know," skip to question 12.

**11b.** When did you have your most recent PSA blood test for prostate cancer?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**11c.** What was the main reason you had this PSA blood test for prostate cancer?

Mark the box indicating the appropriate reason for the PSA blood test. The possible reasons include the following:

*Because of a specific prostate problem:* The participant had a PSA blood test for prostate cancer due to a particular prostate problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past prostate problem for which he has previously had an exam.

*Follow-up to a previous health problem:* The participant had a PSA blood test for prostate cancer due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a PSA blood test for prostate cancer during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

- 12. Today's Date:** This is the date the form is completed. Instruct the participant to enter the month, day, and year. Month and day should be zero filled, if applicable, and the year should be four digits.

*SC Instructions: If this item is incomplete or not answered, use the date of receipt of the form as the date of completion according to the following guidelines:*

- 1. If the participant left all parts of the date blank (month, day, and year), replace the blanks with the full receipt date (month, day, and year). Record this date in another color ink in the space provided.*
- 2. If the participant wrote a partial date (e.g., month, day only) or a partially incorrect date (e.g., month and day fall prior to date questionnaire was sent to him/her), replace what the participant wrote with the full receipt date (month, day, and year). Record this date in another color ink in the white space near the participant's response. Do not replace part(s) of the completion date with part(s) of the receipt date.*
- 3. In the For Office Use Only box at the bottom of the page, check the box indicating that the completion date is estimated (see below).*

#### **ADMINISTRATIVE SECTION (FOR OFFICE USE ONLY):**

This section is to be completed by the SC staff.

- 1.** Method of Administration: Check the box corresponding to the method of administration of the Men's Health Status Questionnaire. Definitions of methods of administration are as follows:

**Self-Administered:** The participant completed the questionnaire by himself without assistance. Unless the SC staff becomes aware that the participant did not complete the form himself without assistance, it should be assumed that the questionnaire was self-administered.

**Self-Administered with Assistance:** The participant completed the questionnaire by himself (i.e., it was not administered to him) but required assistance from another person (relative, friend, SC staff member) to clarify one or more of the questions or to physically complete the form.

**Telephone Administered:** The questionnaire was administered to the participant by telephone by an SC staff member.

**In-Person Interview:** The questionnaire was administered to the participant in person by an SC staff member.

- 2.** Estimated Date of Completion: Check the box if the date of completion is estimated (i.e., the receipt date was recorded by the SC staff according to the specifications for #12 above).

## **A-17-9**

**A-17-9: Health Status Questionnaire for Female Participants (HSW)**

**Specifications for the Health Status Questionnaire for Female Participants**

**PLCO Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE WOMEN'S HEALTH STATUS**  
**QUESTIONNAIRE (HSW)**

This form is designed for self-administration by all female participants selected for the contamination survey. However, if the participant has difficulty completing the form, an SC staff member may assist the participant (by telephone or in person). Furthermore, if the participant does not return a completed questionnaire within three weeks of the initial mailing, an SC staff member may administer the questionnaire by telephone or, in a rare situation, administer the questionnaire in person. The specifications include guidelines for the completion of each question on the form, whether it is completed by the participant or by some other person. All items on the questionnaire are considered critical and therefore, require data retrieval. Specifications for each item on the form are given below:

**Form Type:** This information will be pre-printed in barcode format. The letters "HSW" will also be pre-printed below the barcode. The barcode may be read by a barcode reader (wand) during receipt of the form into the SMS.

**Participant ID and Study Year:** The PID and study year will be printed on labels in both numeric format and in barcode format. The CC will affix the labels to each page of the HSW. If an SC uses an "unintelligent" version of the form, the SC must affix a PID label to each page of the HSW in the boxes provided. The barcodes may be read by a barcode reader (wand) during receipt of the form into the SMS.

1. **Date of Birth:** Instruct the participant to enter the month, day, and year she was born.

**PHYSICAL EXAMINATIONS:**

This section of the questionnaire is concerned with the participant's past physical examinations, when the examinations occurred, and the reason for the examinations. The participant should mark only one response for each question on this form.

- 2a. Have you ever had an eye examination for glaucoma or cataracts?

Glaucoma is a disease of the eye characterized by high pressure within the eyeball, damage to the optic disk, hardening of the eyeball, and partial or complete loss of vision. Cataracts involve opacity of the lens of the eye, causing partial or total blindness.

Mark the appropriate response. If "No" or "Don't Know," skip to 3a.

- 2b. When did you have your most recent eye examination for glaucoma or cataracts?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

- 2c. What was the main reason you had this eye examination for glaucoma or cataracts?

We are interested here in why the participant had an eye examination for glaucoma or cataracts. Mark the box for the appropriate reason. The possible reasons include the following:

*Because of a specific eye problem:* The participant had an eye exam for glaucoma or cataracts due to a particular eye problem, not as part of a regular or routine physical or eye exam and not as part of a follow-up exam for a pre-existing or past eye problem for which she has already had an exam.

*Follow-up to a previous eye problem:* The participant had an eye exam for glaucoma or cataracts due to a previous eye problem and for follow-up purposes only. The exam was not due to a new eye problem or part of a regular or routine physical or eye exam.

*Part of a routine physical exam:* The participant had an eye exam for glaucoma or cataracts during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific eye problem or as a follow-up exam due to a specific eye problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

*Part of a routine eye exam:* The participant had an eye exam for glaucoma or cataracts as part of a regular and routine—usually annual—eye examination or check-up.

**3a.** Have you ever had a chest x-ray?

This does not include diagnostic procedures, such as a GI series or a CT scan.

Mark the appropriate response. If "No" or "Don't Know," skip to 4a.

**3b.** When did you have your most recent chest x-ray?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**3c.** What was the main reason you had this chest x-ray?

Mark the box for the appropriate reason for her chest x-ray. The possible reasons include the following:

*Because of a specific health problem:* The participant had a chest x-ray due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a chest x-ray due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a chest x-ray during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific chest problem or as a follow-up exam due to a specific chest problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**4a.** Have you ever had a pelvic examination?

A pelvic examination is defined as a routine gynecological exam, with or without a PAP smear.

Mark the appropriate response. If "No" or "Don't Know," skip to 5a.

**4b.** When did you have your most recent pelvic examination?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**4c.** What was the main reason you had this pelvic examination?

Mark the box indicating the appropriate reason for her pelvic examination. The possible reasons include the following:

*Because of a specific health problem:* The participant had a pelvic examination due to a particular health problem, not as part of a regular or routine physical exam and

not part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a pelvic examination due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a pelvic examination during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**5a.** Have you ever had a transvaginal ultrasound examination?

A TVU exam involves the use of high-frequency waves to visualize the ovaries.

Mark the appropriate response. If "No" or "Don't Know," skip to 6a.

**5b.** When did you have your most recent transvaginal ultrasound examination?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**5c.** What was the main reason you had this transvaginal ultrasound examination?

Mark the box indicating the appropriate reason for her transvaginal ultrasound examination. The possible reasons include the following:

*Because of a specific health problem:* The participant had a transvaginal ultrasound examination due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a transvaginal ultrasound examination due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a transvaginal ultrasound examination during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**6a.** Have you ever had a mammogram?

A mammogram is an x-ray photograph of the breast. This question includes mammograms performed for any reason.

Mark the appropriate response. If "No" or "Don't Know," skip to 7a.

**6b.** When did you have your most recent mammogram?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**6c.** What was the main reason you had this mammogram?

Mark the box indicating the appropriate reason for her mammogram. The possible reasons include the following:

*Because of a specific breast problem:* The participant had a mammogram due to a particular breast problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past breast problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a mammogram due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a mammogram during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**7a.** Have you ever had a barium enema to examine your colon and rectum?

A barium enema involves drinking a white, chalky liquid containing barium and taking x-rays of the colon and rectum.

Mark the appropriate response. If "No" or "Don't Know," skip to 8a.

**7b.** When did you have your most recent barium enema to examine your colon and rectum?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**7c.** What was the main reason you had this barium enema to examine your colon and rectum?

Mark the box indicating the appropriate reason for the barium enema. The possible reasons include the following:

*Because of a specific health problem:* The participant had a barium enema to examine the colon and rectum due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a barium enema to examine the colon and rectum due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a barium enema to examine the colon and rectum during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**8a.** Have you ever had a flexible sigmoidoscopy examination of your colon and rectum?

A flexible sigmoidoscopy examination involved the insertion of a thin, lighted viewing instrument into the rectum to look at the rectum and partial length of the colon.

Mark the appropriate response. If "No" or "Don't Know," skip to 9a.

**8b.** When did you have your most recent flexible sigmoidoscopy examination of your colon and rectum?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

- 8c.** What was the main reason you had this flexible sigmoidoscopy examination of your colon and rectum?

Mark the box indicating the appropriate reason for the flexible sigmoidoscopy examination. The possible reasons include the following:

*Because of a specific health problem:* The participant had a flexible sigmoidoscopy examination of the colon and rectum due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a flexible sigmoidoscopy examination of the colon and rectum due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a flexible sigmoidoscopy examination of the colon and rectum during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

- 9a.** Have you ever had a colonoscopic examination of your colon and rectum?

A colonoscopy is a procedure in which a doctor or health care provider inserts a long, flexible viewing tube into the rectum to inspect rectum and the entire length of the colon.

Mark the appropriate response. If "No" or "Don't Know," skip to 10a.

- 9b.** When did you have your most recent colonoscopic examination of your colon and rectum?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

- 9c.** What was the main reason you had this colonoscopic examination of your colon and rectum?

Mark the box indicating the appropriate reason for the colonoscopic examination. The possible reasons include the following:

*Because of a specific health problem:* The participant had a colonoscopic examination of the colon and rectum due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a colonoscopic examination of the colon and rectum due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a colonoscopic examination of the colon and rectum during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the

participant's regular office visit. An insurance physical is considered a routine physical exam.

**10a.** Have you ever had your blood pressure checked?

Mark the appropriate response. If "No" or "Don't Know," skip to 11a.

**10b.** When did you have your most recent blood pressure check?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**10c.** What was the main reason you had this blood pressure check?

Mark the box indicating the appropriate reason for the blood pressure check. The possible reasons include the following:

Because of a specific health problem: The participant had her blood pressure checked due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

Follow-up to a previous health problem: The participant had her blood pressure checked due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

Part of a routine physical exam: The participant had her blood pressure checked during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

### **BLOOD TESTS:**

This section of the questionnaire is concerned with blood tests the participant may have had, when she had the tests, and the reason for the tests. Again, the participant should mark only one response for each question.

**11a.** Have you ever had a test to check your blood cholesterol level?

Mark the appropriate response. If "No" or "Don't Know," skip to 12a.

**11b.** When did you have your most recent test to check your blood cholesterol level?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**11c.** What was the main reason you had this test to check your blood cholesterol level?

Mark the box indicating the appropriate reason for the blood cholesterol test. The possible reasons include the following:

Because of a specific health problem: The participant had a blood cholesterol test due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

Follow-up to a previous health problem: The participant had a blood cholesterol test due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

Part of a routine physical exam: The participant had a blood cholesterol test during the course of and as part of a regular physical exam. The exam was not performed as

a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**12a.** Have you ever had a test to check your blood glucose (sugar) level?

Mark the appropriate response. If "No" or "Don't Know," skip to 13a.

**12b.** When did you have your most recent test to check your blood glucose (sugar) level?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**12c.** What was the main reason you had this test to check your blood glucose (sugar) level?

Mark the box indicating the appropriate reason for the blood glucose level test. The possible reasons include the following:

*Because of a specific health problem:* The participant had a test to check her blood glucose level due to a particular health problem, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past health problem for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a test to check her blood glucose level due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

*Part of a routine physical exam:* The participant had a test to check her blood glucose level during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

**13a.** Have you ever had a CA-125 blood test for ovarian cancer?

CA-125 is a substance in the blood called a tumor marker that can be produced by ovarian cancer cells.

Mark the appropriate response. If "No" or "Don't Know," skip to 14.

**13b.** When did you have your most recent CA-125 blood test for ovarian cancer?

Read the response categories exactly as they are written. Mark the appropriate response. If the participant does not know, mark "Don't Know."

**13c.** What was the main reason you had this CA-125 blood test for ovarian cancer?

Mark the box indicating the appropriate reason for the CA-125 blood test. The possible reasons include the following:

*Because of a specific problem with your ovaries:* The participant had a CA-125 blood test for ovarian cancer due to a particular problem with her ovaries, not as part of a regular or routine physical exam and not as part of a follow-up exam for a pre-existing or past problem with her ovaries for which she has already had an exam.

*Follow-up to a previous health problem:* The participant had a CA-125 blood test for ovarian cancer due to a previous health problem and for follow-up purposes only. The exam was not due to a new health problem or part of a regular or routine physical exam.

Part of a routine physical exam: The participant had a CA-125 blood test for ovarian cancer during the course of and as part of a regular physical exam. The exam was not performed as a result of a specific health problem or as a follow-up exam due to a specific health problem, but as one of many routine checks during the participant's regular office visit. An insurance physical is considered a routine physical exam.

- 14. Today's Date:** This is the date the form is completed. Instruct the participant to enter the month, day, and year. Month and day should be zero filled, if applicable, and the year should be four digits.

*SC Instructions: If this item is incomplete or not answered, use the date of receipt of the form as the date of completion according to the following guidelines:*

- 1. If the participant left all parts of the date blank (month, day, and year), replace the blanks with the full receipt date (month, day, and year). Record this date in another color ink in the space provided.*
- 2. If the participant wrote a partial date (e.g., month, day only) or a partially incorrect date (e.g., month and day fall prior to date questionnaire was sent to her), replace what the participant wrote with the full receipt date (month, day, and year). Record this date in another color ink in the white space near the participant's response. Do not replace part(s) of the completion date with part(s) of the receipt date.*
- 3. In the For Office Use Only box at the bottom of the page, check the box indicating that the completion date is estimated (see below).*

#### **ADMINISTRATIVE SECTION (FOR OFFICE USE ONLY):**

This section is to be completed by the SC staff.

- 1.** Method of Administration: Check the box corresponding to the method of administration of the Women's Health Status Questionnaire. Definitions of methods of administration are as follows:

**Self-Administered:** The participant completed the questionnaire by herself without assistance. Unless the SC staff becomes aware that the participant did not complete the form herself without assistance, it should be assumed that the questionnaire was self-administered.

**Self-Administered with Assistance:** The participant completed the questionnaire by herself (i.e., it was not administered to her) but required assistance from another person (relative, friend, SC staff member) to clarify one or more of the questions or to physically complete the form.

**Telephone Administered:** The questionnaire was administered to the participant by telephone by an SC staff member.

**In-Person Interview:** The questionnaire was administered to the participant in person by an SC staff member.

- 2.** Estimated Date of Completion: Check the box if the date of completion is estimated (i.e., the receipt date was recorded by the SC staff according to the specifications for #14 above).

## **A-17-10**

**A-17-10: Record of Credentials, Medical Record  
Abstractor and Nosologist Registration Form (CAN)**

**Specifications for the Record of Credentials, Medical  
Record Abstractor and Nosologist Registration Form**



**6. TRAINING:** (Complete for all that apply. The required training on protocols and forms must be documented for each Medical Record Abstractor and Nosologist position marked in Question 4.)

- PLCO Protocol for Abstracting (MOOP, Appendix K)
- PLCO Diagnostic Evaluation Form-Prostate
- PLCO Treatment Information Form-Prostate
- PLCO Diagnostic Evaluation Form-Lung
- PLCO Treatment Information Form-Lung
- PLCO Diagnostic Evaluation Form-Colorectum
- PLCO Treatment Information Form-Colorectum
- PLCO Diagnostic Evaluation Form-Ovary
- PLCO Treatment Information Form-Ovary

This staff member has completed the required training and is qualified to perform PLCO medical record abstracting and/or coding.

SC Coordinator or Principal Investigator Signature: \_\_\_\_\_

SC Coordinator or Principal Investigator Name (Please print): \_\_\_\_\_

Date: \_\_\_\_\_

**7. REGISTRATION:** (To be completed by the NCI Reviewer) This individual is qualified to perform as a PLCO: (Please mark all that apply)

- Medical Record Abstractor
- Nosologist, ICD9-CM Coder
- Nosologist, ICD-0 Coder
- Nosologist, TNM Staging Coder

Signature of NCI Reviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**8. STAFF ID# ASSIGNMENT:** (To be completed by the Screening Center **after** NCI approval)

Staff ID#: 

--	--	--	--

Date: \_\_\_\_\_

## PLCO Cancer Screening Trial

### **SPECIFICATIONS FOR COMPLETION OF RECORD OF CREDENTIALS (MEDICAL RECORD ABTRACTOR AND NOSOLOGIST) REGISTRATION FORM (CAN)**

The CAN is to be completed by the Screening Center Principal Investigator or Coordinator for all individuals who are to perform medical record abstraction and/or medical coding for the PLCO trial. One form should be completed for each individual. When the form is completed and approved by the NCI Reviewer, it will be sent to the Screening Center for assignment of a staff ID number. No individual may perform medical record abstraction or medical coding for the PLCO study without a staff ID number.

**Questions 1-6 are to be completed by SC staff. Specifications for the completion of these questions are given below.**

- 1. Screening Center ID:** Enter the 2-digit SC ID number.
- 2. Satellite Center ID:** If the staff member will not be working in a satellite center leave these boxes blank. If the staff member is to perform abstraction or coding at a satellite center, enter the 2-digit satellite center ID number. If the staff member is to perform abstraction or coding at more than one satellite center, record the ID of one satellite in the space provided and list the additional satellite IDs in the margin.
- 3. Name of Staff Member to be Registered:** Enter the full name (Last, First, Middle) of the staff member to be registered.
- 4. Staff Position:** Place a check mark in the box next to each staff position that this individual will assume. Mark all staff positions that apply for this individual.
- 5. Credentials and Experience:** For each position marked in Question 4, place a check mark in the box next to the credential(s) and/or experience that qualifies the individual for this position. Attach a photocopy of any qualifying documentation (such as a license, accreditation certificate, etc.).

For each position, the minimum qualifications, as given in the October 1997 Manual of Operations and Procedures (MOOP), are listed below. If the individual does not possess any of the credentials listed, but possesses some other credential or prior experience that qualifies him/her to perform abstracting or coding for PLCO, check the box next to "Other" and record the type of credential(s) being submitted or describe the individual's experience. For any credential specified, attach a photocopy of the documentation of the credential. For any individual who does not possess the credentials required, the Principal Investigator must submit a letter to attest to the individual's qualifications to perform as a PLCO abstractor or coder.

Position	Minimum Qualifications
Medical Record Abstractor	<ul style="list-style-type: none"> <li>• At least 2 years on the job experience abstracting medical records.</li> <li>• Demonstrated knowledge of medical record terminology, anatomy, and physiology.</li> </ul>
Nosologist, ICD9-CM Coding	<ul style="list-style-type: none"> <li>• Certified Coding Specialist (CCS), Registered Health Information Technician (RHIT), or Registered Health Information Administrator (RHIA).</li> <li>• Medical background, including knowledge of medical terminology, anatomy, physiology, and concepts of disease.</li> </ul>
Nosologist, ICD-O Coding	<ul style="list-style-type: none"> <li>• Certified Tumor Registrar (CTR) or CTR eligible</li> <li>• Medical background, including knowledge of medical terminology, anatomy, physiology, and concepts of disease.</li> </ul>
Nosologist, TNM Staging Coder	<ul style="list-style-type: none"> <li>• Certified Tumor Registrar (CTR) or CTR eligible</li> <li>• Medical background, including knowledge of medical terminology, anatomy, physiology, and concepts of disease.</li> </ul>

- 6. Training:** For each position marked in Question 4, place a check mark next to each training activity completed by the individual. All Medical Record Abstractors and Nosologists must undergo training on the appropriate protocols and form completion.

For individuals required to perform abstraction and coding, the SC Coordinator or Principal Investigator must attest to the fact that the training was performed and that the individual is qualified to perform as a PLCO abstractor or coder. For each position marked in Question 4, the SC Coordinator or Principal Investigator should sign the statement, print his/her name and record the date of signature.

**Question 7 is to be completed by the NCI Reviewer. Specifications for the completion of this question are given below.**

- 7. Registration:** For each position marked in Question 4, review the credentials and experience (Question 5) as well as the training (Question 6) to determine whether or not the individual is qualified to perform in that position for PLCO. If so, place a check mark in the box for the appropriate position.

Sign the form and record the date of signature. In the Comments section, record any additional comments regarding this staff member.

**Question 8 is to be completed by the Screening Center following NCI approval of staff member. Specifications for completion of this item are given below.**

- 8. Staff ID# Assignment:** Record the 4-digit staff ID number and the date it was assigned in the space provided.

When the form is received by the SC, the coordinator should enter the information regarding the staff member (i.e., full name, staff ID#, and all positions held in the study) in the System Administration module of SMS. Refer to the *SMS User's Guide* for information regarding the use of the System Administration module.

## **A-17-11**

A-17-11: Adverse Events Report (AER)

Report of Adverse Events for NIH-Sponsored Clinical  
Trials

Specifications for the Report of Adverse Events for  
NIH-Sponsored Clinical Trials

# Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

## REPORT OF ADVERSE EVENTS FOR NIH-SPONSORED CLINICAL TRIALS

Screening Center: ..... |\_\_|\_\_|

Screening Center Staff ID: ..... |\_\_|\_\_|\_\_|\_\_|

Date Event Occurred: .... |\_\_|\_\_|\_|-|\_\_|\_\_|\_|-|\_\_|\_\_|\_\_|\_\_|  
MO DY YEAR

Date Reported to SC: .... |\_\_|\_\_|\_|-|\_\_|\_\_|\_|-|\_\_|\_\_|\_\_|\_\_|  
MO DY YEAR



Participant ID Label

**INSTRUCTIONS:** Please refer to the Specifications for Completion of the Report of Adverse Events for NIH- Sponsored Clinical Trials. (Please attach copies of any relevant exam forms, AE reports, or other documentation regarding the event)

1. Category of Event: (Check all that apply)

- Death
- Life-threatening event
- Inpatient hospitalization
- Persistent or significant disability/incapacity
- Medical or surgical intervention to prevent one of the above outcomes
- Other: \_\_\_\_\_

2. Description of participant who experienced the adverse event, such as gender, age, etc. (no identifiers):

---

---

---

3. Brief description of event:

---

---

---

4. Description of the outcome of the event:

---

---

---

5. Using your best judgement, do you believe that the adverse event was related to one of the screening examinations?

- Yes, study related
- Possibly study related
- Not study related
- Unknown

6. Do you feel revision to the informed consent document is necessary?

- Yes, revision of the informed consent form is necessary
- Possible revision of the informed consent form is necessary
- No revision of the informed consent form is necessary
- Unknown

Investigator's signature and date: \_\_\_\_\_

Investigator's Printed Last Name and Initial: \_\_\_\_\_

## PLCO Cancer Screening Trial

# SPECIFICATIONS FOR COMPLETION OF THE REPORT OF ANNUAL STUDY UPDATE (ASU) ADVERSE EVENTS FOR NIH-SPONSORED CLINICAL TRIALS

The Report of Adverse Events for NIH-Sponsored Clinical Trials is to be completed for all serious adverse events that are a direct result of the screening procedures performed by PLCO. The SCs should use the following criteria to determine whether or not the event should be classified as serious:

- Death
- Life threatening
- Inpatient hospitalization
- Persistent or significant disability/incapacity
- Medical or surgical intervention to prevent one of the above outcomes
- Other (Specify).

The specifications for completing each question are listed below:

**Name of Center:** Enter the name of the Screening Center where the participant was enrolled at the time of the event.

**Screening center staff ID:** Enter the identification number of the screening center staff member who completed the form.

**Date event occurred:** Enter the date in MM/DD/YYYY format. This should be the date that the participant received the PLCO screening exam that is considered the cause of the event.

**Date event was reported to Screening Center:** Enter the date in MM/DD/YYYY format. This should be the date that the SC received a report of an event. This should be the same date the event occurred.

**1. Category of event:** Check all categories that describe the event.

- Death: This category should be used if the participant died as a result of his/her participation in the PLCO Trial.
- Life threatening event: This category should be used if the participant experience events such as cardiac/respiratory arrest, cardiac arrhythmia, significant blood loss, etc.
- In-patient hospitalization: This category should be used if the event required the participant to be hospitalized. This would include visits to the emergency room during which the participant was admitted to the hospital.
- Persistent or significant disability/incapacity: This category includes events that caused the participant a significant reduction in daily functioning and activities. This would include any paralysis or loss of organ function.
- Medical or surgical intervention to prevent one of the above outcomes: This category should be used if the participant required a major medical or surgical intervention as a result of the event. This would include surgery performed or medication given to repair internal injury or organ damage caused by the participant's involvement in the PLCO Trial.
- Other: If none of the above categories describe the event, this "other" option should be used. The SC should enter a more appropriate category on the line.

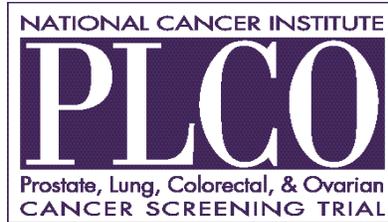
Questions 5 and 6 ask for a description of the event and its outcome so there is no need to include a lengthy description on this specify line.

2. **Description of participant who experienced the adverse event:** Include items such as gender, age and race. It is also important to note any other characteristics of the participant that may have played a role in the event, such as comorbidities or medications. Note: please be sure that this description does not contain any participant identifiers.
3. **Brief description of event:** This item should include any symptoms that the participant reported, the timing of the onset of these symptoms, and the manner in which the SC became aware of the event.
4. **Description of the outcome of the event:** This should be a description of any medical interventions that the participant received and their outcome. Any persistent or significant disability/incapacity (as described above) should be described here as well.
5. **Do you believe that the adverse event was related to one of the screening examinations?:** The SC PI should decide whether or not the event reported by the participant was related to their involvement in the PLCO Trial. The four responses are:
  - Yes, study related: This should be used if the PI feels certain that the event occurred as a result of the participant's PLCO screening exam.
  - Possibly study related: This means that the PI is not certain that the event occurred as a result of the participant's PLCO involvement but it is likely.
  - Not study related: This should be used if the PI feels certain that the event did not occur as a result of the participant's PLCO screening exam.
  - Unknown: The PI is unsure if the event was related to the PLCO screening exam, this response should be used.
6. **Do you feel revision to the informed consent document is necessary?:** The SC PI should decide whether or not the event warrants revision of the PLCO consent forms to mention it as a possible danger. The four responses are:
  - Yes, revision of the informed consent document is necessary: This should be used if the PI feels certain that all participants should be made aware of the potential danger.
  - Possible revision of the informed consent document is necessary: This means that the PI is not certain that all participants should be made aware of the potential danger but it may be necessary.
  - No revision of the informed consent document is necessary: This should be used if the PI feels certain that the event does not warrant announcement in the informed consent document.
  - Unknown: The PI is unsure whether or not the event warrants announcement in the informed consent document.

After these questions are completed, the PI is required to sign and date the form as well as print his/her last name and initial below the signature. At this time the SC should keep a copy of the form for their files and forward the original to Westat. The SC may also attach any relevant exam forms, AE forms, or other documentation regarding the event. If any other documentation is attached, the SC should be sure that no personal identifying information is present.

**A-18-1**

A-18-1: Buccal Cell Participant Directions



## **DIRECTIONS FOR COLLECTING THE SAMPLE**

The purpose of this simple procedure is to collect some loose cells from your mouth. Please follow the directions below. You may request help reading the instructions from a member of your household, but **please do not permit anyone else to handle the collection materials.**

In addition to these directions, here is a list of what you should find in the large plastic bag:

- Plastic bottle of commercial mouthwash;
  - Small leak-proof plastic bag (with a blue strip) that contains a screw top collection container and a small absorbent sheet; and
  - Postage paid, pre-addressed, small padded mailing envelope.
1. **Do not eat, drink, or rinse your mouth for one hour before collecting the saliva sample.**
  2. Open the bottle of commercial mouthwash. Open the screw top collection container and fill it half full of mouthwash (to the red fill line).
  3. Swish the mouthwash from the container around in your mouth vigorously for 45 seconds. **Watch the clock while you do this.** Do not gargle or clear your throat.
  4. Holding the container close to your mouth, spit the mouthwash back into the container. Replace the top on the container and screw it on tightly. Please discard the remaining portion of commercial mouthwash or keep it for your own use.

## **DIRECTIONS FOR MAILING THE SAMPLE**

Prepare the screw top collection container for mailing as follows:

1. Place the screw top collection container back into the small leak-proof plastic bag (with the blue strip). Do not remove the absorbent sheet in case anything spills in the mail.
2. Remove any air from the small leak-proof plastic bag and seal the bag using the blue strip.
3. Place the small leak-proof plastic bag and its contents into the small padded mailing envelope that is addressed to our laboratory in Maryland.
4. **Mail the sample within 24 hours of collection.** No additional postage is required.

*Thank you for your participation.*

**A-18-2**

A-18-2: Buccal Cell Frequently Asked Questions

# **Frequently Asked Questions**

## **about the PLCO Etiologic Studies Consent and Saliva Sample Collection**

### **Why do I have to sign another consent form?**

The consent form you signed when you enrolled in the study indicated your agreement to participate in the PLCO Trial. The Etiologic Studies Consent (ESC) indicates your agreement to participate in additional studies associated with the PLCO Trial, for example saliva sample collection.

### **How many times will the saliva sample be collected?**

The saliva sample will be collected from each participant one time. The sample will then be stored at the National Cancer Institute for future research including research on DNA in the sample.

### **Will I have to come to the clinic to give the sample?**

No, the saliva sample collection kit will be mailed directly to your home. It will contain all the supplies you will need to provide the sample, along with detailed instructions. The kit will also contain a pre-addressed postage paid envelope for you to return your sample to the National Cancer Institute.

### **Is the information you get from my sample kept confidential?**

Yes, any information obtained from the sample you provide will be kept confidential. The information will not be shared with anyone outside the PLCO Trial, nor will anyone outside the PLCO Trial have access to it. Even for the researchers at the National Cancer Institute, your DNA will be associated with a sample number and will not be stored in connection with your name.

### **Will I get test results after I provide the saliva sample?**

No, since any studies that will be done on the saliva samples are for research purposes only, there will be no results to report. The studies will not be looking specifically for disease but will be looking for things that might be risk factors for disease.

### **How long will it take to receive the saliva sample collection kit?**

After you sign and return the consent form, you will be added to the pool of approximately 77,000 study participants who want to receive a collection kit. It will take at least two months for the kit to be assembled and mailed. Because there are so many participants in the PLCO Trial, it may take up to 2 years for you to receive your kit.

# **Frequently Asked Questions about the PLCO Etiologic Studies Consent and Saliva Sample Collection**

## **Will I have to provide a tissue sample?**

No, you will not have to provide a tissue sample as part of the PLCO study. However, if you happen to have certain surgical procedures performed by your physician in the future, we might ask your physician for a part of the tissue sample he or she collected during the procedure.

## **What if I do want to participate in these additional studies?**

If you agree to participate in the additional studies described in the consent form, please indicate this by circling "yes" for questions 1 and 2 on the last page of the consent form. Then print and sign your name and, if possible, have a witness sign the form. Return the consent form to the screening clinic by mailing it in the pre-addressed postage paid envelope provided with the consent form.

## **What if I do not want to participate in these additional studies?**

If you do not want to participate in the additional studies described in the consent form, please indicate this by circling "no" for questions 1 and 2 on the last page of the consent form. Then print and sign your name and, if possible, have a witness sign the form. Return the consent form to the screening clinic by mailing it in the pre-addressed, postage paid envelope provided with the consent form. Although you will not be participating in the additional studies, you will still be part of the PLCO Trial. Someone from the trial will continue to contact you each year for health updates.

## **Do I need a witness signature on the consent form?**

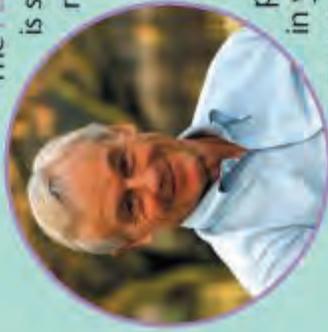
Yes, please have someone you know witness your signature on the consent form before returning it to the screening clinic. If you are not able to obtain a witness signature, you can return the consent form with just your signature.

**A-18-3**

A-18-3: Buccal Cell Brochure

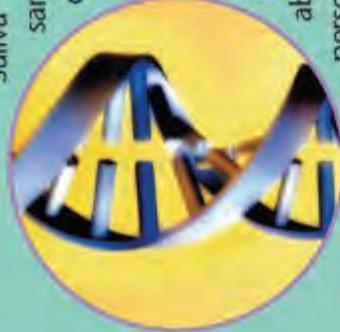
## WE NEED YOUR HELP!

The **PLCO Trial** is starting a new study to collect saliva samples from participants in your study group.



## What can we learn from saliva samples?

Saliva samples contain cells with DNA, the genetic or inherited information about the person. The



National Cancer Institute (NCI) will study the DNA to determine if genetic factors play a role in the development of cancer and other diseases.

## Why should **YOU** participate?

This is an opportunity for you to be more involved in the **PLCO Trial**.



You can contribute valuable information that will help us learn more about cancer and other diseases.

The scientific information learned from the saliva samples will benefit future generations.

Collecting the saliva sample is quick, easy, and painless. We will send you all the supplies you need to collect



and mail the sample, and you can collect the sample in the privacy of your home.

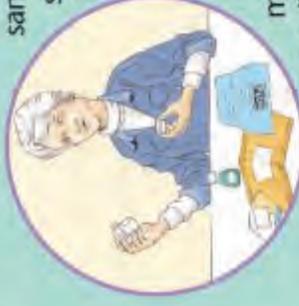
When you participate, all you have to do is...



**Receive** a collection kit in the mail.

### **Collect** the

sample by simply rinsing your mouth with the mouthwash we provide and spitting the mouthwash into a collection cup.



**Mail** the sample to the NCI Laboratory in the postage-paid envelope.



## HOW DO YOU AGREE TO PARTICIPATE?

Simply...



**Complete and Sign** the enclosed consent form indicating your willingness to participate.



**Return** it in the enclosed, postage-paid envelope.

After we receive your signed consent, you will receive a collection kit in the mail.

If you choose not to participate, note this on the consent form and return it to us. Your participation in these additional studies will not affect your participation in the PLCO Trial.

Thank you for letting us know **as soon as possible** if you will participate.

## SCREENING CENTER CONTACT INFORMATION



# WE NEED YOUR HELP!



**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**

**PLCO Web Site:**  
<http://cancer.gov/plco>

For answers to your questions about cancer, or studies like the PLCO Cancer Screening Trial, call the National Cancer Institute's toll-free Cancer Information Service at:

**1-800-4-CANCER  
(1-800-422-6237)**

**TTY: 1-800-332-8615  
For Hearing Impaired**

**NATIONAL  
CANCER  
INSTITUTE**

**PLCO**  
PROSTATE, LUNG, COLORECTAL & OVARIAN  
CANCER SCREENING TRIAL

## **A-18-4**

A-18-4: Shipment Notification for Pittsburgh and Minnesota

Shipment Notification, Verification, and Reorder Form  
for the University of Minnesota and the University of  
Pittsburgh

**BUCCAL CELL KIT  
SHIPMENT NOTIFICATION,  
RECEIPT VERIFICATION AND REORDER FORM**

**MINNESOTA**

**Notification of Shipment - (McKesson Use Only)**

**Fax to: (612) 625-4363**

**Attention: Deb Engelhard**

Number of Kits Shipped: \_\_\_\_\_

Sample ID Range Included: \_\_\_\_\_

Date of Shipment: \_\_\_\_\_

Number of Shipping Boxes: \_\_\_\_\_

UPS Tracking Numbers: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**Verification of Receipt - (Minnesota Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date Shipment Received: \_\_\_\_\_

Number of Boxes Received: \_\_\_\_\_

Sample ID Range Received: \_\_\_\_\_

Confirmed By: \_\_\_\_\_

**Kit Reorder - (Minnesota Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date of Request: \_\_\_\_\_

Number of Kits Needed: \_\_\_\_\_

Requestor: \_\_\_\_\_

**BUCCAL CELL KIT  
SHIPMENT NOTIFICATION,  
RECEIPT VERIFICATION AND REORDER FORM**

**PITTSBURGH**

**Notification of Shipment - (McKesson Use Only)**

**Fax to: (412) 383-1511**

**Attention: Betsy Gahagan**

Number of Kits Shipped: \_\_\_\_\_

Sample ID Range Included: \_\_\_\_\_

Date of Shipment: \_\_\_\_\_

Number of Shipping Boxes: \_\_\_\_\_

UPS Tracking Numbers: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**Verification of Receipt - (Pittsburgh Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date Shipment Received: \_\_\_\_\_

Number of Boxes Received: \_\_\_\_\_

Sample ID Range Received: \_\_\_\_\_

Confirmed By: \_\_\_\_\_

**Kit Reorder - (Pittsburgh Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date of Request: \_\_\_\_\_

Number of Kits Needed: \_\_\_\_\_

Requestor: \_\_\_\_\_

## **A-18-5**

### **A-18-5: Buccal Cell Collection Tracking Form**

#### **Specifications for the Buccal Cell Collection Tracking Form**

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

**BUCCAL CELL KIT  
SHIPMENT NOTIFICATION,  
RECEIPT VERIFICATION AND REORDER FORM**

MINNESOTA

**Notification of Shipment - (McKesson Use Only)**

**Fax to: (612) 625-4363**

**Attention: Deb Engelhard**

Number of Kits Shipped: \_\_\_\_\_

Sample ID Range Included: \_\_\_\_\_

Date of Shipment: \_\_\_\_\_

Number of Shipping Boxes: \_\_\_\_\_

UPS Tracking Numbers: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**Verification of Receipt - (Minnesota Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date Shipment Received: \_\_\_\_\_

Number of Boxes Received: \_\_\_\_\_

Sample ID Range Received: \_\_\_\_\_

Confirmed By: \_\_\_\_\_

**Kit Reorder - (Minnesota Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date of Request: \_\_\_\_\_

Number of Kits Needed: \_\_\_\_\_

Requestor: \_\_\_\_\_

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

**BUCCAL CELL KIT  
SHIPMENT NOTIFICATION,  
RECEIPT VERIFICATION AND REORDER FORM**

**PITTSBURGH**

**Notification of Shipment - (McKesson Use Only)**

**Fax to: (412) 383-1511**

**Attention: Betsy Gahagan**

Number of Kits Shipped: \_\_\_\_\_

Sample ID Range Included: \_\_\_\_\_

Date of Shipment: \_\_\_\_\_

Number of Shipping Boxes: \_\_\_\_\_

UPS Tracking Numbers: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**Verification of Receipt - (Pittsburgh Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date Shipment Received: \_\_\_\_\_

Number of Boxes Received: \_\_\_\_\_

Sample ID Range Received: \_\_\_\_\_

Confirmed By: \_\_\_\_\_

**Kit Reorder - (Pittsburgh Use Only)**

**Fax to: McKesson Bioservices**

**(301) 838-9753**

Date of Request: \_\_\_\_\_

Number of Kits Needed: \_\_\_\_\_

Requestor: \_\_\_\_\_

**BUCCAL CELL COLLECTION TRACKING FORM**

PID Label

Sample  
ID  
Label

Date Scanned

Date Mailed

\_\_\_\_\_

\_\_\_\_\_

PID Label

Sample  
ID  
Label

Date Scanned

Date Mailed

\_\_\_\_\_

\_\_\_\_\_

PID Label

Sample  
ID  
Label

Date Scanned

Date Mailed

\_\_\_\_\_

\_\_\_\_\_

PID Label

Sample  
ID  
Label

Date Scanned

Date Mailed

\_\_\_\_\_

\_\_\_\_\_

PID Label

Sample  
ID  
Label

Date Scanned

Date Mailed

\_\_\_\_\_

\_\_\_\_\_

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**  
**SPECIFICATIONS FOR COMPLETION OF THE BUCCAL CELL COLLECTION**  
**TRACKING FORM**

This form is to be completed by the SC coordinator or buccal cell staff member. The purpose of the form is to link Participant ID numbers (PIDs) with the Sample ID numbers for the Buccal Cell Collection effort. The form should be completed while preparing buccal cell collection kits for mailing to participants.

The specifications for completing the form are given below:

**PID Label:** After assembling all participant specific paperwork for a buccal cell collection kit, affix a Participant ID label to the next available space in the left hand column of the form.

**Sample ID Label:** Remove the Sample ID label from the side pouch of the partially assembled kit assigned to the participant whose PID label has been affixed to the space on the form. Affix the sample ID label in the space provided next to the PID label.

**Date Scanned:** After affixing the PID label and Sample ID label to the form, scan the barcodes of the PID and the sample ID labels into the SMS, thereby creating the "link". Record the date on the line. If multiple persons are working on the buccal cell effort at your screening center, it is suggested that you initial on the line beside the date.

**Date Mailed:** Record the date the kit was mailed or will be mailed to the participant on the line provided. Mailing dates should follow the SC Buccal Cell Kit Mailout Schedule. If multiple persons are working on the buccal cell effort at your screening center, it is suggested that you initial on the line beside the date.

Continue this process, recording five PID/Sample ID links on each form. The five links recorded on this form do not necessarily have to be prepared, scanned or mailed on the same day. This form does not need to be filed in the participant's folders. Please keep all Buccal Cell Collection Tracking Forms in a central location.

## **APPENDIX B**

### **Appendix B: System Reports**

## **Appendix B-2-1: Recruitment Summary Report**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Recruitment Summary Report***

**This report summarizes the recruitment status of all potential participants in TASR. It can be requested for the current reporting period, or a previous reporting period. It also lists the reasons specified for the recruitment category “Non-Participant, Other Reason”.**

---

12/16/97  
3:22 pm

PLCO CANCER SCREENING TRIAL  
Recruitment Summary Report

Page 1  
SMS 3.4

Report As Of Date: 12/16/97

	Cumulative	
Total Identified	13629	
Total no Contact	0	
Total Uninterested	2087	
Total Ineligible	4760	
01 = age < 55 or >= 75	133	
UN = age ineligible, unspecified		16
1A = age >= 75		66
1B = age < 55 throughout recruitment		36
1C = age < 55 now		15
02 = current treatment	27	
03 = history of PLCO cancer	112	
04 = PLC organ removed	868	
05 = another cancer study	100	
06 = Proscar/Finasteride/Tamoxifen/Nolvadex	130	
07 = unable to sign consent	7	
08 = more than one PSA blood test	1621	
09 = colonoscopy/sigmoidoscopy/barium enema	1762	
Total NonParticipants Other Reasons	75	
Total Eligible	6675	
Total Participants Enrolled	8753	
Total with Eligibility Pending	31	

## Appendix B-2-2: Recruitment Progress Report

PLCO Reports - Tracking and Summarizing Recruitment

---

### *Recruitment Progress Report - Parts I, II, III*

This is a three part report of eligibility status of all potential participants. Part I lists contacts by gender, Part II lists contacts by race, and Part III lists contacts by age group.

---

Part I: Gender

Status	Male	Female	Missing Data	Total
Eligible	0	0	0	0
Ineligible, total	3933	2742	0	6675
Inelig, Current Cancer	2969	1779	4	4752
Inelig, History PLCO Cancr	15	12	0	27
Inelig, PLC Organ Removed	82	30	0	112
Inelig, Other Study	29	839	0	868
Inelig, Proscar/Finasterid	33	67	0	100
Inelig, No Sign Consent	99	31	0	130
Inelig, >1 PSA test	4	3	0	7
Inelig, Colon Procedure(s)	1619	0	2	1621
Age >= 75	1026	735	1	1762
Age <55 throughout recruit	43	23	0	66
Age <55 now	10	25	1	36
Age ineligible, unspecified	3	12	0	15
Age ineligible, total	11	5	0	16
Non Participant (Other)	67	65	1	133
Eligibility Status Pending	39	35	1	75
Uninterested in Study	8	8	15	31
Missing Data	941	1139	7	2087
Total	7895	5707	0	13629

Part II: Race

Status	White Not Hispanic	White Hispanic	White Un-specified	Black Not Hispanic	Black Hispanic	Black Un-specified	Asian	Pacific Islander	Amer. Ind or Alaskan	Missing	Total
Eligible	6278	19	1	351	1	1	20	1	1	2	6675
Ineligible, total	4500	10	0	192	5	0	19	0	0	26	4752
Inelig. Current Cancer	25	0	0	2	0	0	0	0	0	0	27
Inelig. History FLCO Cancr	101	0	0	11	0	0	0	0	0	0	112
Inelig. FLC Organ Removed	798	2	0	60	0	0	3	0	0	5	868
Inelig. Other Study	90	0	0	2	4	0	2	0	0	2	100
Inelig. Proscar/Finaaterid	120	0	0	6	0	0	1	0	0	3	130
Inelig. No Sign Consent	7	0	0	0	0	0	0	0	0	0	7
Inelig. >1 PSA test	1576	2	0	32	2	0	4	0	0	5	1621
Inelig. Colon Procedure(s)	1684	6	0	60	0	0	9	0	0	3	1762
Age >= 75	56	0	0	9	0	0	0	0	0	1	66
Age <55 throughout recruit	24	0	0	8	0	0	0	0	0	4	36
Age <55 now	13	0	0	0	0	0	0	0	0	2	15
Age ineligible, unspecified	13	0	0	2	0	0	0	0	0	1	16
Age ineligible, total	106	0	0	19	0	0	0	0	0	8	133
Non Participant (Other)	71	0	0	3	0	0	0	0	0	1	75
Eligibility Status Pending	7	4	0	1	1	0	0	0	0	18	31
Uninterested in Study	1937	3	0	123	0	0	3	0	2	19	2087
Missing Data	1	0	0	0	0	0	0	0	0	0	1
Total	12801	36	1	670	8	1	42	1	3	66	13629

Part III: Age Groups

Status	<55	55-59	60-64	65-69	70-74	>=75	Missing Data	Total
Eligible	0	0	0	0	0	0	0	0
Ineligible, total	0	1176	2362	1932	1205	0	0	6675
Inelig, Current Cancer	103	944	1364	1335	877	82	47	4752
Inelig, History PLCO Cancr	0	1	4	10	10	2	0	27
Inelig, PLC Organ Removed	1	10	27	32	37	5	0	112
Inelig, Other Study	5	152	278	272	148	1	12	868
Inelig, Proscar/Finasterid	0	24	29	30	15	1	1	100
Inelig, No Sign Consent	1	11	38	32	46	1	1	130
Inelig, >1 PSA test	0	2	2	1	2	0	0	7
Inelig, Colon Procedure(s)	10	279	467	496	357	2	10	1621
Age >= 75	29	465	520	465	262	2	19	1762
Age <55 throughout recruit	0	1	0	0	2	62	1	66
Age <55 now	32	0	0	0	0	0	4	36
Age ineligible, unspecified	15	0	0	0	0	0	0	15
Age ineligible, total	10	0	0	0	0	6	0	16
Non Participant (Other)	57	1	0	0	2	68	5	133
Eligibility Status Pending	0	33	26	7	7	0	2	75
Uninterested in Study	1	4	6	2	1	4	13	31
Missing Data	8	351	697	594	399	6	32	2087
Total	0	0	1	0	0	0	0	1
	112	2509	4457	3873	2491	92	95	13629

## Appendix B-2-3: Eligibility Screener Review

### PLCO Reports - Tracking and Summarizing Recruitment

---

#### *Eligibility Screener Review - Parts I and II*

This is a two part report of eligibility information.

**Part I** provides a list of potential participants who have not yet returned their Eligibility Screener. It lists the tracking number, the potential participant name, and telephone number. It may be used for follow-up of individuals to ascertain their interest in the trial.

**Part II** provides a list of potential participants who have returned their Eligibility Screener but for whom eligibility has not yet been determined. It lists the tracking number, the potential participant name, telephone number, and date the Screener was returned. It may be used for follow-up of individuals to verify the information on the screener or to sign an informed consent.

---

12/16/97  
3:09 pm

PLCO CANCER SCREENING TRIAL  
Eligibility Screener Review

Page 1  
SMS 3.41

Part I: Screeners Not Returned

Total Number of Screeners Not Returned: 68

TrackNum	Last Name		First Name	Phone
ABBA0002	Abbot		Alan	
ABBA0003	Abbot		Albert	
BARB0006	barnside		barbara	(214) 214-2141
BBBM0001	Bbbbb		Mbbb	
BROJ0016	Janiszewski	RSM	Adrija	
BXXM0001	Bxxxx		Mxxxx	
BYYM0001	Byyyy		Mxxxx	
BZZB0001	Bzzz		Bzzz	
BZZM0001	Bzzz		Mzzz	
CALC0001	CALVIN		COUNT	
CALC0003	calcutta		caliope	(211) 234-5678
CALC0004	calliente		carmella	(394) 223-4567
CAPE0002	Isler	R.N.	Cuddy	
CHEA0003	Cherla	R.N.	Avis	(217) 234-9876
CONR0007	Jessop	Ph.d	Jonathan	
C 0003	Tuttle	Ph.d	Clement	
CZ 0001	Czzz		Czzz	
DORC0001	Roach	Sr.	Roxane	
DUCD0001	Duck	Sr.	Donald	(313) 789-5436
DUCD0002	Duck	Jr.	Donald	(313) 789-5436
DUCD0003	Ducker		David	(313) 789-5436
DUCD0004	Duckling		Daniel	(313) 789-5436
FAST0001	FASHION		TERRY	
FAST0002	FASQUE		TERI	
FIND0003	FINEL		DIXIE	
FIXB0001	Gordon	MD	Ernestine	
FURM0003	Farrish	R.M.	Emily	
GEAG0001	Kasper	MD	Ceola	
GOJR0001	Riggs	jr	Milton	
GRAM0005	Granfredi	R.M.	Mervis	(217) 234-5678
GREE0004	Schaefer	II	Giuseppe	
GRUM0001	Cicco	Jr.	Lydia	
HEAM0003	Madeyski	RSM	Jean	
KINA0005	Wiezorek	Sr.	Alban	
KOVA0001	Collie	III	Ludwig	
LAVA0001	LaVertullo	Sr.	Attilia	(217) 841-8151
LEVS0002	Hochreiter	CSJ	Manfred	
MACR0002	Sentner	R.N.	Theresa	
MART0005	Merryman	Ph.d	Verletta	
MAXD0001	MAXIMY		DIANE	
M 0002	MAXAMO		DEBRA	
M .0001	MAXIMIZE		XER	

12/16/97  
3:29 pm

PLCO CANCER SCREENING TRIAL  
Eligibility Screener Review

Page 1  
SMS 3.41

Part II: Returned Screeners

Total Number of Returned Screeners: 3

Eligibility Pending (of Returned Screeners):

TrackNum	Last Name	First Name	Phone	Date Returned
CANR0002	Bvxca	Ruth	(703) 555-9999	10/21/94
CAST0002	case	test		10/07/97
JONC0006	jones	casey		10/07/97

## **Appendix B-2-4: Session Edit Report for Individual Tracking**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Session Edit Report (Production Edits) for Individual Tracking***

**This report prints a list of errors and inconsistencies for each record in the TASR database, as well as a key for decoding error message codes.**

---

12/16/97  
3:54 pm

PLCO CANCER SCREENING TRIAL  
Session Edit Report for Individual Tracking

Page 1  
SMS 3.41

Tracknum	Error Numbers for this record
-----	-----
2	
ABBA0003	10 11 13 16 18
ABRA0002	13
ABRB0002	13 14
ABRE0001	13
ABRS0002	13
ABTD0001	13
ACHW0001	13
ACKG0001	13
ADLB0001	13
AIEA0001	13
ALBH0001	13
ALEG0001	13
ALEM0001	13
ALET0001	13
ALFT0001	13
ALLA0001	13
ALLA0002	13
ALLB0001	13
ALLC0001	10 13
ALLD0001	13
ALLH0002	13
AMMA0001	13
AMMJ0001	13
AMOB0001	10 13
AMOK0001	10 13
AMSA0001	13
AMSH0001	13
ANAF0001	13
BARB0006	14 17 18
CALC0003	14 15 17 18
CALC0004	14 15 17 18
CAST0002	13 17
CHEA0003	17 18
CUBS0001	10
GRAM0005	17 18
JONC0006	13 17
KRAE0003	10
LAVA0001	17 18
MCSB0001	14 17 18
PARP0003	17 18
SCHE0021	17 18
SPED0001	17 18
TROS0001	14 17 18
ZYWR0001	13
ZYWS0001	13

12/16/97  
3:54 pm

PLCO CANCER SCREENING TRIAL  
Possible Errors and Warnings for Individual Tracking

Page 1  
SMS 3.41

KEY:

Number	Error Message
1	Date cannot be greater than Today Check DateContact1 DateContactLast and DateScreen
2	Latest contact date cannot be earlier than First contact date
3	First contact date is Blank but Latest contact date is Not Blank
4	Eligibility Status=E but DOB is out of range or Gender is Blank
5	Eligibility Status=I but Reason for Ineligibility Not given
6	Eligibility Status not equal Ineligible but Reason is Not Blank
7	Eligibility Status=NP but Reason is Not specified
8	Eligibility Status not equal 'NP' but Reason for NP is Not Blank
9	Reason for Ineligibility='Age out of range' But DOB=Blank
10	First contact date is < today minus 6 months
11	Screeener Date cannot be Blank with this Status
12	Date of Birth cannot be later than 01/01/53
13	One or more Address fields are Blank
14	Race field is Blank
15	Gender field is Blank
16	DOB field is Blank
17	Status field is Blank
18	Screeener Completion Date field is Blank
19	One or more Name fields contain a Double Quote or a Comma
20	One or more Address fields contain a Double Quote or a Comma
21	Gender is Female but reason for Ineligibility is PSA Exam
22	Hispanic Origin should not be filled if Race Group is WH, WN, BH, BN
23	Hispanic Origin should not be filled if Race Group was left blank
24	Hispanic Origin is blank and Race Group is WW or BB

## **Appendix B-2-5: Possible Duplicates in TASR**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Possible Duplicates in TASR (Individual Tracking)***

This report lists possible duplicates among potential participants in the TASR database. It has five options for duplicate searches based on:

1. Same date of birth;
  2. Same last name, first letter of first name, and date of birth;
  3. Same last name and same first letter of first name;
  4. Similar last name and same first letter of first name; and
  5. Similar last name, same first letter of first name, and same month/year of birth.
-

7/10/01  
10:56 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Same Date of Birth

Page 1  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
ADDI0001	Addams	Iris	Marianne		F
ALBH0002	Albinger	Howard	Norbert		M
ALBM0002	Albinger	Madonna	Allyn		F
ALTN0001	Altdorfer	Nessa	Janet		F
AMOR0001	Amos	Rheda	Bessie		F
ANDE0002	Anderson	Edna	Leah		F
ANTD0003	Antis	Dora	Virginia		F
BARJ0023	Barren	Jerald	Guy		M
BARJ0029	Barker	Johanne	Julia		F
BEAF0002	Beaumont	Fern	Alberta		F
BEIE0002	Beilstein	Edna	Virginia		F
BERB0007	Berrington	Betsy	Alexandria		F
BERG0003	Berger	Glenna	Joy		F
BLAJ0006	Blanchard	Jarius	Matthew		M
BOLE0001	Bollens	Enrico	Bert		M
BRUC0005	Bruckman	Clareann	Emily		F
BUKW0001	Bukauskas	Wren	Isaiah		M
BURD0001	Buranosky	Deane	Nedra		F
BUYJ0001	Buybonds	Juliann	Florria		F
CAMC0004	Campbell	Conrad	Antonio		M
CAMD0005	Campeau	Dora	Usha		
COOD0004	Cooperman	Doyle	Conrad		
DALD0001	Dalbey	Dwight	Bruce		M
DEBA0001	Debski	Alexandria	Marilane		F
DEFB0001	DeFazio	Burton	Justin		M
DIUA0001					M
DOMR0001	Domske	Ross	Hershey		M
FOSR0003	Foster	Ray	Cazmier		M
GAIL0001	Gaines	Lorraine	India		F
GAUF0001	Gault	Fernando	Erich		M
GOEM0001	Goerl	Macy	Ruthe		F
GOGD0001	Goggins	Doyle	Rifkie		M
GOOJ0002	Good	Juanita	Jo-Ann		F
GOUB0001	Goude	Bert	Jameson		
GRIA0003	Griser	Albert	Aloysius		
GRIR0011	Gripp	Roslyn	Jo-Ann		F
HANR0003	Hanna	Ruzhi	Alda		M
HAWH0001	Hawkins	Herbert	Tsung		
HENW0003	Henkel	Wilbur	Berton		M
HIRM0001	Hirschfield	Myron	Ferdinand		M
JOHV0001	Johnston	Verna	Aija		
KALR0001	Kalinoski	Ruthann	Geraldine		F
KOSM0005	Kosowan	Malcolm	Nicholas		M
KRAN0002	Kraynik	Nira	Josephine		F
LACD0001	LaCapra	Deanna	Leonora		F
LIGJ0002	Lightbown	Johnboy	Rifkie		M
LISA0001	Liszewski	Alena	Filonelda		F
LUNR0005	Lunz	Ralph	Wilbert		
MANS0001	Mannella	Stuart	Wade		M
MCCB0002	McCrum	Bessie	Alberta		F
MCCE0004	McComb	Evaline	Carrie		F

7/10/01  
10:56 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Same Date of Birth

Page 2  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
MCCF0003	McCulloch	Freeman	James		M
MCEJ0001	McEllis	Julian	Leroy		M
MCID0005	McIlvane	Dorothy	Jeannette		F
MEHM0001	Mehrmann	Malvern	Martin		M
MENU0001	Mengo	Una	Camille		
MERV0001	Meray	Von	Dolso		M
MONV0001	Montrenes	Vida	Marshall		M
MCOJ0006	Moody	Joseph	Morris		M
MORC0005	Moran	Cuddy	Ervel		M
MULR0005	Mularski	Ruthe	Roxane		F
MURR0003	Murray	Raeleen	Rudy		
MYED0003	Myers	Delores	Bertha		F
NOTD0001					F
PINR0001	Pinkerton	Robert	Lynn		M
POLA0002	Pollard	Alda	Marc		M
RANE0001	Rankin	Eithne	Noreen		F
REDD0001	Reding	Darryl	Arthur		M
RITE0003	Ritner	Elayne	Susie		
ROBD0005	Robinson	Darlene	Rose Mary		F
ROHJ0002	Rohm	Janet	Glenna		
ROOE0001	Rood	Edgar	Cloyed		M
SADF0001	Saddler	Fletcher	Bernard		M
SANM0008	Sander	Marienne	Elenora		F
SANR0007	Sanfilippo	Romeo	O.J.		M
SCHA0016	Scheier	Agnes	Eleanor		F
SCHM0012	Schweizer	Milan	Dennis		M
SELB0002	Selmeczy	Blaine	Charlotte		
SHAE0004	Shagas	Enio	Odger		M
SICP0001	Sicelli	Paulina	Marianna		F
SOKP0002	Sokolowski	Phyllis	Catharine		F
SPID0001	Spisak	Doris	Zylphia		
SRAK0001	Sradder	Karen	Gisele		F
STUN0001	Stundon	Nira	Mathilda		
SULN0001	Sullivan	Norine	Juliann		F
SWEC0003	Sweitzer	Carrie	Cecelia		
TALG0002	Talarico	Guido	Sigrid		M
TAYJ0004	Taylor	Johnboy	Chester		M
TAYS0001	Taylor	Susannaa	Bernice		F
VAUL0001	Vaughan	Lysle	Thekla		F
WASD0001	Wasilowski	Deane	Irene		F
WILM0012	Willis	Milan	Edwardo		M
WOSJ0001	Woskowicz	Johnboy	Rosario		M
WOSL0001	Woskowicz	Lida	Mabel		F
YOVR0001	Yovl	Regis	Horace		M
ZACP0001	Zacharias	Philip	Vernon		M
ZELI0001	Zelinsky	Ivan	Sorel		M
ZIMW0001	Zimmerman	Wesley	Henry		M
GRIB0005	Grimson	Bard	Jerzy	7/10/09	M
GRIB0006	Grimson	Bard	Jerzy	7/10/09	M

7/10/01  
10:56 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Same Date of Birth

Page 3  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
XELT0001	Xellaston	Tamaria	Flo	3/17/10	F
YELT0001	Yellaston	Tamaria	Flo	3/17/10	F
FLOF0002	Flounder	Frederick	Felix	8/14/10	M
FLOF0003	Flounder	Frederick	Felix	8/14/10	M
BEAM0004	Beaverton	Michael	Kasten	10/25/11	M
GRAM0007	Graverton	Michael	Kasten	10/25/11	M
CIAL0001	Cianflone	Leslie	Harrison	6/19/17	M
LEVJ0001	Levine	Junetta	Natalie	6/19/17	F
RUDJ0001	Rudov	Jonathan	Warren	6/19/17	M
ROGA0002	Rogow	Angelo	Jan	2/27/19	M
WYCH0001	Wycoff	Herminie	Carrie	2/27/19	F
FALT0001	Falkner	Ted	Meade	4/13/19	M
PERB0001	Perilli	Betty	Clair	4/13/19	F
LONM0001	Long	Martha	Marlene	7/03/19	F
SAGS0001	Sage	Sophie	Karen	7/03/19	F
SIMM0001	Simmons	Meade	Tony	9/08/19	M
SINA0001	Singer	Aloysius	Judson	9/08/19	M
PARS0002	Parrish	Sallie	Betty Jane	11/16/19	F
STAH0001	Stamerra	Hermon	Petro	11/16/19	M
GOLC0001	Golier	Carolyn	Nona	12/18/19	F
HARC0001	Hartle	Clarion	Leon	12/18/19	M
SARS0001	Sarricks	Stephen	Miletto	12/18/19	M
DAVM0001	Davis	Marian	Christopher	1/10/20	M
MAYJ0001	Maynard	Julia	Burnet	1/10/20	F
OBLJ0001	Oblich	Julie	Juanita	2/04/20	F
POPF0001	Popovich	Filonelda	Renee	2/04/20	F

7/10/01  
10:59 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Same Lastname, 1st letter of Firstname, and DOB

Page 1  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
ALLH0001				6/01/35	M
CACR0001				6/01/35	M
ALLL0002				3/31/40	M
MINR0003				3/31/40	M
FIEG0002	Fielder	George	Ramone	8/14/38	M
FIEG0003	Fielder	George	Ramone	8/14/38	M
FLEA0003	Flemings	Aldo	Wallace	8/19/41	M
FLEA0004	Flemings	Austin	Andre	8/19/41	M
FLOF0002	Flounder	Frederick	Felix	8/14/10	M
FLOF0003	Flounder	Frederick	Felix	8/14/10	M
GRIB0005	Grimson	Bard	Jerzy	7/10/09	M
GRIB0006	Grimson	Bard	Jerzy	7/10/09	M
HIGF0001	Higgins	Freeman	Norbert	1/09/23	M
HIGF0002	Higgins	Fletcher	Michael	1/09/23	M
MCCR0008	McClelland	Ronald	Lane	3/05/26	M
MCCR0011	McClelland	Rifkie	Neil	3/05/26	M
MILG0006	Millar	Gerhard	Edmund	7/18/30	M
MILG0012	Millar	Gustave	Johnboy	7/18/30	M
MURC0004	Murin	Cuddy	Joshua	4/07/29	M
MURC0005	Murin	Cyril	Joboo	4/07/29	M
SEWR0001	Sewell	Romaine	Sonia	7/22/28	F
SEWR0002	Sewell	Romaine	Letitia	7/22/28	F
DIUA0001					M
NOTD0001					F

7/10/01  
10:54 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TADR  
Same Lastname and 1st letter of Firstname

Page 1  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
ABRA0001	Abromaitis	Anacletus	Aloysius	11/20/31	M
ABRA0002	Abromaitis	Adolph	Cornelius	3/31/26	M
ABRA0003	Abromaitis	August	Irving	9/24/37	M
ABRA0004	Abromaitis	Aileen	Catina	12/26/41	F
ABRH0001	Abromaitis	Hayward	Fredrick	8/03/19	M
ABRH0002	Abromaitis	Helen	Johanna	5/30/27	F
ABRP0001	Abromaitis	Pinkie	Merwyn	7/09/33	M
ABRP0002	Abromaitis	Penny	Leonora	9/03/25	F
ABRS0001	Abromaitis	Sabina	Phyllis	3/31/33	F
ABRS0002	Abromaitis	Silver	Regis	3/29/25	M
ACKJ0001	Ackerman	Joseph	Noah	8/13/29	M
ACKJ0002	Ackerman	Jan	Emmert	2/23/25	M
ACKJ0004	Ackerman	Julius	Berton	11/24/42	M
ADAJ0002	Adametz	Jessie	Aton	9/10/23	M
ADAJ0008	Adametz	Johnboy	Linus	6/06/30	M
ADAM0001	Adametz	Mark	Eberhard	2/24/35	M
ADAM0002	Adametz	Marvin	Doyle	2/23/39	M
ADAP0001	Adam	Peggy	Meri	6/19/39	F
ADAP0002	Adam	Philip	Keith	12/18/32	M
ADAR0001	Adam	Rudolph	Fletcher	9/04/38	M
ADAR0003	Adam	Rudolph	Vincent	1/31/42	M
ADAJ0001	Adamson	Juris	Petro	1/15/29	M
ADAJ0003	Adamson	Julie	Connie	6/23/26	F
ADAJ0004	Adamson	Joboo	Wilbur	5/05/32	M
ADAJ0005	Adamson	Jesse	Orville	4/14/40	M
ADAJ0007	Adamson	Jacob	Alexander	5/01/30	M
ADAW0001	Adam	Willa	Wen	3/24/29	M
ADAW0002	Adam	Wayne	DeSales	2/21/39	M
ALBA0001	Albinger	Amy	Harriet	7/23/33	F
ALBA0002	Albinger	Alpha	Juris	6/05/28	M
ALBH0001	Albinger	Henry	Shue-Ying	9/08/31	M
ALBH0002	Albinger	Howard	Norbert		M
ALBJ0001	Albinger	Judy	Lenora	5/17/33	F
ALBJ0002	Albinger	Jennifer	Korleen	8/22/38	F
ALBL0001	Albinger	Lymen	Kleber	2/04/31	M

7/10/01  
10:54 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TADR  
Same Lastname and 1st letter of Firstname

Page 2  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
ALBL0002	Albinger	Lexine	Georgia	2/03/28	F
ALEM0001	Albinger	Madeline	Pasquale	8/25/33	F
ALEM0002	Albinger	Madonna	Allyn		F
ALEN0001	Albinger	Warren	Berton	7/31/30	M
ALEN0002	Albinger	Wen	Juris	11/19/22	M
ALDE0001	Aldridge	Bert	Jesse	10/31/40	M
ALDE0002	Aldridge	Breiner	John	5/01/36	M
ALDN0001	Aldridge	Nedra	Hilda	5/14/32	F
ALDN0002	Aldridge	Nicolette	Jennifer	10/01/37	F
ALDR0001	Aldridge	Rudy	Lee	9/05/31	M
ALDR0002	Aldridge	Roberte	Georgie	11/23/43	M
ALEA0001	Aleprate	Amy	Mercedes	8/02/30	F
ALEA0002	Aleprate	Allyn	Margaret	1/04/36	F
ALET0001	Aleprate	Thomas	Waldo	5/05/28	M
ALET0002	Aleprate	Theodore	Ernst	10/18/40	M
ALEX0002	Alexander	Betsy	Joyce	3/01/28	F
ALEX0003	Alexander	Bernhardena	Ida	4/22/42	F
ALEX0001	Alexander	Renee	Frieda	9/07/39	F
ALEX0003	Alexander	Reyman	Clarion	2/10/40	M
ALEV0001	Alexander	Vivian	Verda	6/07/30	F
ALEV0002	Alexander	Victor	Alan	2/22/31	M
ALSD0001	Alston	Daniel	Sorel	7/30/35	M
ALSD0002	Alston	Delores	Jeanne	7/12/33	F
ALSM0001	Alston	Meyer	Armand	12/14/34	M
ALSM0002	Alston	Naura	Darlene	8/27/34	F
ALTJ0001	Aldorfer	Jewel	Ludwig	6/17/28	M
ALTJ0002	Aldorfer	Jeannette	Natalie	6/28/41	F
ALTJ0003	Aldorfer	Jannene	Kathleen	1/09/29	F
ALTJ0004	Aldorfer	Joel	Jessie	6/16/25	M
ALTM0001	Aldorfer	Mathilda	Betty Lou	9/14/25	F
ALTM0002	Aldorfer	Malvern	Alpha	8/08/36	M
ALTP0001	Aldorfer	Patrick	Chester	3/17/38	M
ALTP0002	Aldorfer	Pauline	Leona	8/16/29	F

7/10/01  
10:54 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Same Lastname and 1st letter of Firstname

Page 3  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
ALWR0001	Alwyzch	Rossov	Leroy	3/05/32	M
ALWR0002	Alwyzch	Romeo	Leon	12/31/42	M
AMEE0001	Amenta	Ernest	Domenic	10/02/34	M
AMEE0002	Amenta	Elinor	Nina	6/09/31	F
ANDB0002	Anderson	Blanche	Lydia	7/13/43	F
ANDB0003	Anderson	Bonnie	Justine	8/30/42	F
ANDC0001	Anderson	Clifford	Clyde	6/16/37	M
ANDC0003	Anderson	Cyril	Wilbur	1/07/31	M
ANDE0002	Anderson	Edna	Leah		F
ANDE0003	Anderson	Emma	Ruthe	2/11/30	F
ANDH0002	Anderson	Hubert	Rudy	2/06/23	M
ANDH0004	Anderson	Harvey	Irving	3/03/25	M
ANDJ0004	Anderson	Josephine	Elsemarie	2/14/34	F
ANDJ0010	Anderson	Jeanette	Allyn	8/13/21	F
ANDR0001	Anderson	Ross	Doyle	11/08/27	M
ANDR0003	Anderson	Richard	Joboo	9/23/26	M
ANDW0002	Anderson	Wilfred	Timothy	12/19/33	M
ANDW0003	Anderson	Winifred	Attila	5/26/32	M
ANDA0001	Andreassi	Alison	Bernice	5/03/25	F
ANDA0004	Andreassi	Anzy	Ernst	1/23/43	M
ANDA0005	Andreassi	Alfred	Lester	6/21/42	M
ANDD0001	Andreassi	Dorothy	Roberta	6/10/32	F
ANDD0004	Andreassi	Despina	Pilonelda	8/20/28	F
ANDJ0005	Andreassi	Jere	Milford	12/14/35	M
ANDJ0007	Andreassi	Julian	Kin	9/27/41	M
ANDJ0012	Andreassi	Johnny	Herman	7/10/36	M
ANDJ0013	Andreassi	Johnnie	Leo	5/15/25	M
ANDL0002	Andreassi	Laura	Bernetta	2/28/41	F
ANDL0004	Andreassi	Lucille	Maudie	7/22/40	F
ANDW0001	Andreassi	Willam	Hugo	10/13/28	M
ANDW0004	Andreassi	Willard	Allen	12/07/40	M
ANDD0003	Andres	Dorothy	Ileana	11/11/38	F
ANDD0005	Andres	DeWayne	Leroy	9/17/34	M
ANDM0002	Andres	Mary Louise	Elisabeth	1/16/41	F

7/10/01  
11:04 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Similar Lastname and Same 1st Letter of Firstname

Page 1  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
ACCE0001				5/23/34	F
AIRN0001				5/18/27	F
ALLJ0001				8/22/29	M
ALLA0001				12/25/33	M
ALLA0002				7/04/34	M
ALLA0003				1/25/39	M
ALLA0004				7/29/40	F
ALLB0001				8/02/34	F
ALLC0001				1/28/39	M
ALLC0002				7/14/40	F
ALLD0001				8/01/37	M
ALLD0002				7/04/39	M
ALLD0003				5/07/37	M
ALLE0001				3/18/30	M
ALLH0001				6/01/35	M
ALLH0002				6/30/37	F
ALLH0003				1/02/39	F
ALLJ0001				3/31/22	M
ALLJ0002				10/29/28	M
ALLJ0003				2/05/28	M
ALLJ0004				4/11/34	M
ALLJ0005				4/01/26	M
ALLK0001				1/15/37	F
ALLK0002				10/29/35	M
ALLL0001				1/16/31	F
ALLL0002				3/31/40	M
ALLM0001				11/13/30	F
ALLM0002				11/24/25	F
ALLM0003				10/01/39	F
ALLM0004				7/20/27	F
ALLM0005				10/05/35	F
ALLM0006				8/24/25	F
ALLN0001				12/16/31	M
ALLN0002				1/08/22	F
ALLN0003				1/08/27	F
ALLO0001				9/17/23	F
ALLR0001				2/22/26	F
ALLR0002				6/18/30	M
ALLS0001				2/09/25	M
ALLT0001				9/12/28	F
ALLT0002				2/22/25	F
ALLT0003				7/02/19	M
ALLT0004				9/30/23	M
ALLW0001				5/04/24	M
ALLW0002				2/12/31	M
ALLW0003				11/10/42	M
ALOE0001				6/30/29	M
ALUD0001				4/06/33	F
ALUD0002				8/07/30	M
AMDT0001				7/29/40	M
AMID0001				4/24/43	F

7/10/01  
11:04 am

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Similar Lastname and Same 1st Letter of Firstname

Page 2  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
AMIJ0001				11/30/36	M
ANZK0001				12/28/38	F
ARGL0001				4/07/42	M
AROD0001				10/23/35	M
ASPW0001				2/09/27	M
AUEA0001				4/16/30	F
AUEF0001				5/10/31	M
AYER0001				3/07/42	M
BEKL0001				5/11/31	F
BIBD0001				7/27/26	M
BOMT0001				8/22/30	M
BUHT0001				6/23/26	M
BUQD0001				6/03/34	F
CACR0001				6/01/35	M
CAGA0001				12/14/30	M
CAGE0001				5/23/31	F
CAGM0001				4/02/33	F
CAGS0001				7/18/43	F
CHVL0001				5/14/40	F
CIBE0001				9/19/24	M
CITG0001				9/07/37	F
CSOA0001				3/21/36	M
CZID0001				4/28/40	F
CZYB0001				3/06/42	F
DACC0002				12/13/41	F
DEUA0001				7/21/20	F
DEUA0002				1/02/32	M
DEUJ0001				9/11/36	F
DIUA0001					M
DIUE0001				9/02/30	F
DLES0001				6/17/38	M
DLUF0001				3/18/25	M
DLUJ0001				9/04/35	F
DOFM0001				12/29/27	M
DOOJ0001				2/27/24	M
DWYR0001				6/15/37	F
DYAJ0001				1/21/27	M
EAGJ0001				10/31/28	F
EAGR0001				6/14/28	M
EDRC0001				8/15/31	M
EMIR0001				1/07/32	F
EMPP0001				8/24/41	F
ERHJ0001				3/15/39	M
ERMR0001				9/16/28	M
ERVN0001				8/05/30	F
EUKJ0001				1/27/42	M
EUTJ0001				5/01/40	F
FYEM0001				11/25/32	F
FYOC0001				12/07/37	F
GAHL0001				10/26/32	M
GOHR0001				6/22/31	M

7/10/01  
12:01 pm

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Similar Lastname, Same 1st Letter of  
Firstname and Same MMY of DOB

Page 1  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
DIUA0001					M
NOTD0001					F
ALLN0002				1/08/22	F
SUMR0001				1/04/22	F
ALLO0001				9/17/23	F
ALLT0004				9/30/23	M
DOOJ0001				2/27/24	M
KRNJ0001				2/02/24	M
NOTA0001				6/18/24	M
YOBL0001				6/20/24	F
ALLS0001				2/09/25	M
ALLT0002				2/22/25	F
MAXA0001				2/19/25	F
JUMJ0001				12/31/26	M
MCJW0001				12/30/26	M
ALLR0001				2/22/26	F
SETM0001				2/15/26	F
ALLJ0005				4/01/26	M
MINP0001				4/29/26	M
BIBD0001				7/27/26	M
TYGD0001				7/18/26	M
ALLN0003				1/08/27	F
DYAJ0001				1/21/27	M
MINK0001				10/29/27	M
SYKF0001				10/21/27	F
DOFM0001				12/29/27	M

7/10/01  
12:01 pm

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Similar Lastname, Same 1st Letter of  
Firstname and Same MMY of DOB

Page 2  
SMS 7.1.

TrackNum	Lastname	Firstname	Midname	DOB	Gender
SETS0001				12/15/27	F
ASPW0001				2/09/27	M
HYLF0001				2/05/27	M
KEUC0001				1/29/28	M
YAGC0001				1/14/28	M
ALLJ0002				10/29/28	M
EAGJ0001				10/31/28	F
SUMH0001				10/27/28	M
KEBA0001				12/16/28	F
UMBR0001				12/06/28	F
ALLJ0003				2/05/28	M
UMBD0001				2/17/28	M
EAGR0001				6/14/28	M
MINF0002				6/08/28	M
ST.D0001				6/12/28	M
ALLT0001				9/12/28	F
ERMR0001				9/16/28	M
ST.C0001				1/23/30	F
YILS0001				1/09/30	M
CAGA0001				12/14/30	M
OLHJ0001				12/05/30	M
ALLE0001				3/18/30	M
MINO0001				3/19/30	M
AUEA0001				4/16/30	F
ZAGS0001				4/07/30	F
ALUD0002				8/07/30	M

7/10/01  
12:01 pm

PLCO CANCER SCREENING TRIAL  
POSSIBLE DUPLICATES IN TASR  
Similar Lastname, Same 1st Letter of  
Firstname and Same MMY of DOB

Page 3  
SMS 7.1

TrackNum	Lastname	Firstname	Midname	DOB	Gender
BOMT0001				8/22/30	M
ERVN0001				8/05/30	F
MAXR0001				8/03/30	M
ALLL0001				1/16/31	F
J0001				1/18/31	M
ALLN0001				12/16/31	M
ODRM0001				12/23/31	F
SUOA0001				12/01/31	F
AUEF0001				5/10/31	M
BEKL0001				5/11/31	F
CAGE0001				5/23/31	F
ZUME0001				5/16/31	M
EDRC0001				8/15/31	M
MINO0002				8/15/31	F
OWIG0001				8/30/31	M
DEUA0002				1/02/32	M
EMIR0001				1/07/32	F
MINJ0006				1/18/32	M
VAIM0001				1/09/32	F
GAHL0001				10/26/32	M
GOHT0001				10/09/32	F
SETJ0001				7/13/32	M
TOHD0001				7/11/32	M
MINR0001				9/12/32	F
TEEI0001				9/16/32	M
ALUD0001				4/06/33	F
CAGM0001				4/02/33	F
GOWN0001				4/12/33	F
MINA0001				4/02/33	M
MINH0001				4/22/33	M

## **Appendix B-2-6: Age Review Report**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Age Review Report***

**This report lists potential age ineligible for whom a recruitment status has not been set in TASR. The report shows their tracking number, name, date of birth, gender, and current age. It can be used to identify those potential participants who need to be contacted as they become age eligible.**

---

12/16/97  
4:06 pm

PLCO CANCER SCREENING TRIAL  
AGE REVIEW REPORT  
Potential Age Ineligibles without Final Status

Page 1  
SMS 3.41

TrackNum	Last Name	First Name	Middle Name	DOB	Gender	Age
----------	-----------	------------	-------------	-----	--------	-----

INELIGIBLE FOR TRIAL: AGE >=75

CANR0002	Bvxca	Ruth	Bob	9/29/21	F	76
OPAP0002	Opan	Peter		1/01/20	M	77
OPAP0003	Opan	Peter		1/01/20	M	77
OPAP0004	Opan	Peter		1/01/20	M	77

POTENTIAL ELIGIBLES: AGE ELIGIBLE BY OCTOBER 1, 1999

OPAP0001	Opan	Peter		1/01/44	M	53
----------	------	-------	--	---------	---	----

AGE UNKNOWN: DATE OF BIRTH NOT ENTERED

CALC0001	CALVIN	COUNT				
FAST0001	FASHION	TERRY				
FAST0002	FASQUE	TERI				
FIND0003	FINEL	DIXIE				
MAXD0001	MAXIMY	DIANE				
MAXD0002	MAXAMO	DEBRA				
MAXX0001	MAXIMIZE	XER				
ONLY0001	ONLANARD	YANY				
ONLY0002	ONLOO	YANKE				
SETD0001	SETTING	DORIS				
SHOI0002	Jones	Mathew	Attila			
TOBJ0002	Brickner	Clinton	Cuddy			
ZAKE0001	Ham (DECEASED)	Cornelius	Felicia			

## **Appendix B-2-7: Organization Report**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Organization Report***

**This report lists information on organizations the SC has contacted for recruitment using data entered into TASR from the Contact Information screens. The user may print either complete organization information or simply the name, city, state, and ID of the organization.**

---

9/17/96

Organizations sorted by ID  
Complete Information

Page 1

Organization ID: 0001

Name: nih  
Address: 2222 Wisconsin Ave  
Bethesda MD 20000  
Phone: (301)555-1212  
Type: hospital  
Hrs:  
Contact1: Ms Beth Anne Bridgeman  
Title1: Administrative Assistant  
Phone1: (301)555-1212 Fax1: (301)294-2085  
Contact2:  
Title2:  
Phone2: Fax2:  
Comments:  
FreeFld1: 10/10/95 FreeFld2: 10/10/96  
FreeFld3: free field 3 FreeFld4: free field4  
FreeFld5: free field 5

9/17/96

Organizations sorted by ID - Names only

Page 1

ID	Name	City	State
0001	nih	Bethesda	MD

## **Appendix B-2-8: Scheduled and Complete Presentations**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Scheduled and Complete Presentations***

**This report summarizes information on presentations entered into TASR using the Presentations to Organization screen. The list includes the organization ID, the date of the presentation, the program name, the ID of presenting staff, and the number of attendees.**

---

8/13/96

Presentations sorted by Organization ID  
and Date of Presentation

Page 1

Organization ID -----	Date of Presentation -----	Program -----	Staff ID -----	Number Attendees -----
0001	10/20/95	importance of screening	0000	500

## **Appendix B-2-9: Materials Distribution**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Materials Distribution***

**This report shows the distribution cycle for distribution of PLCO materials to organizations. It displays organization ID, type of materials, resupply cycle, and last supply date. It may be sorted by organization ID or date. This report may be used to monitor the success of recruitment materials (such as brochures) in recruiting through organizations, and to ensure the availability of such materials throughout the recruitment period.**

---

ID	Materials	Resupply Cycle	Number PerCycle	Total Num Cycles	Last Supply Date
0001	Study Brochures	1	10000	1	10/10/95

8/13/96

Materials Distribution sorted by Resupply Cycle  
and Last Supply Date

Page 1

Resupply Cycle	Last Supply Date	ID	Materials	Number PerCycle	Total Num Cycles
1/Weekly	10/10/95	0001	Study Brochures	10000	1

## **Appendix B-2-10: Summary of Contacts with Organizations**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Summary of Contacts with Organizations***

**This report summarizes contacts with organizations. It shows the number of organizations in the database, the number for whom at least one presentation was done, the total number of presentations to date, and the total number of attendees over all presentations.**

---

SUMMARY OF CONTACTS WITH ORGANIZATIONS

Screening Center: 08 / Westat

Report Date: 12/16/97

Total Number of Organizations Identified: 2

Total Number of Organizations with at least 1 Presentation: 1

Total Number of Presentations: 1

Total Number of Attendees: 0

## Appendix B-2-11: TASR/RAND Comparison Report

### PLCO Reports - Tracking and Summarizing Recruitment

---

#### *TASR/RAND Comparison Report*

This is a four-part report.

**Part I** identifies potential participants who have an eligible status in TASR, but have not been randomized into the trial. It is sorted by the tracking ID number and includes the DOB, gender, and date the Eligibility Screener was completed.

**Part II** identifies randomized participants who appear in TASR but whose eligibility status is not 'E' (eligible). It is sorted by the tracking number and includes the DOB, gender, date of screen, eligibility status, reason for ineligibility (if applicable), randomization group and randomization date.

**Part III** identifies participants who do not appear in TASR, but are randomized into the trial. It is sorted by the Participant ID number and includes the participant's name, DOB, gender, and randomization group.

**Part IV** identifies randomized participants who match TASR potential participants on DOB and gender but not on name (i.e., the names are similar, but not identical). It is sorted by the tracking ID number and displays the TASR last name, first name, DOB, gender, and PID number. This information is compared to the randomized participant's last name, first name, randomization group and randomization date.

---

8/13/96  
1:48 pm

PLCO CANCER SCREENING TRIAL  
TASR/RAND COMPARISON REPORT

Page 1  
SMS 2.04

Part II: Randomized participants who appear on TASR but whose  
Eligibility Status is not E

TrackNum	Lastname	Firstname	DOB	Gender	Datescreen	EligStatus	Reason	PID	EndGroup	EndDate
TEMA0001	Ferts	Albert	11/26/34	M	12/09/94	I	04	802978-3	I	6/11/96

8/13/96  
1:20 pm

PLCO CANCER SCREENING TRIAL  
TASR/RAND COMPARISON REPORT

Page 1  
SMS 2.04

Part III: Randomized participants who do not appear in TASR

PID	Lastname	Firstname	DOB	Gender	RndGroup	RndDate
800001-4	AQOBL	Cynthia"	11/18/31	F	C	11/08/93
800002-0	Nvbxw	Veronica	3/03/27	F	I	11/08/93
800003-6	Nkhpv	Roma	5/23/30	F	C	11/08/93
800004-2	Kmbsq	Janet	6/10/30	M	C	11/08/93
800005-8	Fujcp	Ann	12/28/26	M	I	11/08/93
800006-4	Rmpjw	Edward	9/01/21	M	C	11/08/93
800007-0	Hvpxe	Gerald	11/04/33	M	I	11/08/93
800008-6	Khdwg	Paul	8/28/28	F	I	11/09/93
800009-2	Jpdnk	Ruth 'Coochie'	6/17/29	M	I	11/09/93
800010-3	Gwpus	Harriet	5/23/25	M	C	11/10/93
800011-9	Bohgn	William	6/10/31	M	C	11/10/93
800012-5	Wfleg	Lenora	5/12/32	F	C	11/10/93
800013-1	Pwihf	Odameil	9/27/24	F	C	11/19/93
800014-7	Krara	Eugene	1/15/29	M	I	11/19/93
800015-3	Tfglo	David	9/07/33	M	C	11/19/93
800016-9	Omiye	Alfred	6/26/21	M	I	3/03/96
800017-5	Pbqkk	Lucy	7/05/22	F	I	11/19/93
800018-1	Naekf	Edith	12/23/29	F	I	11/19/93
800019-7	Etict	Charles	6/20/27	M	C	11/19/93
800020-8	Pfkqy	John	5/20/20	M	I	11/19/93
800021-4	Kixdk	Charlotte	12/27/23	F	I	11/19/93
800022-0	Pukbw	Mina	10/16/28	F	C	11/19/93
800023-6	Ltreh	Jerome	6/20/21	M	I	11/19/93
800024-2	Zdcwl	Irwin	3/03/28	M	I	11/19/93
800025-8	Tidah	Catherine	3/29/24	F	I	11/19/93
800026-4	Etprv	Dorothy	7/07/26	F	I	11/19/93
800027-0	Qppnc	Patricia	11/08/25	F	C	11/19/93
800028-6	Iujyy	Lawrence	8/27/21	M	C	11/19/93
800029-2	Owoin	Jeanne	9/09/25	F	C	11/23/93
800030-3	Rfmpx	William	12/21/27	M	C	12/01/93
800031-9	Ofbms	Millie	11/16/29	F	I	12/01/93
800032-5	Vrqxj	Richard	11/12/31	M	C	12/01/93
800033-1	Ywnot	Helen	8/12/25	F	I	12/01/93
800034-7	Udrkh	Richard	10/17/25	M	C	12/01/93
800035-3	Cbspp	Priscilla	9/29/26	F	C	12/01/93
800036-9	Jknjv	Herbert	1/08/23	M	C	12/01/93

8/13/96  
1:44 pm

PLCO CANCER SCREENING TRIAL  
TASR/RAND COMPARISON REPORT

Page 1  
SMS 2.04

Part IV: Randomized participants who match TASR recruits on Date of Birth  
and Gender but where the names are only similar (not identical)

TrackNum	TASR Lastname	TASR Firstname	DOB	Gender	PID	RAND Lastname	RAND Firstname	RandGroup	RadDate
AL 0002	Alcott	Louisa	3/04/25	F	803057-4	Alco	Louis	C	1/10/96
ALCL001	Alcott	Louisa	3/04/25	F	803057-4	Alco	Louis	C	1/10/96
ALCL003	Alcott	Louisa	3/04/25	F	803057-4	Alco	Louis	C	1/10/96
ALCL004	Alcott	Louisa	3/04/25	F	803057-4	Alco	Louis	C	1/10/96
MCC0002	Ugnyv	Gerald	2/18/31	M	800529-2	Ubuvs	Gerald	C	4/14/94
PIG0001	Pig	Porcky	9/15/24	M	803060-7	Pigs	Porcky	I	1/10/96
PIG0002	Pig	Porcky	9/15/24	M	803060-7	Pigs	Porcky	I	1/10/96
PIG0003	Pig	Porcky	9/15/24	M	803060-7	Pigs	Porcky	I	1/10/96
PIG0004	Pig	Porcky	9/15/24	M	803060-7	Pigs	Porcky	I	1/10/96
STAR0002	Star	Brenda	11/21/30	F	803061-3	Star	Brenda	C	1/10/96
STAR0003	Star	Brenda	11/21/30	F	803061-3	Star	Brenda	C	1/10/96
STAR0004	Star	Brenda	11/21/30	F	803061-3	Star	Brenda	C	1/10/96
STAR0005	Star	Brenda	11/21/30	F	803061-3	Star	Brenda	C	1/10/96

## **Appendix B-2-12: Eligibility Contact Report**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Eligibility Contact Report***

**This report lists the last date contacted and current age for those individuals in TASR that have not yet been enrolled in the study. The information is given for those individuals contacted within a specified time period and sorted by age group.**

---

12/17/97  
8:43 am

PLCO CANCER SCREENING TRIAL  
Eligibility Contact Report

Page 2  
SMS 3.41

SC Name: Westat

Selection Criteria:

Last contacted between 6/01/97 and 12/01/97 for participants of all ages.  
Previous Batch Randomization records excluded.

Part 1: Selection Matches

Age Group: 55 to <60  
Total Records considered: 3

Tracking Number	Date Last Contacted	Current Age
BJOP0001	8/04/97	58
CONV0001	8/04/97	58
CUBS0001	7/24/97	55

Age Group: 60 to <65  
Total Records considered: 2

Tracking Number	Date Last Contacted	Current Age
CHIM0003	8/04/97	63
KRAE0003	6/30/97	60

Age Group: 65 to <70  
Total Records considered: 10

Tracking Number	Date Last Contacted	Current Age
APPC0001	8/28/97	65
BALK0001	8/04/97	66
BARA0005	8/04/97	68
BECD0002	8/04/97	68
BIHJ0001	8/04/97	67
BLAJ0003	8/04/97	69
BLAS0003	8/04/97	65
BLOG0001	8/04/97	68
BLOW0003	8/04/97	67
BRAM0004	8/04/97	68

Age Group: 70 to <75  
Total Records considered: 9

Tracking Number	Date Last Contacted	Current Age
ARAL0001	8/04/97	72

12/17/97  
8:43 am

PLCO CANCER SCREENING TRIAL  
Eligibility Contact Report

Page 3  
SMS 3.41

SC Name: Westat

Selection Criteria:

Last contacted between 6/01/97 and 12/01/97 for participants of all ages.  
Previous Batch Randomization records excluded.

Part 1: Selection Matches

Age Group: 70 to <75

Total Records considered: 9

Tracking Number	Date Last Contacted	Current Age
BAND0001	8/04/97	71
BARJ0003	8/04/97	74
BARR0003	8/04/97	74
BELJ0001	8/04/97	70
BIOM0001	8/04/97	73
BLAE0001	8/04/97	74
BRIS0001	11/08/97	74
CLAR0001	8/04/97	71

Age Group: ≥75

Total Records considered: 2

Tracking Number	Date Last Contacted	Current Age
BAIJ0001	8/04/97	75
BIAA0001	8/04/97	76

12/17/97  
8:43 am

PLCO CANCER SCREENING TRIAL  
Eligibility Contact Report

Page 4  
SMS 3.41

SC Name: Westat

Selection Criteria:

Last contacted between 6/01/97 and 12/01/97 for participants of all ages.  
Previous Batch Randomization records excluded.

Part 2: Records with no dates for comparison

Age Group: 55 to <60

Total Records considered: 1

Tracking Number	Date of Last Update	Current Age
----- FIXB0001	----- 6/21/96	----- 56

Age Group: 70 to <75

Total Records considered: 1

Tracking Number	Date of Last Update	Current Age
----- SHED0001	----- 4/18/95	----- 71

## **Appendix B-2-13: Number of TASR Eligibles Report**

### **PLCO Reports - Tracking and Summarizing Recruitment**

---

#### ***Number of TASR Eligibles Report***

**(Participants Randomized and Screens Performed Per Recruitment Source)**

**This report counts the number of participants eligible, randomized, and screened by recruitment source. The screening information is given as a total and broken down into study year. This report can be generated overall or by gender.**

---

Report Date: 9/02/98  
 Time: 3:49 pm

Page 1  
 SMS 4.21

PLCO CANCER SCREENING TRIAL  
 Number of TADR Eligibles, Participants Randomized  
 and Screens Performed Per Recruitment Source  
 Overall

Recruitment Source	Number Eligible	Number Randomized	Total # Screened	# Screened at			
				T0	T1	T2	T3
	29	1759	2537	740	682	637	478
1202	1	1	0	0	0	0	0
?	12	3	4	1	1	1	1
Frie	1	1	0	0	0	0	0
Jack	2	2	6	2	2	2	0
VA	13	13	19	6	6	7	0
VOTE	0	1	3	1	1	1	0
Vote	1	2	4	2	1	1	0
WHI	1	0	0	0	0	0	0
adv	1	1	1	0	1	0	0
call	4	4	1	1	0	0	0
comm	9	0	0	0	0	0	0
dr.	2	2	0	0	0	0	0
e	1	1	0	0	0	0	0
frie	110	53	70	24	20	14	12
frnd	4	4	2	1	1	0	0
jack	3	3	2	1	1	0	0
lath	12	12	9	9	0	0	0
lunc	15	4	3	1	1	1	0
mail	3	2	4	2	2	0	0
md	5	4	14	4	4	3	3
mike	4	3	0	0	0	0	0
news	18	1	1	1	0	0	0
othe	1	1	0	0	0	0	0
othr	1	1	2	1	1	0	0
part	1	1	4	1	1	1	1
pitt	3	3	1	1	0	0	0
plco	7	7	4	2	2	0	0
publ	70	3	4	1	1	1	1
radi	1	1	4	1	1	1	1
rel	12	11	8	4	4	0	0
rela	101	69	81	31	26	16	8
tv	48	2	1	1	0	0	0
upmc	14	2	0	0	0	0	0
va	33	33	38	17	14	7	0
vamc	1	1	0	0	0	0	0
voe	1	1	0	0	0	0	0
void	0	2	0	0	0	0	0
vot3	1	1	0	0	0	0	0
vote	9585	8275	8444	3753	2661	1542	488
vpte	1	1	0	0	0	0	0
wes1	1	1	0	0	0	0	0
whi	28	7	2	1	1	0	0

Report Date: 9/02/98  
Time: 3:49 pm

Page 2  
SMS 4.21

PLCO CANCER SCREENING TRIAL  
Number of TADR Eligibles, Participants Randomized  
and Screens Performed Per Recruitment Source  
Overall

Recruitment Source	Number Eligible	Number Randomized	Total # Screened	T0	# Screened at		
					T1	T2	T3
Totals	10161	10299	11273	4610	3435	2235	993

Report Date: 9/02/98  
 Time: 3:50 pm

Page 1  
 SMS 4.21

PLCO CANCER SCREENING TRIAL  
 Number of TADR Eligibles, Participants Randomized  
 and Screens Performed Per Recruitment Source  
 By Gender

Recruitment Source	Number Eligible	Number Randomized	Total # Screened	# Screened at			
				T0	T1	T2	T3
Gender = Female							
1202	12	715	969	281	256	241	191
?	1	1	0	0	0	0	0
Frie	3	2	0	0	0	0	0
Jack	1	1	0	0	0	0	0
VA	1	1	3	1	1	1	0
Vote	1	1	3	1	1	1	0
WHI	1	2	4	2	1	1	0
call	1	0	0	0	0	0	0
comm	3	3	1	1	0	0	0
dr.	4	0	0	0	0	0	0
e	2	2	0	0	0	0	0
frie	1	1	0	0	0	0	0
frnd	58	28	32	11	10	7	4
jack	4	4	2	1	1	0	0
lath	1	1	0	0	0	0	0
lunc	6	6	6	6	0	0	0
mail	10	3	3	1	1	1	0
md	1	1	2	1	1	0	0
mike	4	3	10	3	3	2	2
news	2	1	0	0	0	0	0
othe	8	0	0	0	0	0	0
othr	1	1	0	0	0	0	0
pitt	1	1	2	1	1	0	0
plco	3	3	1	1	0	0	0
publ	4	4	2	1	1	0	0
radi	31	1	0	0	0	0	0
rel	1	1	4	1	1	1	1
rela	9	8	6	3	3	0	0
tv	58	40	52	20	16	12	4
upmc	19	1	1	1	0	0	0
va	6	2	0	0	0	0	0
void	4	4	7	3	3	1	0
vot3	0	1	0	0	0	0	0
vote	1	1	0	0	0	0	0
vppe	4331	3835	3543	1702	1084	597	160
whi	1	1	0	0	0	0	0
	22	6	2	1	1	0	0
Totals	4617	4686	4655	2043	1385	865	362

Report Date: 9/02/98  
 Time: 3:50 pm

Page 2  
 SMS 4.21

PLCO CANCER SCREENING TRIAL  
 Number of TADR Eligibles, Participants Randomized  
 and Screens Performed Per Recruitment Source  
 By Gender

Recruitment Source	Number Eligible	Number Randomized	Total # Screened	# Screened at			
				T0	T1	T2	T3
Gender = Male							
	17	1044	1568	459	426	396	287
?	9	1	4	1	1	1	1
Jack	1	1	3	1	1	1	0
VA	12	12	16	5	5	6	0
VOTE	0	1	3	1	1	1	0
adv	1	1	1	0	1	0	0
call	1	1	0	0	0	0	0
comm	5	0	0	0	0	0	0
frie	52	25	38	13	10	7	8
jack	2	2	2	1	1	0	0
lath	6	6	3	3	0	0	0
lunc	5	1	0	0	0	0	0
mail	2	1	2	1	1	0	0
md	1	1	4	1	1	1	1
mike	2	2	0	0	0	0	0
news	10	1	1	1	0	0	0
part	1	1	4	1	1	1	1
plco	3	3	2	1	1	0	0
publ	39	2	4	1	1	1	1
rel	3	3	2	1	1	0	0
rela	43	29	29	11	10	4	4
tv	29	1	0	0	0	0	0
upmc	8	0	0	0	0	0	0
va	29	29	31	14	11	6	0
vamc	1	1	0	0	0	0	0
voe	1	1	0	0	0	0	0
void	0	1	0	0	0	0	0
vote	5254	4440	4901	2051	1577	945	328
wes1	1	1	0	0	0	0	0
whi	6	1	0	0	0	0	0
Totals	5544	5613	6618	2567	2050	1370	631

## **Appendix B-3-1: PCC Directive/Late Directive**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***PCC Directive/Late Directive***

**This report lists the participants who are due to complete the Protocol Changes Consent (PCC) but the form has not been receipted.**

---

Screening Center: University of Pittsburgh / ID# 08

Participants Due for NEW Requests

RANDOMIZATION GROUP: I

Gender: F

PID	Study Year	Form Type	Rand Date
810211-9	T5	PCC	4/06/98
810301-8	T5	PCC	4/20/98
810328-0	T5	PCC	4/28/98
810375-7	T5	PCC	5/04/98
810424-0	T5	PCC	5/07/98
810431-7	T5	PCC	5/11/98
810463-4	T5	PCC	5/14/98
810466-2	T5	PCC	5/14/98
810596-1	T5	PCC	6/01/98
810599-9	T5	PCC	6/01/98
810699-3	T5	PCC	6/16/98
810701-4	T5	PCC	6/16/98
810746-4	T5	PCC	6/23/98
810846-8	T5	PCC	7/01/98
810892-9	T5	PCC	7/07/98
810933-9	T5	PCC	7/09/98
810970-1	T5	PCC	7/13/98
810989-0	T5	PCC	7/15/98
811124-1	T5	PCC	8/03/98
811200-1	T5	PCC	8/05/98
811203-9	T5	PCC	8/05/98
811244-5	T5	PCC	8/10/98
811247-3	T5	PCC	8/10/98
811267-3	T5	PCC	8/10/98

-----  
Total Females (Intervention) : 24

Gender: M

PID	Study Year	Form Type	Rand Date
810220-8	T5	PCC	4/07/98
810241-4	T5	PCC	4/14/98
810327-4	T5	PCC	4/28/98
810462-8	T5	PCC	5/14/98
810470-1	T5	PCC	5/14/98
810700-8	T5	PCC	6/16/98
810715-3	T5	PCC	6/16/98
810816-3	T5	PCC	6/29/98
810889-6	T5	PCC	7/07/98

## Appendix B-4-1: Interactive Randomization Report

### PLCO Reports - Randomization and Enrollment

---

#### *Interactive Randomization Report*

This report combines randomization information including the date of randomization, participant ID, randomization group, confirmation number, and the staff ID for the person completing the Eligibility Verification Form, and performing the randomization. This report prints out after each interactive randomization.

---

8/13/96

INTERACTIVE RANDOMIZATION REPORT

Page 1

Date of Randomization/Enrollment: 8/13/96

Participant ID: 802979-9

Randomization Group: I

ID of Person Completing the Eligibility Verification Form: 0001

ID of Person Performing Randomization/Enrollment: 0

Confirmation Number: 00010813802979

|

## Appendix B-4-2: Batch Randomization Report

### PLCO Reports - Randomization and Enrollment

---

#### ***Batch Randomization Report***

**This report displays information on the participants in the batch who were successfully randomized and listings of potential participants who were not randomized because they were determined to be age ineligible, potential duplicates, or missing necessary data.**

---

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff, and store and dispose of report in \*\*  
\*\* a proper manner. \*\*

8/16/96

BATCH RANDOMIZATION REPORT

Page 1

PID: 802987-2  
DOB: 7/31/30  
SCID: 08  
LastName: Akvss  
FirstName: Walter  
MiddleName: Bob  
Gender: M  
Rndgroup: C  
RndDate: 8/16/96  
UserID: 0  
CallerID: 0  
ConfirmNo: 00816802987  
SatelCenter: 00

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff, and store and dispose of report in \*\*  
\*\* a proper manner. \*\*

PID: 802988-8  
DOB: 8/19/33  
SCID: 08  
LastName: Axoiw  
FirstName: Janet  
MiddleName: Bob  
Gender: F  
Rndgroup: C  
RndDate: 8/16/96  
UserID: 0  
CallerID: 0  
ConfirmNo: 00816802988  
SatelCenter: 00

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff, and store and dispose of report in \*\*  
\*\* a proper manner. \*\*

Lastname: Lpwdd  
Firstname: Ida  
Middlename: Bob  
Suffix:  
Dob: 4/18/20  
Gender: F  
Satelcenter: 00  
TrackNum: ALBI0001  
Error: Y  
Dupli:

Lastname: Mutrm  
Firstname: Thomas  
Middlename: Bob  
Suffix:  
Dob: 4/11/20  
Gender: M  
Satelcenter: 00  
TrackNum: ALCT0001  
Error: Y  
Dupli:

Lastname: Ntpll  
Firstname: Robert  
Middlename: Bob  
Suffix:  
Dob: 8/20/20  
Gender: M  
Satelcenter: 00  
TrackNum: ASHR0001  
Error: Y  
Dupli:

Lastname: Owzyr  
Firstname: William  
Middlename: Bob  
Suffix:  
Dob: 2/25/21  
Gender: M  
Satelcenter: 00  
TrackNum: ARDW0001  
Error: Y  
Dupli:

Lastname: Afqwk  
Firstname: Nancy  
Middlename: Bob  
Suffix:  
Dob: 5/14/32  
Gender: F  
Satelcenter: 00  
TrackNum: ALDN0001  
Error:  
Dupli: Y

Lastname: Rqqcq  
Firstname: David  
Middlename: Bob  
Suffix:  
Dob: 10/07/26  
Gender: M  
Satelcenter: 00  
TrackNum: ALTD0001  
Error:  
Dupli: Y

Lastname: Xzmav  
Firstname: Robert  
Middlename: Bob  
Suffix:  
Dob: 9/05/31  
Gender: M  
Satelcenter: 00  
TrackNum: ALDR0001  
Error:  
Dupli: Y

Line Number: 1  
Line: "Bdzct","Jean","Bob","","11/27/1922","F","00","AIKJ0001"  
Reason: Too many fields

Line Number: 2  
Line: "Qdqdf","Margaret","Bob","","8/25/1933","F","00","ALBM0001"  
Reason: Too many fields

Line Number: 3  
Line: "Afgwk","Nancy","Bob","","5/14/1932","F","00","ALDN0001"  
Reason: Too many fields

Line Number: 4  
Line: "Xzmav","Robert","Bob","","9/05/1931","M","00","ALDR0001"  
Reason: Too many fields

Line Number: 5  
Line: "Qdshz","Jack","Bob","","3/31/1922","M","00","ALLJ0001"  
Reason: Too many fields

Line Number: 6  
Line: "Xktfb","Teresa","Bob","","9/12/1928","F","00","ALLT0001"  
Reason: Too many fields

Line Number: 7  
Line: "Cyyji","Thomas","Bob","","7/02/1919","M","00","ALLT0003"  
Reason: Too many fields

Line Number: 8  
Line: "Vythi","William","Bob","","5/04/1924","M","00","ALLW0001"  
Reason: Too many fields

## **Appendix B-4-3: Enrollment Status Report**

### **PLCO Reports - Randomization and Enrollment**

---

#### ***Enrollment Status Report***

**This report summarizes the number of participants enrolled in each study arm during a specified month and year, and cumulatively.**

---

PLCO CANCER SCREENING TRIAL  
Enrollment Status Report

Page 1  
SMS 3.41

SC Name: Westat

Report Date: 12/16/97  
Time: 4:27 pm

Report for: October, 1997

```
-----  
Randomized      R e p o r t   M o n t h           C u m u l a t i v e  
Participants    Male   Female   Total           Male   Female   Total  
-----  
All              17     20     37             4929   3781   8710  
Intervention     9       7     16             2470   1891   4361  
Control          8      13     21             2459   1890   4349  
-----
```

## **Appendix B-4-4: Enrollment Summary Report**

### **PLCO Reports - Randomization and Enrollment**

---

#### ***Enrollment Summary Report***

**This report summarizes the number of participants in each study arm and age group. It also shows the mean age overall, the mean age by age group, and gender frequency by study arm and age group. It may be generated for a specified range of randomization dates.**

---

PLCO CANCER SCREENING TRIAL  
Enrollment Summary Report

Page 1  
SMS 3.41

SC Name: Westat

Report Date: 12/16/97  
Time: 4:34 pm

Participants Included: Rand Dates 12/01/97 to 12/16/97

	INTERVENTION	CONTROL	TOTAL	
# Participants:	19	34	53	
Mean age:	62	64	63	
# Males:	10	18	28	
# Females:	9	16	25	

	AGE (55-59)	AGE (60-64)	AGE (65-69)	AGE (70-74)
# Participants:	16	13	13	11
Mean Age:	57	62	66	72
# Males:	8	6	7	7
# Females:	8	7	6	4

## Appendix B-4-5: Randomization Assignment Report

### PLCO Reports - Randomization and Enrollment

---

#### *Randomization Assignment Report*

This report shows the study arm assignment, gender, DOB, and randomization date for each participant ID. It is sorted by participant ID and may be generated for a specific range of randomization dates.

---

PLCO CANCER SCREENING TRIAL  
Randomization Assignment Report

Page 1  
SMS 3.41

SC Name: Westat

Report Date: 12/16/97

Participants included: Rand Dates 10/16/97 to 12/16/97

Time: 4:26 pm

PID	CONF NUMBER	GROUP	GENDER	DOB	MOD DOB	RAND DATE
808695-1	00071028808695	C	M	5/17/34		10/28/97
808697-3	00071028808697	C	F	11/08/29		10/28/97
808698-9	00071028808698	C	F	9/01/32		10/28/97
808702-2	00071028808702	C	F	5/09/32		10/28/97
808703-8	00071028808703	I	M	11/24/27		10/28/97
808704-4	00011109808704	I	F	9/15/37		11/09/97
808705-0	10001111808705	I	M	3/25/28		11/11/97
808706-6	00011118808706	C	F	9/15/36		11/18/97
808707-2	10001216808707	C	F	7/03/31		12/16/97
808708-8	10001216808708	C	M	3/13/34		12/16/97
808709-4	10001216808709	C	M	9/10/23		12/16/97
808710-5	10001216808710	C	M	5/01/30		12/16/97
808711-1	10001216808711	I	F	6/19/39		12/16/97
808712-7	10001216808712	C	M	1/25/31		12/16/97
808713-3	10001216808713	C	M	1/29/41		12/16/97
808714-9	10001216808714	I	F	7/25/29		12/16/97
808715-5	10001216808715	C	F	4/24/39		12/16/97
808716-1	10001216808716	I	M	9/22/40		12/16/97
808717-7	10001216808717	I	M	3/14/40		12/16/97
808718-3	10001216808718	I	M	7/24/39		12/16/97
808719-9	10001216808719	C	F	5/12/37		12/16/97
808720-0	10001216808720	C	F	5/21/38		12/16/97
830001-0	10001203830001	C	M	5/16/23		12/03/97
830002-6	10001203830002	C	M	1/09/41		12/03/97
830003-2	10001203830003	C	M	10/15/25		12/03/97
830008-2	10001203830008	C	M	3/26/37		12/03/97
830009-8	10001203830009	C	M	1/19/31		12/03/97
830010-9	10001203830010	I	M	2/16/26		12/03/97
830011-5	10001203830011	C	M	10/22/25		12/03/97
830012-1	10001203830012	C	M	11/18/32		12/03/97
830013-7	10001203830013	C	M	8/12/28		12/03/97
830014-3	10001203830014	C	M	4/18/35		12/03/97
830015-9	10001203830015	I	M	7/07/38		12/03/97
830016-5	10001203830016	I	M	1/28/33		12/03/97
830017-1	10001203830017	C	M	3/06/40		12/03/97
830018-7	10001203830018	I	M	9/03/34		12/03/97
830019-3	10001203830019	C	M	6/02/39		12/03/97
830020-4	10001203830020	C	M	9/19/32		12/03/97
830021-0	10001203830021	I	M	5/07/36		12/03/97
830022-6	10001203830022	C	M	2/09/26		12/03/97
830023-2	10001203830023	I	M	6/17/27		12/03/97
830024-8	10001203830024	I	M	3/20/30		12/03/97
830028-2	10001203830028	C	F	3/20/33		12/03/97
830029-8	10001203830029	C	F	8/14/39		12/03/97
830030-9	10001203830030	C	F	1/27/29		12/03/97
830032-1	10001203830032	I	F	12/05/29		12/03/97
830033-7	10001203830033	C	F	8/08/36		12/03/97

PLCO CANCER SCREENING TRIAL  
Randomization Assignment Report

Page 2  
SMS 3.41

SC Name: Westat

Report Date: 12/16/97  
Time: 4:26 pm

Participants included: Rand Dates 10/16/97 to 12/16/97

PID	CONF NUMBER	GROUP	GENDER	DOB	MOD DOB	RAND DATE
830034-3	10001203830034	C	F	1/05/36		12/03/97
830035-9	10001203830035	I	F	2/22/36		12/03/97
830036-5	10001203830036	I	F	1/22/34		12/03/97
830037-1	10001203830037	I	F	6/23/25		12/03/97
830038-7	10001203830038	I	F	7/11/38		12/03/97
830039-3	10001203830039	C	F	6/23/25		12/03/97
830040-4	10001203830040	I	F	10/03/41		12/03/97
830041-0	10001203830041	C	F	12/04/32		12/03/97
830042-6	10001203830042	C	F	10/24/30		12/03/97
830043-2	10001203830043	C	F	6/17/30		12/03/97
830044-8	10001203830044	C	F	12/25/23		12/03/97
830045-4	10001203830045	I	F	7/17/41		12/03/97
830046-0	10001203830046	C	F	8/28/42		12/03/97
830047-6	10001203830047	C	F	12/04/23		12/03/97

The total number of participants is 61

## Appendix B-4-6: Study ID Assignment Report

### PLCO Reports - Randomization and Enrollment

---

#### *Study ID Assignment Report*

This report lists the name, PID number, randomization date, gender, DOB, modified DOB, randomization group, and home phone number for each participant enrolled in the study. It may be generated for a range of PIDs, a range of dates, and a specified group (Intervention/Control). It may be sorted by PID or alphabetically by last name. This report may be used a reference report for a variety of SC management tasks, and is for internal SC use only.

---

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

PLCO CANCER SCREENING TRIAL  
 Study ID Assignment Report

Page 1  
 SMS 8.1

SC Name: University of Pittsburgh  
 Participants Included: Complete listing  
 Sorted on PID

Report Date: 6/15/03  
 Time: 4:01 pm

LAST NAME	FIRST NAME	MIDDLE NAME	SUFFIX	TITLE	PID	RAND DATE	GENDER	DOB	MOD DOB	GROUP
Marvin	GENNIE	JACALYN	Ph.d	Mayor	305420-4	7/05/96	F	5/05/40		I
Holnan	CHRISTEEN	KATHIE	Jr	LTC	800001-4	11/08/93	F	11/18/31		C
Wenston	TABITHA	KAREN	OSF	Rev	800002-0	11/08/93	F	3/03/27		I
Maksenetz	AMY	YONG	II	Prof.	800003-6	11/08/93	F	5/23/30		C
Williams-Ritter	MARGARETTE	KEENA	Sr	Mayor	800004-2	11/08/93	F	6/10/30		C
Ruhle	JENNI	STARLA	DMD		800005-8	11/08/93	F	12/28/26		I
Drawn	MAURO	LEONARDO	R.N.	Mayor	800006-4	11/08/93	M	9/01/21		C
Slonecker	MALCOLM	TODD	CSJ	Judge	800007-0	11/08/93	M	11/04/33		I
Brzozowski	HARVEY	DARYL	Ph.D	Dr.	800008-6	11/09/93	M	8/28/28		I
Laible	LORY	LIZETH	S.M.	Chief	800009-2	11/09/93	F	6/17/29		I
Mitchell	EMMALINE	LASHUNDA	RSM	Prof.	800010-3	11/10/93	F	5/23/25		C
Park	LOU	ALVARO	III		800011-9	11/10/93	M	6/10/31		C
Orendi	LAJUANA	MICHELINE	DMD	Maj.	800012-5	11/10/93	F	5/12/32	5/12/22	C
Tour	MINERVA	MARIS	MD		800013-1	11/19/93	F	9/27/24		C
Saleme	GREGORIO	RUDOLPH	S.	Sr.	800014-7	11/19/93	M	1/15/29		I
McKinstry	GARRETT	BUDDY	III		800015-3	11/19/93	M	9/07/33		C
Pollock	LYNDON	KING	R.M.	Str.	800016-9	11/19/93	M	6/26/21		I
Garofalo	AMEE	DEBBIE	Jr	Rep	800017-5	11/19/93	F	7/05/22		I
Keefer	MARCIE	DAISEY	Jr	DR.	800018-1	11/19/93	F	12/23/29		I
Siverd	PAT	DEANDRE	PhD	Rev.	800019-7	11/19/93	M	6/20/27		C
Lefkowitz	GIUSEPPE	ALPHONSO	Jr		800020-8	11/19/93	M	5/20/20		I
Neudorfer	JUANITA	MELIDA	S.M.	Capt.	800021-4	11/19/93	F	12/27/23		I
Barshick	MURIEL	JEWELL	PhD	Capt.	800022-0	11/19/93	F	10/16/28		C
Jeffrey	LYNN	ERNESTO	OSF		800023-6	11/19/93	M	6/20/21		I
Letky	CHI	VERNON	Sr	Prof.	800024-2	11/19/93	M	3/03/28		I
Binder	JUSTINE	ROZELLA	Jr	Dr.	800025-8	11/19/93	F	3/29/24		I
Humes	LAVADA	JANEEN	S.	Prof.	800026-4	11/19/93	F	7/07/26		I
Barraclough	YANG	JAIMIE	II	LTC	800027-0	11/19/93	F	11/08/25		C
Arasin	PRINCE	RAISIGH	MD	Sr.	800028-6	11/19/93	M	8/27/21		C
Wolff	OLA	PRICILLA	Ph.D	DR.	800029-2	11/23/93	F	9/09/25		C
Mizel	KOREY	LEON	II	Prof.	800030-3	12/01/93	M	12/21/27		C
Bayne	DEANN	DELAINE	S.	Prof.	800031-9	12/01/93	F	11/16/29		I
Willson	CALVIN	DEXTER	II	Rev.	800032-5	12/01/93	M	11/12/31		C
Meier	LAVETA	MARINE	RSM	Prof.	800033-1	12/01/93	F	8/12/25		I
Zorn	BOYCE	RANDAL	III	Hon.	800034-7	12/01/93	M	10/17/25		C
Puthenpurayil	TABITHA	ROXANA	DMD	Pres.	800035-3	12/01/93	F	9/29/26		C
Banjak	NESTOR	JULES	Sr		800036-9	12/01/93	M	1/08/23		C
Spalla	MILAN	JESUS	RSM		800037-5	12/01/93	M	12/07/30		I
Sorice	CHARLINE	PEARLE	CSJ	Judge	800038-1	12/01/93	F	10/26/31		I
Iskovitz	DERRICK	MITCHEL	CSJ	Judge	800039-7	12/01/93	M	2/01/32		I
Scheier	DOUGLASS	RODERICK	DDS	Bro.	800040-8	12/01/93	M	8/24/25		I
Kengor	DANA	SANTO	Ph.d	Sen	800041-4	12/01/93	M	1/09/25		I

\*\* This report contains data protected by Privacy Act of 1975. \*\*  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

## **Appendix B-4-7: Report of BQ/RAND Discrepancies**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Report of BQ/RAND Discrepancies***

**This report identifies possible randomized ineligible based on participant responses to questions on the Baseline Questionnaire regarding personal cancers and prior use of PLCO screening examinations.**

---



12/18/97  
9:34 am

PLCO CANCER SCREENING TRIAL  
BQ/RAND Discrepancy Report Status

Page 1  
DEES 3.41

Form	Status
-----	-----
BQF	No forms match search criteria.
BQF2	Done.
BQF3	Done.
BQM	No forms match search criteria.
BQM2	Done.
BQM3	Done.

## **Appendix B-5-1: Baseline Directive**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Baseline Directive***

**This report lists the participants who are in their reporting window for the Baseline Questionnaire, Baseline Locator Form, and Dietary Questionnaire and have not completed one or more of the forms.**

---

12/18/97  
3:24 pm

PLCO CANCER SCREENING TRIAL  
Baseline Directive

Page 2  
SMS 3.4

Screening Center: Westat / ID# 08

Participants Due for NEW Requests

RANDOMIZATION GROUP: C

Gender: F

Participant ID	Form Type	Randomization Date
830030-9	BLF	12/03/97
830030-9	BQF	12/03/97
830033-7	BLF	12/03/97
830033-7	BQF	12/03/97
830034-3	BLF	12/03/97
830034-3	BQF	12/03/97
830039-3	BLF	12/03/97
830039-3	BQF	12/03/97
830041-0	BLF	12/03/97
830041-0	BQF	12/03/97
830042-6	BLF	12/03/97
830042-6	BQF	12/03/97
830043-2	BLF	12/03/97
830043-2	BQF	12/03/97
830044-8	BLF	12/03/97
830044-8	BQF	12/03/97
830046-0	BLF	12/03/97
830046-0	BQF	12/03/97
830047-6	BLF	12/03/97
830047-6	BQF	12/03/97
-----		
Total Females (Control)		: 62

Gender: M

Participant ID	Form Type	Randomization Date
808661-2	BLF	10/01/97
808661-2	BQM	10/01/97
808663-4	BLF	10/01/97
808663-4	BQM	10/01/97
808669-0	BLF	10/01/97
808669-0	BQM	10/01/97
808670-1	BLF	10/07/97
808670-1	BQM	10/07/97
808672-3	BLF	10/07/97
808672-3	BQM	10/07/97
808679-5	BLF	10/07/97
808679-5	BQM	10/07/97
808684-0	BLF	10/07/97

12/18/97  
3:24 pm

PLCO CANCER SCREENING TRIAL  
Baseline Directive

Page 5  
SMS 3.4

Screening Center: Westat / ID# 08

Participants Due for NEW Requests

RANDOMIZATION GROUP: I

Gender: F

Participant ID	Form Type	Randomization Date
830032-1	BLF	12/03/97
830032-1	BQF	12/03/97
830032-1	DQX	12/03/97
830035-9	BLF	12/03/97
830035-9	BQF	12/03/97
830035-9	DQX	12/03/97
830036-5	BLF	12/03/97
830036-5	BQF	12/03/97
830036-5	DQX	12/03/97
830037-1	BLF	12/03/97
830037-1	BQF	12/03/97
830037-1	DQX	12/03/97
830038-7	BLF	12/03/97
830038-7	BQF	12/03/97
830038-7	DQX	12/03/97
830040-4	BLF	12/03/97
830040-4	BQF	12/03/97
830040-4	DQX	12/03/97
830045-4	BLF	12/03/97
830045-4	BQF	12/03/97
830045-4	DQX	12/03/97

Total Females (Intervention) : 51

Gender: M

Participant ID	Form Type	Randomization Date
808658-9	BLF	9/30/97
808658-9	BQM	9/30/97
808658-9	DQX	9/30/97
808664-0	BLF	10/01/97
808664-0	BQM	10/01/97
808664-0	DQX	10/01/97
808666-2	BLF	10/01/97
808666-2	BQM	10/01/97
808666-2	DQX	10/01/97
808671-7	BLF	10/07/97
808671-7	BQM	10/07/97
808671-7	DQX	10/07/97

## **Appendix B-5-2: Duplicate Forms Report**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Duplicate Forms Report***

**This report identifies duplicate forms of the same form type (and study year and visit number, if applicable) scanned for the same PID. It also identifies forms with the same serial number scanned for different PIDs.**

---

**PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY**  
**DUPLICATE FORMS REPORT (Duplicate PIDs)**

12/03/2003  
10:43 am

Page: 1  
DEES: 9.1

<b>FORM</b>	<b>PID</b>	<b>SERIAL</b>	<b>STUDYYR</b>	<b>VISIT</b>	<b>FSCAN</b>	<b>LSCAN</b>	<b>COMPDATE</b>
DO2	812159-9	018745	T00		05/15/2001	10/10/2001	04/30/2001
DO3		024644	T00		05/29/2002	05/29/2002	05/15/2002

---

**Total Number of Records: 2**

End of Report

## **Appendix B-6-1: Results Pending Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Results Pending Report***

**This report lists all participants for whom screening examination results are pending (status of RP). The report shows the PID, study year, form type, and examination date.**

---

PLCO CANCER SCREENING TRIAL  
Results Pending Report

Page  
SMS 8.

SC Name: University of Pittsburgh

Report Date: 5/22/  
Time: 1:29

Pid	Study Year	Visit	Exam Form	Exam Date
807897-8	T4	1	BFF	4/05/01
807908-3	T4	1	BFF	4/05/01
810202-0	T3	1	BCF	4/05/01
810206-4	T3	1	BCF	4/05/01
810208-6	T3	1	BCF	4/05/01
810219-7	T3	1	BCF	4/05/01
810230-3	T3	1	BCF	4/05/01
810231-9	T3	1	BCF	4/05/01
810299-7	T3	1	BCF	4/05/01
810305-2	T3	1	BCF	4/05/01
810306-8	T3	1	BCF	4/05/01
810310-7	T3	1	BCF	4/05/01
810314-1	T3	1	BCF	4/05/01
810315-7	T3	1	BCF	4/05/01
810321-8	T3	1	BCF	4/05/01
811857-2	T2	1	BCF	4/05/01
811884-9	T2	1	BCF	4/05/01
812640-0	T2	1	BCF	4/05/01
812677-7	T2	1	BCF	4/05/01
812678-3	T2	1	BCF	4/05/01
812860-8	T2	1	BCF	4/05/01
812955-7	T2	1	BCF	4/05/01
812983-0	T2	1	BCF	4/05/01
813027-1	T2	1	BCF	4/05/01
813033-2	T2	1	BCF	4/05/01
813138-6	T2	1	BCF	4/05/01
813151-4	T2	1	BCF	4/05/01
815246-9	T1	1	BCF	4/05/01
815641-5	T1	1	BCF	4/05/01
815657-6	T1	1	BCF	4/05/01
815660-9	T1	1	BCF	4/05/01
815666-5	T1	1	BCF	4/05/01
810209-2	T3	1	BCF	4/09/01
810210-3	T3	1	BCF	4/09/01
810295-3	T3	1	BCF	4/09/01
810297-5	T3	1	BCF	4/09/01
815457-8	T1	1	BCF	4/09/01
815513-8	T1	1	BCF	4/09/01
802112-5	T5	1	BFF	4/10/01
802696-9	T5	1	BFF	4/10/01
802697-5	T5	1	BFF	4/10/01
804893-5	T5	1	BFF	4/10/01
805120-7	T5	1	BFF	4/10/01
805314-4	T5	1	BFF	4/10/01
805334-4	T5	1	BFF	4/10/01
805397-2	T5	1	BFF	4/10/01

## **Appendix B-6-2: One or More Exam Statuses = Results Pending Three or More Weeks Since Exam Date**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***One or More Exam Statuses = Results Pending Three or More Weeks Since Exam Date***

This report lists all participants for whom at least one examination is still pending (RP status) three or more weeks after the examination date. It shows the PID, study year, exam date, status of all examinations and, date the Screening Test Results Report was sent.

---

PLCO CANCER SCREENING TRIAL  
 One or More Exam Statuses = Result Pending (RP)  
 Three or More Weeks Since Exam Date

Page 1  
 SMS 8.1

SC Name : University of Pittsburgh  
 Comparison Date: 5/22/2003

Report Date : 5/22/03  
 Time : 1:46 pm

Pid	Study Year	Visit	Exam Date	Bcf Bff	Exam Status					STRR Date
					Xry	Ovr	Tvu	Dre	Fsg	
801956-8	T5	1	4/18/01	RP						
802112-5	T5	1	4/10/01	RP						
802696-9	T5	1	4/10/01	RP						
802697-5	T5	1	4/10/01	RP						
803168-9	T5	1	4/18/01	RP						
803889-3	T5	1	4/11/01	RP						
804344-6	T5	1	4/18/01	RP						ND
804562-2	T5	1	4/12/01	RP						AS
804563-8	T5	1	4/12/01	RP						NG
804694-3	T5	1	4/12/01	RP						AN
804885-2	T5	1	4/12/01	RP						NG
804893-5	T5	1	4/10/01	RP						ND
804988-4	T5	1	4/13/01	RP						AN
805013-6	T5	1	4/13/01	RP						NG
805035-8	T5	1	4/12/01	RP						IN
805038-6	T5	1	4/18/01	RP						ND
805087-5	T5	1	4/12/01	RP						AS
805108-5	T5	1	4/16/01	RP						AN
805120-7	T5	1	4/10/01	RP						ND
805125-7	T5	1	4/18/01	RP						ND
805137-4	T5	1	4/13/01	RP						AN
805154-6	T5	1	4/16/01	RP						NG
805195-2	T5	1	4/13/01	RP						AS
805202-3	T5	1	4/16/01	RP						NG
805230-6	T5	1	4/12/01	RP						AN
805234-0	T5	1	4/16/01	RP						AN
805249-5	T5	1	4/16/01	RP						NG
805292-8	T5	1	4/18/01	RP						ND
805298-4	T5	1	4/13/01	RP						AN
805299-0	T5	1	4/13/01	RP						AN
805314-4	T5	1	4/10/01	RP						ND
805325-5	T5	1	4/13/01	RP						AS
805334-4	T5	1	4/10/01	RP						ND
805397-2	T5	1	4/10/01	RP						ND
806387-0	T4	1	4/18/01	RP						
807446-1	T4	1	4/10/01	RP						
807604-7	T4	1	4/10/01	RP						
807611-4	T4	1	4/10/01	RP						
807663-1	T4	1	4/10/01	RP						
807715-2	T4	1	4/18/01	RP						
807717-4	T4	1	4/18/01	RP						
807723-5	T4	1	4/10/01	RP						
807737-4	T4	1	4/18/01	RP						
807739-6	T4	1	4/18/01	RP						

## Appendix B-6-3: Referrals for Exam Forms

### PLCO Reports - Forms and Specimens Tracking

---

#### *Referrals for Exam Forms*

This report displays the referral levels assigned to individual examinations. It may be requested for specific participant IDs, for all examinations that took place during a range of dates or for all participants. The report may be sorted by PID, examination date, referral code or study year.

---

PLCO CANCER SCREENING TRIAL  
 Referrals for Exam Forms  
 (Sorted by PID)

Page 2  
 SMS 9.1

SC Name: Westat

Report Date: 5/13/03  
 Time: 5:20 pm

Pid	Study Year	Most Recent Exam Date	Exam Type	Reported Result	Referral
813900-5	T3	10/26/02	X-ray	ND	4
813906-1	T3	7/02/02	Blood	ND	4
	T3	7/02/02	Dig.Rec.	ND	4
	T3	7/02/02	Flex	ND	4
	T3	7/02/02	X-ray	NG	4
813912-2	T3	11/04/02	Blood	IN	4
	T3	11/04/02	Dig.Rec.	ND	4
	T3	11/04/02	Flex	ND	4
	T3	11/04/02	X-ray	ND	4
813926-1	T3	11/04/02	Blood	ND	4
	T3	11/04/02	Flex	ND	4
	T3	11/04/02	Ovary	ND	4
	T3	11/04/02	Ultrasnd	ND	4
	T3	11/04/02	X-ray	RP	4
813936-6	T3	11/04/02	Blood	ND	4
	T3	11/04/02	Dig.Rec.	ND	4
	T3	11/04/02	Flex	ND	4
	T3	11/04/02	X-ray	RP	4
815109-3	T3	8/09/93	Blood	ND	4
	T3	8/09/93	Flex	ND	4
	T3	8/09/93	Ovary	ND	4
	T3	8/09/93	Ultrasnd	ND	4
	T3	8/09/93	X-ray	NG	4
815131-0	T3	12/23/02	Blood	ND	4
	T3	12/23/02	Flex	ND	4
	T3	12/23/02	Ovary	ND	4
	T3	12/23/02	Ultrasnd	ND	4
	T3	12/23/02	X-ray	ND	4
815132-6	T3	12/12/02	Blood	ND	4
	T3	12/14/02	Flex	AN	3
	T3	12/13/02	Ovary	NG	4
	T3	12/12/02	Ultrasnd	ND	4
	T3	12/12/02	X-ray	ND	4
815141-5	T3	12/28/02	Blood	IN	4
	T3	12/28/02	Flex	ND	4

An asterisk(\*) represents a single overall referral assigned according to the protocol in place prior to January 1, 1996. This report does not perform any edits to ensure the validity of the referral that was entered.

## **Appendix B-6-4: QA Checks Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***QA Checks Report***

**This report prints discrepancies between the results of regular examination and medical record abstract forms and their associated quality assurance forms. It presents counts as well as a listing of discrepant cases.**

---

PLCO CANCER SCREENING TRIAL  
 QA checks - Screening Exam Forms  
 By Study Year for Exam : DRE

SC Name: University of Pittsburgh

Report Date : 5/12/03  
 Time : 3:30 pm

Study Year : T1  
 Total Forms : 3,413  
 Total QA Forms : 135  
 Total Discrepancies : 17

PID	Exam Visit Date	Exam Result	Exam Referral	Exam Referral	Examiner	QA Visit Date	QA Result	QA Referral	QA Referral	QA Examiner	QA Referral	Combined Worst-Case Referral
807026-5	12/10/97	NG	4	4	1000	12/10/97	AN	3	3	3202	3	3202
807528-7	1/28/98	AN	3	3	3202	1/28/98	NG	4	4	1000	4	1000
807945-5	4/08/98	AS	1	1	1000	4/08/98	AN	3	3	3202	3	3202
808806-0	9/23/98	AN	3	3	3303	9/23/98	AS	1	1	3202	1	3202
808881-0	9/09/98	NG	4	4	3202	9/09/98	AN	3	3	3303	3	3303
809615-4	1/13/99	NG	4	4	3303	1/13/99	AS	1	1	3202	1	3202
809726-9	12/16/98	NG	4	4	3303	12/16/98	AN	3	3	3202	3	3202
809974-0	2/24/99	NG	4	4	3303	2/24/99	AN	3	3	3202	3	3202
810744-2	6/02/99	NG	4	4	3303	6/02/99	AN	3	3	3202	3	3202
810757-5	6/02/99	NG	4	4	3202	6/02/99	AN	3	3	3303	3	3303
813188-1	4/05/00	AN	3	3	3202	4/05/00	NG	4	4	3303	4	3303
814290-5	8/02/00	NG	4	4	3303	8/02/00	AN	3	3	3202	3	3202
814549-6	9/13/00	NG	4	4	3202	9/13/00	AN	3	3	3303	3	3303
814774-9	10/04/00	AN	3	3	3202	10/04/00	NG	4	4	3303	4	3303
814853-7	11/01/00	NG	4	4	3202	11/01/00	AN	3	3	3303	3	3303
815063-3	12/06/00	NG	4	4	3303	12/06/00	AN	3	3	3202	3	3202
815446-7	2/28/01	AN	3	3	3202	2/28/01	NG	4	4	3303	4	3303

## **Appendix B-6-5: Examination Summary Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Examination Summary Report***

**This report generates summaries of exams performed. The user may select any combination of exams and a range of visit dates. This is a five-part report: (1) exams performed, (2) exams by examiner ID, (3) exams by outcomes, (4) outcome by examiner, and (5) exams by gender.**

---











PLCO CANCER SCREENING TRIAL  
Examination Summary Report

SC Name : University of Pittsburgh

Report Date : 6/10/03  
Time : 5:21 pm

Report Period : 1/01/2001 to 3/01/2001

Selection Criteria : BCF

Part 5 : Examinations Performed by Gender - Male

Exam Type	# Exams					# QA Exams								
	T0	T1	T2	T3	T4	T5	Total	T0	T1	T2	T3	T4	T5	Total
BCF	19	70	88	97	0	58	332	0	0	0	0	0	0	0

## **Appendix B-6-6: Screening Test Results Report (STRR)**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Screening Test Results Report (STRR)***

**This report shows the results of each participant's screening tests for a given study year. It is automatically generated upon receipt of the blood test results from UCLA. There is a version for male participants and one for female participants. Copies of the STRR are sent to the participant and to the participant's physician(s), and a copy is retained in the SC files for verification. The SC may also generate a copy with the PID for internal use at the SC.**

---

PLCO CANCER SCREENING TRIAL  
Screening Test Results (Female Participants)

SC Name: Westat

Report Date: 12/17/97  
Time: 9:04 am

---

Participant Name: Theodora Milford Schoenberger DMD Examination Date: 10/14/97

Address:

Telephone number:

Physician Name:  
Physician Phone:

---

Additional Examination  
Date(s):

**Chest X-Ray (Single PA View):**

Final result not available

**Ovarian Palpation:**

Abnormal

**Transvaginal Ultrasound:**

Slight variation from normal

**Flexible Sigmoidoscopy:**

Normal

**CA 125 Blood Test:**

Final result not available

Result: units/ml Normal Reference Value: 0 - 34 units/ml  
Analysis Date:

Blood is analyzed by the UCLA Tissue Typing Laboratory at the UCLA  
School of Medicine. The methodology used is: Centocor CA 125 RIA.

PLCO CANCER SCREENING TRIAL  
Screening Test Results (Male Participants)

SC Name: Westat

Report Date 12/17/97  
Time 9:04 am

---

Participant Name: Roma Willam Kinne Ph.D

Examination Date: 10/27/97

Address:

Telephone number:

Physician Name:

Physician Phone:

---

Additional Examination  
Date(s):

**Chest X-Ray (Single PA View):**

Final result not available

**Digital Rectal Examination  
of the Prostate:**

Abnormal

**Flexible Sigmoidoscopy:**

Slight variation from normal

**PSA Blood Test:**

Final result not available

Result:           ng/ml

Normal Reference Value: 0 - 4.0 ng/ml

Analysis Date:

Blood is analyzed by the UCLA Tissue Typing Laboratory at the UCLA  
School of Medicine. The methodology used is: Hybritech Tandem-r PSA.

## **Appendix B-6-7: Screening Test Result Report Not Sent Three or More Weeks Since Exam Date**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Screening Test Result Report Not Sent Three or More Weeks Since Exam Date***

**This report lists all participants whose screening visit took place three or more weeks previously, but a Screening Test Results Report has not been sent.**

---

PLCO CANCER SCREENING TRIAL  
 Screening Test Result Report Not Sent  
 3 or More Weeks Since Exam Date

Page 1  
 SMS 8.1

SC Name: University of Pittsburgh  
 Comparison Date: 5/22/2003

Report Date: 5/22/03  
 Time: 1:50 pm

Pid	StudyYear	ExamDate	Exam Status					
			Bcf/Bff	Xry	Ovr	Tvu	Dre	Fsg
801956-8	T5	4/18/01	RP	ND	ND	ND	ND	ND
802112-5	T5	4/10/01	RP	ND	ND	ND	ND	ND
802696-9	T5	4/10/01	RP	ND	ND	ND	ND	ND
802697-5	T5	4/10/01	RP	ND	ND	ND	ND	ND
803026-3	T5	4/16/01	IN	ND	ND	ND	ND	ND
803168-9	T5	4/18/01	RP	ND	ND	ND	ND	ND
803889-3	T5	4/11/01	RP	ND	ND	ND	ND	ND
804344-6	T5	4/18/01	RP	ND	ND	ND	ND	ND
804562-2	T5	4/12/01	RP	ND	ND	ND	ND	AS
804563-8	T5	4/12/01	RP	ND	ND	ND	ND	NG
804694-3	T5	4/12/01	RP	ND	ND	ND	ND	AN
804885-2	T5	4/12/01	RP	ND	ND	ND	ND	NG
804893-5	T5	4/10/01	RP	ND	ND	ND	ND	ND
804988-4	T5	4/13/01	RP	ND	ND	ND	ND	AN
805013-6	T5	4/13/01	RP	ND	ND	ND	ND	NG
805035-8	T5	4/12/01	RP	ND	ND	ND	ND	IN
805038-6	T5	4/18/01	RP	ND	ND	ND	ND	ND
805087-5	T5	4/12/01	RP	ND	ND	ND	ND	AS
805108-5	T5	4/16/01	RP	ND	ND	ND	ND	AN
805120-7	T5	4/10/01	RP	ND	ND	ND	ND	ND
805125-7	T5	4/18/01	RP	ND	ND	ND	ND	ND
805137-4	T5	4/13/01	RP	ND	ND	ND	ND	AN
805146-3	T5	4/09/01	IN	ND	ND	ND	ND	AN
805154-6	T5	4/16/01	RP	ND	ND	ND	ND	NG
805195-2	T5	4/13/01	RP	ND	ND	ND	ND	AS
805202-3	T5	4/16/01	RP	ND	ND	ND	ND	NG
805230-6	T5	4/12/01	RP	ND	ND	ND	ND	AN
805234-0	T5	4/16/01	RP	ND	ND	ND	ND	AN
805240-1	T5	4/09/01	IN	ND	ND	ND	ND	NG
805249-5	T5	4/16/01	RP	ND	ND	ND	ND	NG
805289-5	T5	4/12/01	IN	ND	ND	ND	ND	AN
805292-8	T5	4/18/01	RP	ND	ND	ND	ND	ND
805298-4	T5	4/13/01	RP	ND	ND	ND	ND	AN
805299-0	T5	4/13/01	RP	ND	ND	ND	ND	AN
805314-4	T5	4/10/01	RP	ND	ND	ND	ND	ND
805325-5	T5	4/13/01	RP	ND	ND	ND	ND	AS
805334-4	T5	4/10/01	RP	ND	ND	ND	ND	ND
805397-2	T5	4/10/01	RP	ND	ND	ND	ND	ND
806387-0	T4	4/18/01	RP	ND	ND	ND	ND	ND
807446-1	T4	4/10/01	RP	ND	ND	ND	ND	ND
807584-3	T4	4/18/01	IN	ND	ND	ND	ND	ND
807604-7	T4	4/10/01	RP	ND	ND	ND	ND	ND
807611-4	T4	4/10/01	RP	ND	ND	ND	ND	ND
807633-6	T4	4/10/01	IN	ND	ND	ND	ND	ND

## **Appendix B-6-8: Additional Screening Test Result Report Should Be Sent Reflecting New Exam Results**

### **PLCO Reports – Forms and Specimen Tracking**

---

#### ***Additional Screening Test Result Report Should Be Sent Reflecting New Exam Results***

**This report lists participants whose exam results have changed. Listed on the report are the PID, Study Year, Exam Date, Final Worst-Case Exam Result (for all exams) STRR Date and Last Updated date for the STRR.**

---

PLCO CANCER SCREENING TRIAL  
 Additional Screening Test Result Report  
 Should Be Sent Reflecting New Exam Results

SC Name: University of Pittsburgh

Report Date: 5/22/03  
 Time: 1:52 pm

Pid	Study Year	Exam Date	Final Worst-Case Exam Result						STRR Date	Last Updated
			BCF/ BFF	DRE	FSG	OVR	TVU	XRY		
800618-5	T3	5/15/97	NG4	AS1	AN3	ND4	ND4	AN2	5/28/97	5/30/97
800628-0	T3	9/15/97	NG4	ND4	AN3	NG4	NG4	AS1	10/01/97	10/03/97
800766-2	T3	9/11/97	NG4	ND4	AN3	NG4	NG4	AN2	10/01/97	10/03/97
800775-1	T3	6/09/97	NG4	AN3	AN3	ND4	ND4	AS1	6/25/97	6/26/97
800897-7	T3	8/25/97	NG4	ND4	AN3	NG4	NG4	AS1	9/18/97	9/23/97
800899-9	T3	2/10/98	NG4	AN3	AN3	ND4	ND4	AN2	3/20/98	6/22/98
800946-0	T3	8/26/97	NG4	AN3	AN3	ND4	ND4	AN2	9/18/97	10/23/99
800947-6	T3	8/21/97	NG4	ND4	ND4	AN3	AN3	AN2	9/18/97	9/19/97
801674-4	T3	11/19/97	NG4	IN4	ND4	ND4	ND4	AN2	12/17/97	1/09/98
801838-6	T3	1/29/98	NG4	ND4	AN3	NG4	NG4	AS1	2/19/98	2/25/98
801856-4	T3	1/29/98	NG4	ND4	ND4	NG4	NG4	AS1	2/19/98	3/09/98
802069-8	T3	2/26/98	NG4	AN3	ND4	ND4	ND4	AS1	3/18/98	3/25/98
802490-5	T3	6/23/98	NG4	AN3	ND4	ND4	ND4	AS1	7/22/98	9/09/98
802526-0	T2	5/14/97	NG4	AN3	ND4	ND4	ND4	AS1	5/28/97	5/30/97
802545-4	T3	6/01/98	NG4	AN3	ND4	ND4	ND4	AS1	6/10/98	6/22/98
802546-0	T2	5/29/97	NG4	ND4	ND4	AN3	NG4	AS1	6/25/97	6/26/97
802552-1	T3	4/30/98	NG4	ND4	IN3	NG4	NG4	AN2	5/18/98	5/20/98
802606-4	T3	4/27/98	NG4	ND4	NG4	NG4	NG4	AS1	5/18/98	5/20/98
802664-2	T2	5/07/97	NG4	NG4	ND4	ND4	ND4	AS1	5/30/97	6/04/97
802666-4	T2	5/14/97	NG4	AN3	ND4	ND4	ND4	AS1	5/28/97	5/30/97
802778-5	T3	9/14/98	NG4	NG4	AN3	ND4	ND4	AN2	9/24/98	9/30/98
802796-3	T2	5/07/97	AS1	AN3	ND4	ND4	ND4	AS1	5/30/97	6/04/97
802814-5	T2	5/14/97	NG4	AN3	ND4	ND4	ND4	AS1	5/28/97	5/30/97
802856-7	T2	6/09/97	NG4	ND4	ND4	NG4	AN2	AN2	6/25/97	6/26/97
802886-2	T3	5/28/98	NG4	ND4	AN3	NG4	NG4	AN2	6/10/98	6/22/98
802968-8	T2	6/04/97	NG4	NG4	ND4	ND4	ND4	AN2	6/25/97	6/26/97
803041-3	T2	5/28/97	NG4	AN3	ND4	ND4	ND4	AN2	6/25/97	6/26/97
803041-3	T3	6/23/98	NG4	AN3	AS1	ND4	ND4	AN2	7/02/98	8/26/98
803074-6	T2	5/28/97	NG4	NG4	ND4	ND4	ND4	AS1	6/25/97	6/26/97
803179-0	T2	9/08/97	NG4	ND4	ND4	NG4	NG4	AS1	10/02/97	10/03/97
803180-1	T2	8/20/97	NG4	AN3	ND4	ND4	ND4	AS1	9/18/97	9/23/97
803186-7	T2	8/20/97	NG4	AN3	ND4	ND4	ND4	AS1	9/18/97	9/23/97
803242-7	T3	7/09/98	AS1	AS1	ND4	ND4	ND4	AN2	8/12/98	2/25/99
803246-1	T2	8/25/97	NG4	ND4	ND4	NG4	AN2	AN2	9/18/97	9/23/97
803286-1	T2	9/11/97	NG4	ND4	ND4	NG4	AN3	AN2	10/01/97	10/03/97
803287-7	T2	8/20/97	NG4	AN3	ND4	ND4	ND4	AS1	9/18/97	9/23/97
803334-8	T2	8/07/97	NG4	ND4	ND4	NG4	AS1	AS1	9/05/97	1/16/99
803376-0	T5	1/12/01	IN4	ND4	IN3	ND4	ND4	ND4	1/26/01	3/26/01
803432-0	T3	8/03/98	NG4	ND4	ND4	NG4	IN4	AN2	8/12/98	9/08/98
803452-0	T2	8/20/97	NG4	AN3	ND4	ND4	ND4	AN2	9/18/97	9/23/97
803473-6	T2	8/20/97	NG4	NG4	ND4	ND4	ND4	AS1	9/18/97	9/23/97
803504-1	T3	9/14/98	NG4	AN3	ND4	ND4	ND4	AN2	9/24/98	9/30/98
803535-2	T3	9/14/98	NG4	AN3	ND4	ND4	ND4	AN2	9/24/98	9/30/98
803613-4	T2	8/20/97	AS1	AN3	ND4	ND4	ND4	AS1	9/18/97	9/23/97

PLCO CANCER SCREENING TRIAL  
 Additional Screening Test Result Report  
 May Need To Be Sent Reflecting New Exam Results

SC Name: University of Pittsburgh

Report Date: 5/22/03  
Time: 1:54 pm

Pid	Study Year	Exam Date	Final Worst-Case Exam Result						STRR Date	Last Updated
			BCF/ BFF	DRE	FSG	OVR	TVU	XRY		
202664-6	T0	1/03/96	NG4	AN3	AS1	ND4	ND4	NG4	2/02/96	2/13/96
800002-0	T0	11/15/93	NG4	ND4	AS1	NG4	NG4	AS1	11/24/93	5/07/96
800007-0	T0	11/16/93	NG4	IN4	NG4	ND4	ND4	NG4	11/24/93	7/01/94
800007-0	T2	12/06/95	NG4	AN3	ND4	ND4	ND4	AN3	12/20/95	5/02/96
800008-6	T0	11/16/93	NG4	NG4	NG4	ND4	ND4	NG4	11/24/93	7/01/94
800009-2	T0	12/02/93	NG4	ND4	AN3	NG4	NG4	NG4	12/21/93	10/13/94
800014-7	T0	12/07/93	NG4	AN3	NG4	ND4	ND4	NG4	12/21/93	10/13/94
800014-7	T2	11/29/95	AS1	AS1	ND4	ND4	ND4	AN3	12/13/95	5/02/96
800016-9	T0	12/07/93	AS1	AS1	AN3	ND4	ND4	NG4	12/21/93	10/13/94
800016-9	T1	11/17/94	NG4	ND4	ND4	ND4	ND4	AN3	12/06/94	7/11/96
800016-9	T2	11/29/95	IN4	ND4	ND4	ND4	ND4	AN3	1/03/96	7/11/96
800017-5	T0	12/02/93	NG4	ND4	NG4	NG4	NG4	NG4	12/21/93	10/13/94
800018-1	T0	12/02/93	NG4	ND4	AS1	NG4	AS1	NG4	12/21/93	10/13/94
800020-8	T0	12/14/93	NG4	AN3	AN2	ND4	ND4	NG4	12/21/93	10/13/94
800021-4	T0	12/02/93	NG4	ND4	IN4	NG4	NG4	AN3	12/21/93	10/13/94
800023-6	T0	12/14/93	NG4	AN3	AN3	ND4	ND4	NG4	12/21/93	5/07/96
800023-6	T2	11/08/95	NG4	AS1	ND4	ND4	ND4	NG4	11/22/95	5/03/96
800024-2	T0	12/07/93	NG4	NG4	IN4	ND4	ND4	NG	12/21/93	10/13/94
800024-2	T2	11/16/95	NG4	AN3	ND4	ND4	ND4	AN3	12/06/95	5/02/96
800025-8	T0	12/02/93	NG4	ND4	AS1	NG4	NG4	NG4	12/21/93	10/13/94
800026-4	T0	2/14/94	NG4	ND4	ND4	NG4	NG4	NG4	2/28/94	7/11/96
800026-4	T1	1/30/95	NG4	ND4	ND4	NG4	NG4	ND4	2/09/95	7/11/96
800031-9	T0	2/25/94	NG4	ND4	AN3	NG4	NG4	NG4	3/10/94	10/13/94
800031-9	T2	2/01/96	NG4	ND4	ND4	NG4	NG4	ND4	2/21/96	7/11/96
800033-1	T0	12/13/93	NG4	ND4	AS1	NG4	NG4	NG4	12/21/93	10/13/94
800037-5	T0	12/07/93	NG4	ND4	NG4	ND4	ND4	AN3	12/21/93	7/11/96
800038-1	T0	12/13/93	NG4	ND4	IN4	AN2	AS1	NG4	12/21/93	10/13/94
800039-7	T0	12/07/93	NG4	AN3	AN3	ND4	ND4	NG4	12/21/93	10/13/94
800039-7	T2	12/06/95	NG4	AN3	ND4	ND4	ND4	NG4	12/20/95	5/02/96
800040-8	T0	12/07/93	AS1	AN3	AN3	ND4	ND4	NG4	12/21/93	10/13/94
800040-8	T2	12/06/95	AS1	AN3	ND4	ND4	ND4	NG4	12/20/95	5/02/96
800041-4	T0	12/14/93	NG4	AS1	AN3	ND4	ND4	AS1	12/21/93	5/07/96
800041-4	T2	12/13/95	NG4	AN3	ND4	ND4	ND4	ND4	1/03/96	7/11/96
800043-6	T0	12/13/93	NG4	ND4	ND4	NG4	NG4	NG4	12/21/93	7/11/96
800043-6	T2	12/07/95	NG4	ND4	ND4	NG4	NG4	ND4	12/20/95	7/11/96
800045-8	T0	12/14/93	NG4	AS1	AN3	ND4	ND4	AS1	12/21/93	5/07/96
800045-8	T1	12/07/94	NG4	AS1	ND4	ND4	ND4	AS1	1/05/95	4/21/95
800049-2	T0	1/11/94	NG4	AS1	AN3	ND4	ND4	AS1	1/25/94	5/27/97
800049-2	T1	12/07/94	NG4	AN3	ND4	ND4	ND4	AS1	1/05/95	4/21/95
800049-2	T2	12/13/95	NG4	AN3	ND4	ND4	ND4	AS1	1/05/96	5/02/96
800051-9	T0	12/13/93	NG4	ND4	NG4	NG4	NG4	AN3	12/21/93	5/07/96
800052-5	T0	12/14/93	NG4	NG4	AN3	ND4	ND4	AN3	12/21/93	5/07/96
800053-1	T0	12/14/93	NG4	AN3	AN3	ND4	ND4	NG4	12/21/93	5/07/96
800053-1	T2	12/06/95	NG4	AN3	ND4	ND4	ND4	AN3	12/20/95	5/02/96

## **Appendix B-6-9: Dietary Questionnaire Transmittal Log**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Dietary Questionnaire Transmittal Log***

**This report shows the participant ID number of each receipted Dietary Questionnaire not previously shipped to be scanned. Generally the report is generated once a month and should accompany the completed questionnaires to the organization responsible for scanning and a copy retained at the SC for verification. The report lists the PID number and the completion date of the questionnaire.**

---

6/14/03  
4:05 pm

PLCO CANCER SCREENING TRIAL  
Dietary Questionnaire Transmittal Log

Page 1  
SMS 8.1

Screening Center: University of Pittsburgh / Id#: 01

Shipment Date: 6/14/2003

Batch #: D010614A

Total number of questionnaires: 1

NCS RECEIPT CONFIRMATION	PARTICIPANT ID	COMPLETION DATE	COMMENTS
-----	-----	-----	-----
__	816907-6	4/15/02	

Total number of this Batch #: 1

## **Appendix B-6-10: DHQ Directive/Late Directive**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***DHQ Directive/Late Directive***

**This report lists the participants who are due to complete the DHQ but the form has not been received. The PIDs are listed in addition to the study year, form type and randomization date. The PIDs are sorted by randomization group and gender.**

---

Screening Center: University of Pittsburgh / ID# 01

Participants Due for NEW Requests

RANDOMIZATION GROUP: I

Gender: F

PID	Study Year	Form Type	Rand Date
815751-4	T3	DHQ	4/19/00
815753-6	T3	DHQ	4/19/00
815755-8	T3	DHQ	4/19/00
815757-0	T3	DHQ	4/19/00
815758-6	T3	DHQ	4/19/00
815764-7	T3	DHQ	4/19/00
815766-9	T3	DHQ	4/19/00
815767-5	T3	DHQ	4/19/00
815770-8	T3	DHQ	4/19/00
815774-2	T3	DHQ	4/19/00
815784-7	T3	DHQ	4/20/00
815793-6	T3	DHQ	4/28/00
815796-4	T3	DHQ	4/28/00
815798-6	T3	DHQ	4/28/00
815802-9	T3	DHQ	4/28/00
815807-9	T3	DHQ	4/28/00
815810-2	T3	DHQ	4/28/00
815812-4	T3	DHQ	4/28/00
815815-2	T3	DHQ	4/28/00
815819-6	T3	DHQ	4/28/00
815820-7	T3	DHQ	4/28/00
815826-3	T3	DHQ	4/28/00
815827-9	T3	DHQ	4/28/00
815828-5	T3	DHQ	4/28/00
815830-2	T3	DHQ	4/28/00
815832-4	T3	DHQ	4/28/00
815833-0	T3	DHQ	5/01/00
815836-8	T3	DHQ	5/03/00
815839-6	T3	DHQ	5/03/00
815840-7	T3	DHQ	5/03/00
815844-1	T3	DHQ	5/03/00
815847-9	T3	DHQ	5/03/00
815848-5	T3	DHQ	5/03/00
815855-2	T3	DHQ	5/03/00
815861-3	T3	DHQ	5/03/00
815862-9	T3	DHQ	5/03/00
815875-2	T3	DHQ	5/03/00
815876-8	T3	DHQ	5/03/00
815879-6	T3	DHQ	5/03/00
815881-3	T3	DHQ	5/03/00
815883-5	T3	DHQ	5/03/00
815884-1	T3	DHQ	5/03/00
815888-5	T3	DHQ	5/03/00

## **Appendix B-6-11: Diet History Questionnaire Transmittal Log**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Diet History Questionnaire Transmittal Log***

**This report shows the participant ID number of each receipted Diet History Questionnaire not previously shipped to be scanned. Generally the report is generated once a month and should accompany the completed questionnaires to the organization responsible for scanning**

**and a copy retained at the SC for verification. The report lists the PID number and the completion date of the questionnaire.**

---

6/14/03  
3:23 pm

PLCO CANCER SCREENING TRIAL  
Diet History Questionnaire Transmittal Log

Page 1  
SMS 8.1

Screening Center: University of Pittsburgh / Id#: 01

Shipment Date: 6/14/2003

Batch #: H010614A

Total number of questionnaires: 110

NCS RECEIPT CONFIRMATION	PARTICIPANT ID	COMPLETION DATE	COMMENTS
-----	-----	-----	-----
_____	812638-3	4/17/02	
_____	812774-3	4/12/02	
_____	812801-4	4/16/02	
_____	812833-1	4/17/02	
_____	812924-6	2/14/02	
_____	812991-3	4/24/02	
_____	813001-5	4/01/02	
_____	813009-3	3/13/02	
_____	813025-9	4/17/02	
_____	813054-8	4/05/02	
_____	813069-3	3/21/02	
_____	813089-3	4/09/02	
_____	813115-8	3/15/02	
_____	813184-7	4/07/02	
_____	813188-1	3/22/02	
_____	813193-6	4/11/02	
_____	813194-2	4/25/02	
_____	813195-8	4/16/02	
_____	813202-9	4/19/02	
_____	813204-1	4/11/02	
_____	813210-2	4/13/02	
_____	813213-0	4/12/02	
_____	813214-6	4/11/02	
_____	813216-8	4/14/02	
_____	813218-0	4/12/02	
_____	813219-6	4/16/02	
_____	813222-9	4/18/02	
_____	813223-5	4/12/02	
_____	813224-1	4/11/02	
_____	813227-9	4/11/02	
_____	813228-5	4/12/02	
_____	813229-1	4/13/02	
_____	813239-6	4/11/02	
_____	813240-7	4/12/02	
_____	813241-3	4/11/02	

Total number of this Batch #: 35

## **Appendix B-7-1: ASU Directive - Participant due for New Form**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***ASU Directive - Participant due for New Form***

**This is a list of participants to whom a new request should be made to complete their Annual Study Update. The directive may be created for all participants in the reporting window who do not have a mailing recorded in the SMS, or for individual participant IDs specified by the user.**

---

Screening Center: University of Pittsburgh / ID# 01

Participants Due for NEW Requests

RANDOMIZATION GROUP: C

Gender: F

PID	Study Year	Form Type	Rand Date
810037-7	T5	ASU	3/11/98
810044-4	T5	ASU	3/11/98
810051-1	T5	ASU	3/11/98
810053-3	T5	ASU	3/11/98
810054-9	T5	ASU	3/11/98
810060-0	T5	ASU	3/11/98
810061-6	T5	ASU	3/11/98
810065-0	T5	ASU	3/17/98
810069-4	T5	ASU	3/17/98
810070-5	T5	ASU	3/17/98
810073-3	T5	ASU	3/17/98
810076-1	T5	ASU	3/17/98
810092-7	T5	ASU	3/17/98
810096-1	T5	ASU	3/20/98
810101-0	T5	ASU	3/20/98
810102-6	T5	ASU	3/24/98
810103-2	T5	ASU	3/24/98
810105-4	T5	ASU	3/24/98
810106-0	T5	ASU	3/24/98
810109-8	T5	ASU	3/24/98
810116-5	T5	ASU	3/24/98
810119-3	T5	ASU	3/24/98
810121-0	T5	ASU	3/24/98
810122-6	T5	ASU	3/24/98
810127-6	T5	ASU	3/24/98
810135-9	T5	ASU	3/26/98
810139-3	T5	ASU	3/26/98
810143-2	T5	ASU	3/26/98
810144-8	T5	ASU	3/26/98
810149-8	T5	ASU	3/26/98
810157-1	T5	ASU	3/26/98
810162-6	T5	ASU	3/31/98
810165-4	T5	ASU	3/31/98
810166-0	T5	ASU	3/31/98
810169-8	T5	ASU	3/31/98
810170-9	T5	ASU	3/31/98
810174-3	T5	ASU	3/31/98
810184-8	T5	ASU	3/31/98
810186-0	T5	ASU	3/31/98
810188-2	T5	ASU	3/31/98
810191-5	T5	ASU	3/31/98
810194-3	T5	ASU	3/31/98
810196-5	T5	ASU	3/31/98

## Appendix B-7-2: ASU Directive - Late Respondents

### PLCO Reports - Forms and Specimens Tracking

---

#### ***ASU Directive - Late Respondents***

This is a list of participants to whom a new request was made to complete their Annual Study Update more than 3 weeks earlier, but have not yet responded. The directive may be created for all participants in the reporting window who have not responded to a prior request, or for individual participant IDs specified by the user.

---

6/26/03  
11:26 am

PLCO CANCER SCREENING TRIAL  
ASU Directive

Page 4  
SMS 9.1

Screening Center: Westat / ID# 08

Late Respondents - Request was already sent but Form not received  
Phone Calls Only

RANDOMIZATION GROUP: I

Gender: F

PID	Study Year	Form Type	Rand Date	First Mailing	Last Mailing	ASU Type
802640-8	T8	ASU	4/19/95	4/29/03	4/29/03	
802646-4	T8	ASU	4/19/95	4/29/03	4/29/03	Phone Call Only
802654-7	T8	ASU	4/19/95	4/29/03	4/29/03	
802656-9	T8	ASU	4/19/95	4/29/03	4/29/03	
802658-1	T8	ASU	4/19/95	4/29/03	4/29/03	
802672-5	T8	ASU	4/21/95	4/29/03	4/29/03	
802675-3	T8	ASU	4/21/95	4/29/03	4/29/03	
802681-4	T8	ASU	4/21/95	4/29/03	4/29/03	
802688-6	T8	ASU	4/25/95	4/29/03	4/29/03	
802691-9	T8	ASU	4/25/95	4/29/03	4/29/03	
802694-7	T8	ASU	4/25/95	4/29/03	4/29/03	
802697-5	T8	ASU	4/25/95	4/29/03	4/29/03	
802699-7	T8	ASU	4/27/95	4/29/03	4/29/03	
802700-2	T8	ASU	4/27/95	4/29/03	4/29/03	
802704-6	T8	ASU	4/27/95	4/29/03	4/29/03	
802722-4	T8	ASU	4/27/95	4/29/03	4/29/03	
802727-4	T8	ASU	4/28/95	4/29/03	4/29/03	
802734-1	T8	ASU	4/28/95	4/29/03	4/29/03	
802747-4	T8	ASU	5/02/95	4/29/03	4/29/03	
802749-6	T8	ASU	5/02/95	4/29/03	4/29/03	
802750-7	T8	ASU	5/02/95	4/29/03	4/29/03	
802752-9	T8	ASU	5/02/95	4/29/03	4/29/03	
802753-5	T8	ASU	5/02/95	4/29/03	4/29/03	
802755-7	T8	ASU	5/02/95	4/29/03	4/29/03	
802760-2	T8	ASU	5/02/95	4/29/03	4/29/03	
802763-0	T8	ASU	5/02/95	4/29/03	4/29/03	
802767-4	T8	ASU	5/02/95	4/29/03	4/29/03	
802774-1	T8	ASU	5/04/95	4/29/03	4/29/03	
802780-2	T8	ASU	5/04/95	4/29/03	4/29/03	
802785-2	T8	ASU	5/04/95	4/29/03	4/29/03	
802799-1	T8	ASU	5/08/95	4/29/03	4/29/03	
802807-8	T8	ASU	5/08/95	4/29/03	4/29/03	
802812-3	T8	ASU	5/08/95	4/29/03	4/29/03	
802817-3	T8	ASU	5/08/95	4/29/03	4/29/03	
802824-0	T8	ASU	5/10/95	4/29/03	4/29/03	
802826-2	T8	ASU	5/10/95	4/29/03	4/29/03	
802827-8	T8	ASU	5/10/95	4/29/03	4/29/03	
802848-4	T8	ASU	5/10/95	4/29/03	4/29/03	
802849-0	T8	ASU	5/11/95	4/29/03	4/29/03	
802852-3	T8	ASU	5/11/95	4/29/03	4/29/03	
802856-7	T8	ASU	5/11/95	4/29/03	4/29/03	
802861-2	T8	ASU	5/16/95	4/29/03	4/29/03	

## Appendix B-7-3: Tracing Log

### PLCO Reports - Forms and Specimens Tracking

---

#### *Tracing Log*

This report provides all current locator information for the participant, obtained from the Baseline Locator Form and Follow-Up Locator Form. It shows the PID, full name of participant, date and place of birth, social security number, mother's maiden name, and other names.

---

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff, and store and dispose in a proper manner. \*\*

PLCO CANCER SCREENING TRIAL  
Tracing Log

Participant ID: 802670-3

Report Date: 6/15/03

Full Name: ELIJAH SPENCER Killeen OSF  
Maiden Name:  
SSN: 931-53-2728  
Mother's Maiden Name: Shevlin

Other Names: BENITO BILLY  
Place of Birth: Buffington PA  
Mother's POB: Muleshoe

Date of Birth: 11/14/30      Gender: M  
Modified Date of Birth:

Randomization Date: 4/21/95      Group: I  
Date of Death:

CURRENT HOME ADDRESS:

RT 1 BOX 392A 1821 ILLINOIS AVE  
Brown PA 15212  
Hphone: (414)347-1825      Wphone: (414)861-6164

VACATION HOME/OTHER RESIDENCE:

RT 1 BOX 3A 1958 27TH AVE  
Brockway  
Phone: (414)490-6855  
Time of Year:

HOUSEHOLD MEMBERS:

Relationship

2 Zelda Bertha Mannino

Relative (Unspecified)

PHYSICIANS:

Specialty

Ella Nick Wanlin  
801 MARQUETTE BLVD 618 HILL ST  
Terra Alta PA 15212  
Phone: (414)731-6413  
Date Last Updated: 10/28/97

Primary Doctor

CONTACTS:

Relationship

Sue JoAnn Coelho  
308 DEPOT ST 1401 O DAY ST  
Westmoreland County PA 15212  
Phone: (414)207-8799

Son

## **Appendix B-7-4: List Of Participants in Tracing**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***List Of Participants in Tracing***

**This report lists the PIDs for participants currently “In Tracing.” Each time a Tracing Log is generated for a participant, the number of tracing attempts is automatically updated in this report. The report shows the PID, DOB, gender, randomization group, participant status, number of tracing efforts.**

---

6/15/03  
2:55 pm

List of Participants In Tracing

Page  
SMS 8.1

Participant ID	DOB	Gender	Rnd Group	Prtcpt Status	Date Status Entered	Date TraceLog Generated	No. of Tracing Efforts
802670-3	11/14/30	M	I	IT	1/19/00	9/09/02	
803639-0	10/10/32	F	I	IT	1/19/01	9/09/02	
804116-5	12/06/23	M	C	IT	1/19/01	9/09/02	
804559-9	9/15/27	M	I	IT	1/16/01	9/09/02	
804873-5	5/10/38	F	C	IT	1/19/01	9/09/02	
805848-3	3/28/36	F	I	IT	1/19/01	9/09/02	
807473-8	12/22/39	M	I	IT	2/10/00	9/09/02	

## Appendix B-7-5: PSH/ASU Forms Received

### PLCO Reports - Forms and Specimens Tracking

---

#### *PSH/ASU Forms Received*

This report lists PSH/ASU forms received within a specified date range. The report may be sorted by receipt date, PID, study group, or study year.

---

PLCO CANCER SCREENING TRIAL  
 ASU/PSH Forms Received from 3/01/01 to 3/15/01  
 Sorted by PID

Page 1  
 SMS 8.1

SC Name : University of Pittsburgh

Report Date : 5/15/03  
 Time : 4:52 pm

Pid	Study Year	Study Group	Receipt Date	P	Cancer Status			Other
					L	C	O	
304265-3	T5	I	3/12/01					
407632-6	T4	I	3/06/01					
800391-1	T7	I	3/02/01					
800399-9	T7	I	3/14/01					
800410-9	T7	I	3/02/01					
800412-1	T7	C	3/14/01					
800422-6	T7	C	3/02/01					
800426-0	T7	C	3/02/01					
800427-6	T7	I	3/02/01					
800433-7	T7	I	3/02/01					
800437-1	T7	C	3/14/01					
800441-0	T7	C	3/02/01					
800445-4	T7	I	3/06/01					
800447-6	T7	I	3/14/01					
800451-5	T7	C	3/14/01					
800453-7	T7	I	3/02/01					
800460-4	T7	C	3/14/01					
800462-6	T7	C	3/06/01					
800463-2	T7	I	3/02/01					
800464-8	T7	C	3/02/01					
800465-4	T7	C	3/06/01					
800466-0	T7	C	3/14/01					
800467-6	T7	I	3/02/01					
800470-9	T7	I	3/06/01					
800471-5	T7	I	3/14/01					
800475-9	T7	I	3/14/01					S
800476-5	T7	I	3/14/01					
800479-3	T7	I	3/14/01					
800483-2	T7	C	3/14/01					
800485-4	T7	C	3/14/01					
800487-6	T7	C	3/14/01					
800491-5	T7	C	3/14/01					
800492-1	T7	C	3/14/01					
800493-7	T7	C	3/14/01					
800494-3	T7	I	3/14/01					
800498-7	T7	I	3/14/01					
800499-3	T7	I	3/14/01					
800502-0	T7	C	3/14/01					
800505-8	T7	I	3/14/01					
800514-7	T7	C	3/14/01					
800753-9	T6	C	3/06/01					
801195-0	T6	I	3/14/01					
801271-0	T6	C	3/14/01					
802035-9	T6	I	3/14/01					
802215-7	T6	I	3/02/01					
802259-1	T6	C	3/14/01					

## **Appendix B-7-6: ASU Response Rate Report**

### **PLCO Reports – Forms and Specimen Tracking**

---

#### ***ASU Response Rate Report***

**This report gives the response rate for the ASU forms by study year. This report lists the Number Expected, Number Received, and Response Rate for the Intervention Group, the Control Group, and an Overall Rate.**

---

PLCO CANCER SCREENING TRIAL  
ASU Response Rate Report

Report Date: 6/07/03  
Time: 4:27 pm

SC Name: University of Pittsburgh

Study Year	INTERVENTION GROUP			CONTROL GROUP			OVERALL		
	Number Expected	Number Received	Response Rate (%)	Number Expected	Number Received	Response Rate (%)	Number Expected	Number Received	Response Rate (%)
T1	8,431	7,845	93.0	8,437	7,763	92.0	16,868	15,608	92.5
T2	8,388	6,601	78.7	8,383	6,499	77.5	16,771	13,100	78.1
T3	7,950	5,072	63.8	7,954	5,031	63.3	15,904	10,103	63.5
T4	6,793	3,829	56.4	6,787	3,787	55.8	13,580	7,616	56.1
T5	5,273	2,567	48.7	5,258	2,507	47.7	10,531	5,074	48.2
T6	4,027	1,294	32.1	4,022	1,274	31.7	8,049	2,568	31.9
T7	2,793	267	9.6	2,791	255	9.1	5,584	522	9.3
T8	1,494	0	0.0	1,504	0	0.0	2,998	0	0.0
T9	366	0	0.0	375	0	0.0	741	0	0.0

## Appendix B-7-7: FLF Directive

### PLCO Reports – Forms and Specimen Tracking

---

#### *FLF Directive*

This is a list of participants to whom a new request should be made to complete their Follow-up Locator Form. The directive may be created for all participants in the reporting window who do not have a mailing recorded in the SMS, or for individual participant IDs specified by the user.

---

6/07/03  
4:55 pm

PLCO CANCER SCREENING TRIAL  
FLF Directive

Page :  
SMS 8.1

Screening Center: University of Pittsburgh / ID# 01

Participants Due for NEW Requests

RANDOMIZATION GROUP: C

Gender: F

PID	Study Year	Form Type	Rand Date
810037-7	T5	FLF	3/11/98
810044-4	T5	FLF	3/11/98
810051-1	T5	FLF	3/11/98
810053-3	T5	FLF	3/11/98
810054-9	T5	FLF	3/11/98
810060-0	T5	FLF	3/11/98
810061-6	T5	FLF	3/11/98
810065-0	T5	FLF	3/17/98
810069-4	T5	FLF	3/17/98
810070-5	T5	FLF	3/17/98
810073-3	T5	FLF	3/17/98
810076-1	T5	FLF	3/17/98
810092-7	T5	FLF	3/17/98
810096-1	T5	FLF	3/20/98
810101-0	T5	FLF	3/20/98
810102-6	T5	FLF	3/24/98
810103-2	T5	FLF	3/24/98
810105-4	T5	FLF	3/24/98
810106-0	T5	FLF	3/24/98
810109-8	T5	FLF	3/24/98
810116-5	T5	FLF	3/24/98
810119-3	T5	FLF	3/24/98
810121-0	T5	FLF	3/24/98
810122-6	T5	FLF	3/24/98
810127-6	T5	FLF	3/24/98
810135-9	T5	FLF	3/26/98
810139-3	T5	FLF	3/26/98
810143-2	T5	FLF	3/26/98
810144-8	T5	FLF	3/26/98
810149-8	T5	FLF	3/26/98
810157-1	T5	FLF	3/26/98
810162-6	T5	FLF	3/31/98
810165-4	T5	FLF	3/31/98
810166-0	T5	FLF	3/31/98
810169-8	T5	FLF	3/31/98
810170-9	T5	FLF	3/31/98
810174-3	T5	FLF	3/31/98
810184-8	T5	FLF	3/31/98
810186-0	T5	FLF	3/31/98
810188-2	T5	FLF	3/31/98
810191-5	T5	FLF	3/31/98
810194-3	T5	FLF	3/31/98
810196-5	T5	FLF	3/31/98

## **Appendix B-7-8: HSQ Directive**

### **PLCO Reports – Forms and Specimen Tracking**

---

#### ***HSQ Directive***

**This is a list of participants to whom a new request should be made to complete their Health Status Questionnaire. The directive may be created for all participants in the reporting window who do not have a mailing recorded in the SMS, or for individual participant IDs specified by the user.**

---

Screening Center: Westat / ID# 08  
Participants Due for NEW Requests

RANDOMIZATION GROUP: C

Gender: F

Participant ID	Study Year	Form Type	Randomization Date
800282-8	T3	HSW	2/07/94
800368-8	T3	HSW	2/22/94
801041-7	T2	HSW	9/07/94
801119-4	T2	HSW	9/16/94
801190-0	T2	HSW	9/22/94

-----  
Total Females (Control) : 5

Gender: M

Participant ID	Study Year	Form Type	Randomization Date
800104-6	T3	HSM	12/16/93
800235-1	T3	HSM	1/28/94
800375-5	T3	HSM	2/22/94
801259-8	T2	HSM	10/13/94
801678-8	T2	HSM	12/05/94
801809-7	T2	HSM	1/04/95

-----  
Total Males (Control) : 6

-----  
Total Controls : 11

-----  
Total : 11

## **Appendix B-7-9: HSQ Transmittal Log**

### **PLCO Reports – Forms and Specimen Tracking**

---

#### ***HSQ Transmittal Log***

**This report shows the participant ID number of each Health Status Questionnaire not previously shipped to Westat. Generally the report is generated once a month and should accompany the completed questionnaires to Westat and a copy retained at the SC for verification. The report lists the PID number, study year, form type, receipt date, and any comments.**

---

12/18/97  
3:17 pm

PLCO CANCER SCREENING TRIAL  
Health Status Questionnaire Transmittal Log

Page 1  
SMS 3.4

Screening Center: Westat / Id#: 08

Shipment Date: 9/29/97

Total number of questionnaires: 5

RECEIPT CONFIRMATION	PARTICIPANT ID	STUDY YEAR	FORM TYPE	RECEIPT DATE	COMMENTS
-----	-----	-----	-----	-----	-----
	802854-5	T2	HSM	8/06/97	
	804477-3	T1	HSM	8/06/97	
	804499-5	T1	HSM	8/06/97	
	804686-0	T1	HSM	8/06/97	
	805850-0	T1	HSM	8/06/97	

## **Appendix B-7-10: HSQ Status Report**

### **PLCO Reports – Forms and Specimen Tracking**

---

#### ***HSQ Status Report***

**This report lists the date the HSM or HSW was generated, loaded, mailed, receipted, and shipped to Westat. This report also lists the participation status, vital status, and transfer status.**

---

PLCO CANCER SCREENING TRIAL  
 HSQ Status Report  
 Sorted By PID  
 Sample Year 2001

SC Name : University of Pittsburgh

Selection Criteria : All Participants

Pid	Study Year	Form Type	Date Generated	Date Loaded	First Mailing	Followup	Receipt Date	Participation Status		Vital Status	Transfer Status	MDF RptDate
								To Westat	Shipped			
802560-4	T5	HSW	12/03/00	2/26/01	2/28/01		3/12/01	4/04/01				
802625-8	T5	HSW	12/03/00	2/26/01	2/28/01		3/20/01	4/04/01				
802754-1	T5	HSW	12/03/00	2/26/01	2/28/01		3/14/01	4/04/01				
802810-1	T5	HSW	12/03/00	2/26/01	2/28/01	3/22/01						
802850-1	T5	HSW	12/03/00	2/26/01	2/28/01	3/22/01	4/03/01	4/04/01				
803024-1	T5	HSW	12/03/00	2/26/01	2/28/01		3/14/01	4/04/01				
803413-6	T5	HSW	12/03/00	2/26/01	2/28/01		3/14/01	4/04/01				
803417-0	T5	HSW	12/03/00	2/26/01	2/28/01	3/22/01	3/26/01	4/04/01				
803721-1	T5	HSW	12/03/00	2/26/01	2/28/01	3/22/01						
803830-4	T5	HSW	12/03/00	2/26/01	2/28/01		3/08/01	4/04/01				
803968-1	T5	HSW	12/03/00	2/26/01	2/28/01		3/08/01	4/04/01				
803996-4	T5	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
804000-0	T5	HSW	12/03/00	2/26/01	2/28/01		3/19/01	4/04/01				
804088-8	T5	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
804114-3	T5	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
804164-8	T5	HSW	12/03/00	2/26/01	2/28/01		3/14/01	4/04/01				
804354-1	T5	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
804437-3	T5	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
804512-7	T5	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
804687-6	T5	HSW	12/03/00	2/26/01	2/28/01		3/20/01	4/04/01				
804792-5	T4	HSW	12/03/00	2/26/01	2/28/01		3/19/01	4/04/01				
804855-7	T4	HSW	12/03/00	2/26/01	2/28/01		3/08/01	4/04/01				
805043-1	T4	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
805219-0	T4	HSW	12/03/00	2/26/01	2/28/01		3/08/01	4/04/01				
805331-6	T4	HSW	12/03/00	2/26/01	2/28/01		3/14/01	4/04/01				
805349-9	T4	HSW	12/03/00	2/26/01	2/28/01		3/08/01	4/04/01				
805366-1	T4	HSW	12/03/00	2/26/01	2/28/01	3/22/01	4/02/01	4/04/01				
805522-5	T4	HSW	12/03/00	2/26/01	2/28/01		3/21/01	4/04/01				
805592-0	T4	HSW	12/03/00	2/26/01	2/28/01		3/07/01	4/04/01				
805672-4	T4	HSW	12/03/00	2/26/01	2/28/01		3/21/01	4/04/01				

## **Appendix B-7-11: HSQ Summary Report**

### **PLCO Reports – Forms and Specimen Tracking**

---

#### ***HSQ Summary Report***

**This report gives summary numbers for the HSM, HSW, and overall HSQs. Listed by study year are the number of forms loaded, mailed, received, and shipped to Westat. Counts are also given for the number of outstanding forms, those which have been “followed-up” and the number of MDFs received.**

---

PLCO CANCER SCREENING TRIAL  
 HSQ Summary Report  
 Sample Year 2001

SC Name: University of Pittsburgh

Report Date: 4/25/03  
 Time: 1:51 PM

HSM Summary

Study Year	Loaded	Mailed	Followup	MDF Receipts	Forms Received	Shipped To Westat	Not Shipped To Westat	Outstanding
T1	9	9	4	0	5	5	0	4
T2	10	10	0	0	10	10	0	0
T3	8	8	1	0	7	7	0	1
T4	13	13	1	0	12	11	1	1
T5	10	10	0	0	10	9	1	0
TOTALS:	50	50	6	0	44	42	2	6

HSW Summary

Study Year	Loaded	Mailed	Followup	MDF Receipts	Forms Received	Shipped To Westat	Not Shipped To Westat	Outstanding
T1	10	10	0	0	10	8	2	0
T2	14	14	1	0	13	13	0	1
T3	13	13	0	0	13	13	0	0
T4	12	12	0	0	12	12	0	0
T5	10	10	2	0	8	8	0	2
TOTALS:	59	59	3	0	56	54	2	3

Overall Summary

Study Year	Loaded	Mailed	Followup	MDF Receipts	Forms Received	Shipped To Westat	Not Shipped To Westat	Outstanding
T1	19	19	4	0	15	13	2	4
T2	24	24	1	0	23	23	0	1
T3	21	21	1	0	20	20	0	1
T4	25	25	1	0	24	23	1	1
T5	20	20	2	0	18	17	1	2
TOTALS:	109	109	9	0	100	96	4	9

## **Appendix B-8-1: Cancer Registries Request List**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Cancer Registries Request List***

**This report will list the participants for whom the SC has not received a death notification or a confirmation of cancer. The list will contain participant identifiers that will be needed to search a cancer registry.**

---

**This Report has not been Developed**

## **Appendix B-8-2: Medical Record Background Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Medical Record Background Report***

**This report is generated for participants with a suspected or confirmed cancer. It lists locator information, date of birth, modified date of birth, and cancer information (such as outstanding medical record abstracting forms, cancer status, cancer type, and ICD-9-CM codes). The report may be generated to facilitate the collection of medical record abstracting information.**

---

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

Medical Record Background Report - Cancer Confirmation (DE/OCF)

Participant ID: 202664-6

Report Date: 6/21/03

PARTICIPANT NAME: FAUSTO MOHAMED Pacolay Ph.d

SOCIAL SECURITY NUMBER: 802-71-6318

Date of Birth: 6/29/34 Gender: M Randomization Date: 12/08/95 Group: I  
Modified Date of Birth: Date of Death:

CURRENT HOME ADDRESS:  
W1054 CTY RD N W206 ELDERBERRY ST  
Brandenburg/Havel PA 15238  
Hphone: (414)345-8755 Wphone: (414)144-9098

VACATION HOME/OTHER RESIDENCE:  
1207 KNOLLWOOD CT RT 1, BOX 304  
Atlasburg  
Phone: (414)301-2949  
Time of Year:

PHYSICIANS: Specialty  
Eda Fran McGlade Primary Doctor  
1216 KILBURN AVE 1201 W 5TH ST N  
McKeesport PA 15223  
Phone: (414)306-4086  
Date Last Updated: 5/18/01

Cancer Confirmation (DE/OCF) needed for: Prostate

Complete Cancer Information:

Study	Year	Type	Cancer Ccode	Source	Status	Identify Date	--Determination-- Date	Source	ICD-9-CM	Other Cancer Description
T0		C	FSG		N	1/03/96	4/24/96	DEC		
T0		C	FSQ		N	1/23/96	4/24/96	DEC		
T3		P	BCF		S	1/26/99				

COMMENTS:

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

## **Appendix B-8-3: Cancer Confirmation List**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Cancer Confirmation List***

**This report contains five sections: DEs expected due to positive screens; DEs expected for reported PLCO cancers; OCFs expected for reported non-PLCO cancers; TIs expected for confirmed PLCO cancers; and a summary section. All participants listed on this report must have a DE, OCF, or TI form completed and receipted in the SMS in order to be removed from the report. In addition, this report has a sort option for data presentation. This report contains Privacy Act data and should be handled with caution.**

---

PLCO CANCER SCREENING TRIAL  
 Cancer Confirmation List  
 Summary Information

Report Date: 5/16/03  
 Time: 4:24 pm

SC Name: Westat

Study Year	Number Of Suspected Cancers To Be Confirmed							Confirmed PLCO Cancers TI expected	Total
	Prostate	Lung	Colorectal	Ovarian	Other				
T0	13	25	64	12	1			1	116
T1	61	45	7	34	20			6	173
T2	101	76	10	57	30			7	281
T3	119	58	10	52	29			5	273
T4	68	10	4	11	34			4	131
T5	103	15	227	15	39			0	399
T6	24	6	10	3	40			1	84
T7	13	9	5	0	19			1	47
T8	4	2	0	0	7			0	13
Overall	506	246	337	184	219			25	1,517

\*\* This report contains data protected by the Privacy Act of 1975.  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

PLCO CANCER SCREENING TRIAL  
 Cancer Confirmation List

Part 3

DBS Expected Due to Positive Screens

Report Date: 5/16/03  
 Time: 4:26 pm

PID	Name	Medical Record #	Study Year	Vital Status	Participant Status	Cancer Type	Source of Identification	Date of Identification
305420-4	JENNIE JACKALIN Marvis		T0			Lung	XXY	9/06/96
413522-2	LORRY PRESTON Ousest		T0			Lung	XXY	4/04/98
800002-0	FABITHA KAREN Robinson		T0			Lung	XXQ	11/15/93
808002-0	FABITHA KAREN Robinson		T3			Lung	XXY	11/11/96
80282-8	TOMKIE WILFORD Maltis		T3			Prostate	BFF	2/27/97
80624-6	EDIE ANTOINE Sauer		T5			Prostate	BFF	8/12/99
801432-4	JONAS DOMINGO Dolphin		T5			Colorectal	BFF	3/27/00
801592-8	AUGUST ANTOINE Schreiber		T5			Prostate	BFF	3/31/00
801592-8	AUGUST ANTOINE Schreiber		T7			Prostate	ASU	10/18/01
801656-6	MAURO SCOTT MERRY		T5			Colorectal	P92	3/23/01
801656-6	MAURO SCOTT MERRY		T5			Prostate	BFF	1/31/01
801939-6	RODOLFO SANTIAGO Abel		T9			Prostate	BFF	11/21/00
801984-1	DENNIS KATE Callaway		T9			Prostate	BFF	2/13/01
802051-8	DANIELLA PIPPE Johnson		T5			Ovarian	BFF	12/08/00
802164-2	EMIL GERARDO Zavala		T5			Prostate	BFF	12/09/00
802358-9	HERSCHEL ERIC Nossano		T5			Prostate	BFF	12/20/00
802514-3	MONTY FERDINAND Curtin		T9			Prostate	BFF	12/07/01
802518-7	TYRONAS MAXWELL McKeag		T5			Colorectal	P92	1/12/01
802577-1	TIM JARRETT Sudd		T5			Prostate	BFF	10/20/00
803014-6	HUNTER LOUIE Bernstein		T5			Prostate	BFF	10/20/00
803014-6	HUNTER LOUIE Bernstein		T7			Prostate	ASU	5/05/02
803186-7	CALVIN CLARK Brooks		T5			Prostate	BFF	10/20/00
803186-7	CALVIN CLARK Brooks		T6			Prostate	ASU	3/28/02
803246-1	HEMELINCA TAYLOR Obbink		T5			Ovarian	BFF	11/15/00
803251-6	DOMINICK MILO McGinley		T5			Prostate	BFF	12/01/00
803251-6	DOMINICK MILO McGinley		T6			Prostate	ASU	6/12/01
803504-1	STEPAN HOLLIS Ship		T5			Prostate	BFF	4/04/01
803535-2	ROBERT WILLIS Hood		T5			Prostate	BFF	10/30/00
803613-4	NICHOLAS JARRETT Haupt		T5			Prostate	BFF	1/17/01

\*\* This report contains data protected by Privacy Act of 1975.  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

\*\* This report contains data protected by the Privacy Act of 1975.  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

Report Date: 5/16/03  
 Time: 4:28 pm

PLCO CANCER SCREENING TRIAL  
 Cancer Confirmation List

Part 2

DEs Expected for Reported PLCO Cancers

PID	Name	Medical Record #	Study Year	Vital Status	Participant Status	Cancer Type	Source of Identification	Date of Identification
800004-4	MARCO LEONARDO DRAMA		T0			Ovarian	OTR	11/05/02
800012-5	LAJURNA MICHELLE Orenski		T3			Lung	ASU	10/31/96
800068-6	CLETA KEMINA Beaud		T7			Lung	ASU	11/08/00
800103-0	LUCIO ROBT TORRES		T8			Prostate	ASU	12/20/01
800117-9	COBY LINDORH Hurman		T8	B		Prostate	ASU	12/03/01
800142-4	ARMAD ANTONIO Woodburn		T8			Prostate	ASU	12/06/01
800248-0	DOMO TROY TANDSCHL		T8			Lung	ASU	1/04/02
800316-1	SCOTT STEPHEN FOUTO		T7			Colorectal	ASU	1/12/01
800350-5	AMOS STERLING Koppke		T5	C		Lung	ASU	4/21/99
800359-5	AMOS STERLING Koppke		T5	C		Lung	DCP	3/26/99
800417-1	BRADLEY KING BRER		T7			Prostate	ASU	3/08/01
800449-8	LAWSTER MILO BIERER		T8			Lung	ASU	3/25/02
800557-5	DALTON IEE BEAULIGAN		T7			Prostate	ASU	4/28/01
800690-7	TREY GARREY Buczkowski		T7			Prostate	ASU	5/02/01
800740-6	WYATT KENNETH Mansinger		T8			Prostate	ASU	5/05/02
800772-1	ANGELA MARCIE McKittray		T7	C		Lung	ASU	11/23/01
800891-9	OFELIA OLSELE BARRY		T6			Colorectal	ASU	2/21/01
800954-2	EDDY QUENTIN DORNEY		T7	C		Lung	ASU	1/03/01
801006-7	NED ALLEN Lippert		T7			Prostate	ASU	7/11/01
801021-7	LORRETTA FRIBBY FIMMELL		T6			Lung	ASU	1/29/01
801046-7	PABLO JEROME McBeide		T4	C		Lung	OCF	1/07/02
801046-7	PABLO JEROME McBeide		T5	C		Lung	DCP	1/10/99
801076-2	AARON JEREMY WELLS		T6			Prostate	ASU	1/29/01
801233-2	LOYD JIMMY Steingert		T7			Colorectal	ASU	9/04/01
801282-6	SPRAIN CHAUNCEY Whalen		T7			Prostate	ASU	10/17/01
801309-7	AL DOYCE O'Leary		T7			Prostate	ASU	5/10/02
801377-0	CHARNAINE TRAE Fulmer		T8			Lung	ASU	10/05/00
801417-4	RANDOLPH OSCAR Mateas		T7			Lung	ASU	1/10/02
801466-3	LEONTINE ANGIETTINA O'Leary		T6	C		Lung	ASU	10/04/00

\*\* This report contains data protected by Privacy Act of 1975.  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

Report Date: 5/16/03  
 Time: 4:29 pm

PLCO CANCER SCREENING TRIAL  
 Cancer Confirmation List

Part 3

OCFs Expected for Reported non-PLCO Cancers (ctype = 'T')

PID	Name	Medical Record #	Study Year	Vital Status	Participant Status	Cancer CODE	Source of Ident.	Date of Ident.
202664-6	FAUSTO MORGAND Pecoley		T1	P		(888) head and toe	ASU	2/05/97
413532-2	LOREN PRESTON Gumbert		T1			(888) don't know	OTH	11/20/02
413532-2	LOREN PRESTON Gumbert		T5			(888) don't know yet	ASU	11/20/02
800462-4	EDUARDO RAMONDO Faust		T6			(042) Endocrine gland	ASU	12/10/01
800173-5	SUZANN MADELINE Pfister		T6			(020) Liver*	ASU	12/28/01
800231-7	WERNER KIRK Crape		T6			(005) Brain*	ASU	1/09/02
800249-0	VICTOR ZETIA Nickl		T6			(019) Leukemia	ASU	1/20/02
800369-4	JAMEL ELVIN Oldham		T3	C		(999) BCC Acetarsine	ICF	5/28/97
800418-7	FABIAN ROMIRIO Grims		T6	C		(050) Multiple myelo	ASU	11/01/01
800419-3	EZEKIEL PARKER Laitta		T6			(026) Non-Hodgkin's	ASU	2/20/02
800456-5	MERRILEE LOUELLA Powers		T6			(006) Breast	ASU	3/10/02
800694-6	BLITT FIDEL GRIFO		T6			(018) Larynx	ASU	4/03/02
800709-0	BRIENT REPOLITO Saxe		T7	C		(013) Leukemia	ASU	12/19/00
800750-1	BENNY EARNEST Jakomas		T7			(014) Hodgkin's dise	ASU	6/28/01
800799-5	DAVIS BABYK Solyan		T7			(026) Non-Hodgkin's	ASU	7/15/01
800829-4	DARYL MERLENE Frank		T6			(006) Breast	ASU	1/08/01
800918-2	JOY NATACHA Ferrar1		T7			(006) Breast	ASU	7/10/01
800962-6	IRAZLEY JESUS Rapine		T6	C		(029) Pancreas*	ASU	2/18/00
801123-1	DREN TONEY Yevich		T6	C		(999) Not Acetarsine	ASU	9/14/00
801423-5	KAROL JERALDINE Greenwald		T7			(006) Breast	ASU	9/28/01
801575-6	LIND SHAO Kelloff		T7			(026) Non-Hodgkin's	ASU	10/23/01
801603-3	JUAN CAROLINA Wood		T7			(006) Breast	ASU	3/01/02
801634-4	ALFONZO SIDNEY Carty		T6	C		(017) Kidney and ren	ASU	11/08/00
801666-1	SALINA KISHA Montgomery		T6	C		(029) Pancreas*	ASU	1/11/01
801706-3	JEANNETTE KIYOKO Gallo		T7	C		(050) Multiple myelo	ASU	11/08/01
801746-5	COURTNEY NATHANIEL Kelley		T6	C		(029) Pancreas*	ASU	1/10/01
801794-8	DEWITT ROGER Hiller		T5			(019) Leukemia	ASU	11/17/99
801800-3	DARRELL JERRELL Lebee		T7			(003) Bladder*	ASU	11/15/01
802157-5	TONEY YONG Herr		T7			(019) Leukemia	ASU	1/17/02

\*\* This report contains data protected by Privacy Act of 1975. \*\*  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

PICO CANCER SCREENING TRIAL  
 Cancer Confirmation List

Part 4

T1s Expected for Confirmed PICO Cancers

Report Date: 5/16/03  
 Time: 4:29 pm

PID	Name	Medical Record #	Study Year	Vital Status	Participant Status	Cancer Type	Date of Diagnosis
800944-8	WILL MERLIN Harnisch		T2	C		Lung	11/24/95
801148-3	ERIC CHARLES Zappa		T7			Prostate	6/05/01
801862-5	ERIKIEL ALAN GOOD		T3			Colorectal	3/18/98
802446-6	RANDOLPH MARSHALL Kasiner		T1	C		Lung	1/12/96
804043-8	SHERWOOD TRACY Grady		T2			Lung	11/07/97
804203-6	MALTON MALCOM Baird		T4			Prostate	5/06/99
804566-0	RAY ROSENDO Rauterbus		T4			Prostate	11/04/99
805142-9	ABRAHAM SHEPHERD Hanna (DECEASED)		T4	C		Lung	8/14/00
805180-7	MICKY KEVIN Nicolaus		T6			Prostate	8/04/01
806549-0	BRYCE COLIN Cicco		T4			Prostate	2/25/00
808626-2	JACQUELIN MARTEL Lewetog		T1			Ovarian	2/09/99
809453-4	CLEVELAND STERLING Macher		T2			Prostate	9/31/99
809799-2	VAUGHN SID Scanlens		T2	P		Lung	5/23/00
810308-6	COSEY CAROL Perilli		T3			Lung	
810956-7	HOAR STAM Walt		T1			Prostate	9/02/99
811415-4	TOMY STEWART Cullen		T3			Lung	
811726-7	ANTHONY DAVID Shuba		T3			Lung	
812000-6	JON TYLER Bettwy		T3			Lung	
812017-3	FRED MITCHEL Ruck		T0			Prostate	3/02/99
813061-5	BLAIR IVORY Vitullo		T3			Prostate	
814133-9	JOHNIE BEAU Peres		T2			Prostate	5/17/02
815119-6	CURT CHARLIE Corcoran		T1			Prostate	
816095-3	ARLENE SILVIA McClintock		T3			Lung	2/17/02
816101-8	MICKY ERVIN Zarnick		T1			Prostate	9/24/01
816639-1	PHYLLIS LESLIE Pano		T1			Lung	5/28/02

\*\* This report contains data protected by Privacy Act of 1975. \*\*  
 \*\* Distribute only to authorized staff, and store and dispose of report in a proper manner. \*\*

## Appendix B-8-4: Abstracting Schedule Report

### PLCO Reports - Forms and Specimens Tracking

---

#### *Abstracting Schedule Report*

[THIS REPORT IS NO LONGER AVAILABLE – the Cancer Confirmation Report (B-8-3) can be used instead]

This is a two-part report.

Part 1 shows suspected cancers for which a Diagnostic Evaluation Form is outstanding.

Part 2 shows confirmed cancers for which a Treatment Information Form is outstanding.

---

## **Appendix B-9-1: National Death Index List**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***National Death Index List***

**This report lists identifiers for all eligible participants for the NDI submission.**

---

6/09/03  
4:12 pm

National Death Index (NDI) List  
Number of Participants : 193  
Earliest Last Contact Date : 11/05/2001

Page 1

PID	Submission Date
-----	-----
202664-6	6/09/03
800004-2	6/09/03
800015-3	6/09/03
800016-9	6/09/03
800037-5	6/09/03
800038-1	6/09/03
800080-8	6/09/03
800109-6	6/09/03
800266-2	6/09/03
800365-0	6/09/03
800434-3	6/09/03
800546-4	6/09/03
800641-8	6/09/03
800661-8	6/09/03
800738-9	6/09/03
800744-0	6/09/03
800773-9	6/09/03
800794-5	6/09/03
800819-9	6/09/03
800879-9	6/09/03
800899-9	6/09/03
801111-6	6/09/03
801191-6	6/09/03
801269-3	6/09/03
801545-1	6/09/03
801765-9	6/09/03
801905-7	6/09/03
801969-1	6/09/03
802235-7	6/09/03
802263-0	6/09/03
802285-2	6/09/03
802315-1	6/09/03
802350-1	6/09/03
802597-1	6/09/03
802598-7	6/09/03
802670-3	6/09/03
802722-4	6/09/03
802786-8	6/09/03
802816-7	6/09/03
802817-3	6/09/03
802943-8	6/09/03
803016-8	6/09/03
803048-5	6/09/03
803146-7	6/09/03
803249-9	6/09/03
803455-8	6/09/03

## **Appendix B-9-2: Vital Status Confirmation List**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Vital Status Confirmation List***

**This list identifies participants whose vital status is listed as presumed deceased (P), confirmed deceased (C), or confirmed deceased without a death certificate (N). There is an option to list each vital status as a separate report.**

---

5/21/03  
3:27 pm

PLCO Cancer Screening Trial  
Vital Status Confirmation List  
Vital Status - All Deceased

Page 1  
SMS 8.1

PID	Vital Status	Source	Date Status Assigned	Date of Death
800387-2	P	ASU RETURN BY PO	3/19/01	
800432-1	P	DTR CALLED IN	2/16/01	
800450-9	P	DIETARY	1/29/01	
800548-6	P	WIFE RECEIVED ASU	3/22/01	
800561-4	P	ASU RETURN BY DTR	4/02/01	
800743-4	P	ASU TRACING	4/05/01	
800844-4	P	ASU RETURN BY WIFE	10/23/00	
801289-3	P	ASU RET BY DTR	12/08/00	
801403-5	P	OBITS	4/09/01	
801708-7	P	CALL FOR ANNUAL	11/06/00	
801741-5	P	PO RET ASU DECEASED	1/27/98	
801746-5	P	OBITS	12/11/00	
801766-5	P	ASU	1/11/01	
801905-7	P	ASU CALL BY SON	12/22/00	
802278-5	P	CALLED FOR ANNUAL	12/06/00	
802330-1	P	ASU TRACING	3/19/01	
802447-2	P	ASU TRACING	9/05/00	
802607-0	P	ASU RETURN BY SON	3/27/01	
802832-3	P	ASU	4/14/00	
802892-3	P	HUSBAND	2/13/01	
803240-5	P	ASU MAILING	6/08/00	
803472-0	P	MED RECORDS	3/15/01	
804092-7	P	TRACING	2/20/01	
804269-2	P	ASU RETURN BY DTR	2/16/01	
804763-6	P	ASU	1/11/01	
804779-7	P	DTR	4/02/01	
805398-8	P	HUSBAND CALLED	11/02/00	
806103-8	P	OBITS	3/05/01	
806600-0	P	ASU HUSBAND	10/16/98	
806826-4	P	DIETARY	1/16/01	
807279-6	P	OBITS	2/28/01	
807280-7	P	CALLED FOR ANNUAL	12/08/00	
807333-4	P	COUSIN CALLED	12/19/00	
807390-6	P	SSDI	3/15/01	
807492-2	P	CALL FOR ANNUAL	2/02/01	
807503-7	P	BROTHER	1/15/99	
807689-7	P	CALL FOR ANNUAL	2/28/01	
808303-2	P	HUSBAND CALLED IN	8/21/98	
808362-6	P	OBITS	3/01/01	
808677-3	P	OBITS	2/14/01	
808840-4	P	DIETARY	11/06/00	
809492-8	P	ASU RETURN BY SON	12/15/00	
809986-7	P	ASU RETURN BY DTR	3/22/01	

## Appendix B-9-3: Death Certificate Receipt Report

### PLCO Reports - Forms and Specimens Tracking

---

#### *Death Certificate Receipt Report*

This report displays the following information for a single participant: PID, death certificate receipt date, whether or not there is confirmation that the death certificate is for the correct participant (Y=Yes, N=No), and the date of death.

---

7/08/98  
2:52 pm

PLCO Cancer Screening Trial  
Death Certificate Receipt Report

Page 1  
SMS 4.2

Participant ID: 802815-1

Receipt Date: 7/08/98

Confirmed to be Certificate of Correct Participant: Y

Date of Death: 3/26/98

## Appendix B-9-4: Death Certificate Transmittal Log

PLCO Reports - Forms and Specimens Tracking

---

### *Death Certificate Transmittal Log*

This is a generated form which lists Death Certificate Forms (DCF) that are ready to be included in a shipment.

---

5/30/03  
1:21 pm

PLCO CANCER SCREENING TRIAL  
Death Certificate Transmittal Log

Page 1  
SMS 8.1

Screening Center: University of Pittsburgh / Id#: 01

Shipment Date: 5/30/2003

Total number of Items: 62

WESTAT RECEIPT CONFIRMATION	PARTICIPANT ID	DATE OF DEATH	DEATH CERTIFICATE RECEIPT DATE	COMMENTS
_____	800097-5	9/29/99	4/04/01	
_____	800114-1	8/18/00	4/04/01	
_____	800272-3	3/12/99	4/04/01	
_____	800293-9	7/08/00	4/04/01	
_____	800418-7	5/10/99	4/04/01	
_____	800709-0	9/01/99	4/04/01	
_____	800893-3	9/06/99	4/04/01	
_____	800962-6	2/10/00	4/04/01	
_____	801035-6	10/06/99	4/04/01	
_____	801323-1	2/21/00	4/04/01	
_____	801578-4	3/03/00	4/04/01	
_____	801610-0	3/02/00	4/04/01	
_____	801634-4	9/27/00	4/04/01	
_____	801666-1	6/04/00	4/04/01	
_____	802003-2	1/17/00	4/04/01	
_____	802042-6	2/15/00	4/04/01	
_____	802081-0	9/07/99	9/27/00	
_____	802657-5	6/06/00	4/04/01	
_____	802887-8	1/27/99	4/04/01	
_____	802917-7	7/05/00	4/04/01	
_____	803051-8	7/16/99	4/04/01	
_____	803425-3	11/20/99	4/04/01	
_____	803459-2	7/16/00	4/04/01	
_____	803521-3	7/26/99	4/04/01	
_____	803668-9	2/21/00	4/04/01	
_____	803877-6	6/11/00	4/04/01	
_____	803955-8	1/16/00	4/04/01	
_____	803963-1	10/06/99	4/04/01	
_____	804323-0	1/16/00	4/05/01	
_____	804389-6	2/07/00	4/04/01	
_____	804446-2	9/03/99	4/04/01	
_____	804576-1	10/03/99	4/04/01	
_____	804782-0	7/12/00	4/05/01	
_____	804911-7	11/06/99	4/04/01	
_____	805404-3	11/22/98	4/04/01	
_____	806003-4	8/05/99	4/04/01	
_____	806065-6	10/26/99	4/04/01	
_____	806753-7	3/11/00	4/04/01	
_____	807266-3	12/05/99	4/04/01	
_____	807319-0	4/20/00	4/04/01	

## **Appendix B-9-5: Participants with Cancer on Death Certificate Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Participants with Cancer on Death Certificate Report***

**This lists the PID, study year, cancer type, date of death, cancer code, and a cancer description for each participant with a cancer reported on their death certificate.**

---

Participants with Cancer on Death Certificate (DCF)

Participant ID	Study Year	Cncr Type	Date Death (Ident.Date)	ICD9 Code*	Cancer Code	Cancer Description	Report Run Date
101815-1	T09	T	06/19/04		029	Pancreas	11/03/04
103611-5	T08	C	05/12/04			Colorectal	11/03/04
109204-0	T06	T	05/29/04		006	Breast	11/03/04
109204-0	T06	T	05/29/04		020	Liver	11/03/04

Participants without Cancer on Death Certificate (DCF)

Participant ID	Study Year	Date of Death	Report Run Date
101844-0	T09	06/12/04	11/03/04
103573-3	T08	05/20/04	11/03/04

## **Appendix B-9-6: Algorithm for Death Review**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Algorithm for Death Review***

**This report lists by SC PIDs assigned to DRC review (AR), certified (AC), or rejected (XX) because of insufficient information.**

---

Algorithm Results - New ACs

PID	Date of Death	Algorithm Result	Algorithm Description	Report Run Date
201261-9	11/20/99	AC	Certified	11/11/04
202340-0	01/19/01	AC	Certified	11/11/04
203375-8	02/18/02	AC	Certified	11/11/04
207080-3	09/12/02	AC	Certified	11/11/04
207552-0	12/29/02	AC	Certified	11/11/04
204617-5	07/23/03	AC	Certified	11/11/04
206752-5	10/20/03	AC	Certified	11/11/04
200324-8	12/30/03	AC	Certified	11/11/04
201741-9	06/07/04	AC	Certified	11/11/04

Algorithm Results - New ARs

PID	Date of Death	Algorithm Result	Reason Selected	Report Run Date
202718-9	12/24/02	AR	AR1 AR2	11/11/04
200538-5	07/25/03	AR	AR1 AR2	11/11/04
201452-8	12/26/03	AR	AR1 AR2	11/11/04

### Algorithm Rejection Report

PID	Date of Death	Reason for Rejection	Date First Rej.	Rejected 2+ Prev.	Report Run Date
203580-1	11/23/98	2	09/01/04	*	11/11/04
202986-0	01/28/01	2	10/13/03	*	11/11/04
203152-2	08/28/01	2	07/21/04	*	11/11/04
206276-9	12/05/01	5	11/10/04	.	11/11/04
207922-1	03/28/02	2	07/21/04	*	11/11/04
206685-4	11/29/02	2	02/06/04	*	11/11/04
200801-0	01/24/03	2	07/21/04	*	11/11/04
206296-9	03/01/03	2	07/21/04	*	11/11/04
207360-5	07/11/03	2	09/01/04	*	11/11/04
205026-3	08/20/03	2	09/01/04	*	11/11/04
200823-2	09/29/03	2	07/21/04	*	11/11/04
204755-7	12/23/03	2	09/01/04	*	11/11/04
200016-3	01/03/04	2	04/20/04	*	11/11/04
207747-3	02/17/04	2	10/21/04	*	11/11/04
200344-8	03/31/04	2	10/21/04	*	11/11/04
210120-8	04/13/04	2	09/01/04	*	11/11/04
200697-3	05/21/04	2	10/21/04	*	11/11/04
201319-6	06/11/04	2	09/01/04	*	11/11/04
201946-7	07/17/04	2 5	11/10/04	.	11/11/04

Algorithm Results - All ARs

PID	Date of Death	Algorithm Result	Date of Algorithm Result	Date Doc Recd at Westat	Status of Death Review	Report Run Date
200058-5	10/13/02	AR	07/13/04	04/07/04	Pending	11/11/04
200114-5	11/20/97	AR	01/17/00	07/10/01	Complete	11/11/04
200209-4	10/10/99	AR	06/11/02	10/10/02	Complete	11/11/04
200263-8	07/25/00	AR	07/13/04	01/10/02	Complete	11/11/04
200278-3	06/20/98	AR	04/07/00	07/10/01	Complete	11/11/04
200292-7	05/05/97	AR	01/12/99	01/10/99	Complete	11/11/04
200316-5	06/24/03	AR	07/13/04	07/09/04	Pending	11/11/04
200351-5	07/11/96	AR	08/08/02	08/21/02	Complete	11/11/04
200431-9	05/15/98	AR	06/11/02	07/10/02	Complete	11/11/04
200438-1	12/09/99	AR	08/08/02	07/10/02	Outstanding	11/11/04
200556-3	03/09/99	AR	08/08/02	08/21/02	Complete	11/11/04
200618-9	08/11/97	AR	11/12/03	01/09/04	Pending	11/11/04
200647-8	08/25/96	AR	04/14/99	04/10/99	Complete	11/11/04
200712-7	11/24/96	AR	03/10/99	04/10/99	Complete	11/11/04
200751-1	05/12/97	AR	09/08/03	10/03/03	Complete	11/11/04
200791-1	09/10/00	AR	01/13/03	01/09/03	Complete	11/11/04
200873-7	02/24/01	AR	11/12/01	01/10/02	Pending	11/11/04
200917-5	04/24/96	AR	01/08/01	07/10/01	Complete	11/11/04
200938-1	12/02/00	AR	01/08/02	07/10/02	Complete	11/11/04
200971-9	08/06/98	AR	07/13/04	04/07/04	Pending	11/11/04
200979-7	02/23/97	AR	07/08/02	07/25/02	Complete	11/11/04
201018-8	06/16/98	AR	09/11/00	10/26/01	Complete	11/11/04
201023-3	05/22/98	AR	12/13/99	07/12/00	Complete	11/11/04
201031-6	09/25/02	AR	04/03/03	06/19/03	Complete	11/11/04
201089-9	02/25/02	AR	08/08/02	06/19/03	Complete	11/11/04
201121-5	03/09/00	AR	08/08/02	01/09/03	Complete	11/11/04
201128-7	11/18/97	AR	10/11/00	10/22/01	Complete	11/11/04
201130-4	12/17/01	AR	05/06/02	07/10/02	Complete	11/11/04
201203-1	01/20/96	AR	03/10/99	04/10/99	Complete	11/11/04
201229-7	06/22/96	AR	03/10/99	04/10/99	Complete	11/11/04
201233-6	09/26/96	AR	04/14/99	04/10/99	Complete	11/11/04
201258-6	11/07/99	AR	11/13/02	06/19/03	Complete	11/11/04
201265-3	01/05/04	AR	07/21/04		Outstanding	11/11/04
201375-2	08/02/00	AR	12/13/01	01/10/02	Pending	11/11/04
201413-4	10/09/00	AR	06/11/02	01/09/03	Complete	11/11/04

### Algorithm Rejection - Key

Rejection Reason key	Key Description
1	Vital Status is not "C"
2	At Least One Cancer Status of "S"
3	Cancer Status of "C" and no ICD-O Code
4	Cancer Status of "N" and no ICD-9 Code
5	No Cancer Record with CSOURCE="DCF"
6	DC Data Not Yet Evaluated for Cancers

### Algorithm Results - Key

Review Results Key	Key Description
AR	Designated by Algorithm for Review
AR1	PID Has Confirmed PLCO Cancer
AR2	PID Has Cause of Death on DCF Master-Codes A,B,C,D (except 196-199)
AR3	PID has Cause of Death on DCF Master-Codes 196-199 & No Other Code of 140-195
AR4	PID has a CSTATUS of N with a Detersource=DEx and ICD9CM Code E
AR5	PID has a Detersource of OCF and ICDO-2 Translates to ICD-9 Code
*	Refer to Death Review Selection Criteria - MOOP Chapter 9.8.3.

## **Appendix B-10-1: UCLA Transmittal Log**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***UCLA Transmittal Log***

**This report shows all blood samples collected and receipted at the SC the previous week before the shipment of samples to UCLA. The report includes the participant ID, draw date, problem codes, and the sample's ID number. A copy of this report should accompany the specimens during shipment to UCLA and a copy should be retained at the SC for verification.**

---

5/30/2003  
3:31 pm

PLCO CANCER SCREENING TRIAL  
UCLA TRANSMITTAL LOG

Page 1  
SMS 8.1

Screening Center: University of Pittsburgh / Id#: 01

Shipment Date: 5/30/2003

Sample Type: PSA

Box Number: UP0866

Total # of Vials: 16

PARTICIPANT ID	DRAW DATE	PROBLEM #1	PROBLEM #2	PROBLEM #3	SAMPLE ID
808159-5	4/18/2001				UZ 0589 001
808020-2	4/18/2001				UZ 0591 001
808091-3	4/18/2001				UZ 0592 001
808094-1	4/18/2001				UZ 0593 001
807937-2	4/18/2001				UZ 0594 001
807787-9	4/18/2001				UZ 0595 001
808030-7	4/18/2001				UZ 0598 001
808106-2	4/18/2001				UZ 0599 001
806387-0	4/18/2001				UZ 0602 001
807742-9	4/18/2001				UZ 0603 001
807717-4	4/18/2001				UZ 0605 001

## **Appendix B-10-2: Biorepository Transmittal Log**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Biorepository Transmittal Log***

**This report shows all blood samples collected, receipted, and stored at the SC, without problems, for the previous month before the shipment of samples to the Biorepository. The report includes the participant ID, draw date, and the Sample ID number. A copy of this report should accompany the specimens during shipment to the Biorepository and a copy retained at the SC for verification.**

---

5/29/03  
3:32 pm

PLCO CANCER SCREENING TRIAL  
Biorepository Transmittal Log  
Study ID : PLC

Page 1  
SMS 8.1

Screening Center : University of Pittsburgh / Id#: 01

Shipment Date : 5/29/2003

Box Number : B2405

Study Year : T0                      Total # of Vials : 27                      Total # of PIDs : 3

PARTICIPANT ID	DRAW DATE	MM1	MM2	MM3	SAMPLE ID
-----	-----	---	---	---	-----
816900-4	4/06/01				UV 8170 003 UV 8170 004 UV 8170 005 UV 8170 006 UV 8170 007 UV 8170 008 UV 8170 009 UV 8170 010 UV 8170 011
816784-0	4/12/01				UV 8171 003 UV 8171 004 UV 8171 005 UV 8171 006 UV 8171 007 UV 8171 008 UV 8171 009 UV 8171 010 UV 8171 011
816785-6	4/12/01				UV 8172 003 UV 8172 004 UV 8172 005 UV 8172 006 UV 8172 007 UV 8172 008 UV 8172 009 UV 8172 010 UV 8172 011

## Appendix B-10-3

### PLCO Reports - Forms and Specimens Tracking

---

#### ***UCLA Laboratory Receipt and Discrepancy Reports***

This report is printed separately for PSA and CA 125II results and has eight parts:

All Original CA-125II/PSA Records Received from UCLA. This report is generated for all samples that are contained in the UCLA file.

Errors on CA-125II/PSA Analysis File Results returned from UCLA with no corresponding vial or blood collection form record or with Blank Shipdate. This report is generated if a UCLA result record is returned and there is no corresponding vial blood collection form record in the SMS, or a matching record exists in the SMS but the UCLA shipdate is blank.

Errors on CA-125II/PSA Analysis File Rejected: blood collection form results already set. **\*\*\*Contact Westat and Fax this report to User Support\*\*\***. This report is generated if the current SMS blood collection form UCLA result is already AS, NG or IN for any of the Sample IDs on the UCLA records.

Rejected: Analysis Date is Blank. This report is generated if the record from UCLA contains a blank analysis date.

Error: Problem plus Result – Notify Westat. This report is generated if the UCLA Analysis record contains a CA-125II or PSA result but there is also a problem code (indicating a lost or damaged vial) present. The update for this Sample ID is rejected.

Unexpected Problem Code – Notify Westat. This report is generated if the UCLA Analysis record contains an unexpected problem code. The update for this Sample ID is rejected.

Damaged Vials: Exam Result will be IN. This report is generated if a UCLA vial was damaged, lost or destroyed after the vial was shipped from the Screening Center. The UCLA analysis record will contain a problem code indicating the type of problem incurred and the SMS will translate the code appropriately and update the blood collection form UCLA result to IN (Inadequate). This report will be used for the SC's information only. The SC does not need to contact the Coordinating Center.

Errors on CA-125II/PSA Analysis File Results returned from UCLA with no corresponding PCR records. This report is generated if a UCLA result is returned and there is no corresponding PCR record for the associated blood collection form and Sample ID.

---

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

All Original PSA Records Imported from UCLA

PID	Sample ID	Draw Date	PSA Date	PSA Result	PSA Prob	Sample ID (Our Vials)	PID (from BCF/BFF)
000000-0		07/19/00	03/25/99	2.06		IZ 0234 001	
100000-1		06/27/00	03/25/99	2.06		IZ 1234 001	
100503-9		10/21/99	03/25/99	2.06		IB 8678 001	
102114-0		11/11/99	03/25/99	2.06		IB 7663 001	
102234-4		11/09/99	03/25/99	2.06		IB 7700 001	
102559-6		09/01/99	03/25/99	2.06		IB 8552 001	
102597-4		08/31/99	03/25/99	2.06		IB 8550 001	
102818-2		08/31/99	03/25/99	2.06		IB 8551 001	
801509-5		03/15/99	03/25/99	2.50		UZ 5555 001	
801846-9		02/07/99	03/25/99	2.50		UW 1000 001	
803103-9		07/07/99	03/25/99	2.06		IZ 1857 001	
803119-0		07/07/99	03/25/99	2.06		IZ 1995 001	
803157-8		09/08/99	03/25/99	2.06		UZ 6969 001	
803815-4	IZ 1250 000	05/13/98	10/22/99	4.06		IZ 1250 001	803815-4
812355-3		12/29/99	03/25/99	2.06		UZ 7635 001	
812575-1		03/21/00	03/25/99	2.06		UZ 7000 001	
812576-7		05/20/99	03/25/99	2.06		UZ 7002 001	

**Errors on PSA Analysis File**

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected PSA: records from UCLA have their BCF results already set

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	PSA Date	Draw Date	PSA Result	Prob	Sample ID (Our Vials)	PID from (BCF/BFF)	Ship Date
803815-4	IZ 1250 000	05/13/98	10/22/99	4.06		IZ 1250 001	803815-4	10/13/99

**Errors on PSA Analysis File**

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected PSA: records from UCLA have no corresponding vial records

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	PSA Date	Draw Date	PSA Result	Prob	Sample ID (Our Vials)	PID from (BCF/BFF)	Ship Date
000000-0		07/19/00	03/25/99	2.06		IZ 0234 001		
100000-1		06/27/00	03/25/99	2.06		IZ 1234 001		
100503-9		10/21/99	03/25/99	2.06		IB 8678 001		
102114-0		11/11/99	03/25/99	2.06		IB 7663 001		
102234-4		11/09/99	03/25/99	2.06		IB 7700 001		
102559-6		09/01/99	03/25/99	2.06		IB 8552 001		
102597-4		08/31/99	03/25/99	2.06		IB 8550 001		
102818-2		08/31/99	03/25/99	2.06		IB 8551 001		
801509-5		03/15/99	03/25/99	2.50		UZ 5555 001		
801846-9		02/07/99	03/25/99	2.50		UW 1000 001		
803103-9		07/07/99	03/25/99	2.06		IZ 1857 001		
803119-0		07/07/99	03/25/99	2.06		IZ 1995 001		
803157-8		09/08/99	03/25/99	2.06		UZ 6969 001		
812355-3		12/29/99	03/25/99	2.06		UZ 7635 001		
812575-1		03/21/00	03/25/99	2.06		UZ 7000 001		
812576-7		05/20/99	03/25/99	2.06		UZ 7002 001		

**Errors on PSA Analysis File**

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected PSA: records from UCLA have no corresponding BCF records

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	PSA Date	Draw Date	PSA Result	Prob	Sample ID (Our Vials)	PID from (BCF/BFF)	Ship Date
000000-0		07/19/00	03/25/99	2.06		IZ 0234 001		
100000-1		06/27/00	03/25/99	2.06		IZ 1234 001		
100503-9		10/21/99	03/25/99	2.06		IB 8678 001		
102114-0		11/11/99	03/25/99	2.06		IB 7663 001		
102234-4		11/09/99	03/25/99	2.06		IB 7700 001		
102559-6		09/01/99	03/25/99	2.06		IB 8552 001		
102597-4		08/31/99	03/25/99	2.06		IB 8550 001		
102818-2		08/31/99	03/25/99	2.06		IB 8551 001		
801509-5		03/15/99	03/25/99	2.50		UZ 5555 001		
801846-9		02/07/99	03/25/99	2.50		UW 1000 001		
803103-9		07/07/99	03/25/99	2.06		IZ 1857 001		
803119-0		07/07/99	03/25/99	2.06		IZ 1995 001		
803157-8		09/08/99	03/25/99	2.06		UZ 6969 001		
812355-3		12/29/99	03/25/99	2.06		UZ 7635 001		
812575-1		03/21/00	03/25/99	2.06		UZ 7000 001		
812576-7		05/20/99	03/25/99	2.06		UZ 7002 001		

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

All Original CA125 Records Imported from UCLA

PID	Sample ID	Draw Date	CA125 Date	CA125 Result	Prob	CA125II Date	CA125II Result	Prob	Sample ID (Our Vials)	PID (from BCF/BFF)
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55		IZ 1698 028	202664-6
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55		IZ 1698 030	202664-6
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55		IZ 1698 031	202664-6
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55		IZ 1698 029	202664-6
202664-6		12/29/99	10/10/00	12		10/10/00	55		IG 3552 00C	
202664-6		11/09/99	10/10/00	12		10/10/00	55		IG 3552 00D	
304265-3	IG 3552 000	07/19/00	10/10/00	4		10/10/00	55		IG 3552 002	304265-3
304265-3	IG 3552 000	06/27/00			XXX1	10/10/00	55		IG 3552 003	304265-3
304265-3	IG 3552 000	10/21/99				10/10/00	7		IG 3552 004	304265-3
304265-3	IG 3552 000	11/11/99				10/10/00	5		IG 3552 005	304265-3
304265-3	IG 3552 000	11/09/99				10/10/00	9		IG 3552 006	304265-3
304265-3	IG 3552 000	11/09/99				10/10/00	7		IG 3552 007	304265-3
304265-3	IG 3552 000	08/31/99				10/10/00	9		IG 3552 008	304265-3
304265-3	IG 3552 000	08/31/99	10/10/00	12	XXX1				IG 3552 009	304265-3
304265-3	IG 3552 000	03/15/99				10/10/00	55	XXX2	IG 3552 010	304265-3
304265-3	IG 3552 000	11/09/99				10/10/00	5	XXX3	IG 3552 011	304265-3
800474-3	UV 0095 000	11/09/99				10/10/00		XXX6	UV 0095 002	800474-3

-----  
 Rejected CA125: records from UCLA have their BCF results already set

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 028	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 030	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 029	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 031	202664-6	06/07/00	
304265-3	IG 3552 000	07/19/00	10/10/00	4		10/10/00	55	IG 3552 002	304265-3	04/08/96	
304265-3	IG 3552 000	06/27/00			xxx1	10/10/00	55	IG 3552 003	304265-3		
304265-3	IG 3552 000	10/21/99				10/10/00	7	IG 3552 004	304265-3		
304265-3	IG 3552 000	11/11/99				10/10/00	5	IG 3552 005	304265-3		
304265-3	IG 3552 000	11/09/99				10/10/00	9	IG 3552 006	304265-3		
304265-3	IG 3552 000	11/09/99				10/10/00	7	IG 3552 007	304265-3		
304265-3	IG 3552 000	08/31/99				10/10/00	9	IG 3552 008	304265-3		
304265-3	IG 3552 000	08/31/99	10/10/00	12	xxx1			IG 3552 009	304265-3		
304265-3	IG 3552 000	03/15/99				10/10/00	55	xxx2 IG 3552 010	304265-3		
304265-3	IG 3552 000	11/09/99				10/10/00	5	xxx3 IG 3552 011	304265-3		
800474-3	UV 0095 000	11/09/99				10/10/00		xxx6 UV 0095 002	800474-3	07/14/99	

**Errors on CA125 Analysis File**

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA have no corresponding vial records

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from Ship BCF/BFF)	Date
			Date	Result	Prob	Date	Result	Prob			
202664-6		12/29/99	10/10/00	12		10/10/00	55		IG 3552 00C		
202664-6		11/09/99	10/10/00	12		10/10/00	55		IG 3552 00D		

Errors on CA125 Analysis File

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA have no corresponding BCF records

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from Ship BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
202664-6		12/29/99	10/10/00	12		10/10/00	55	IG 3552	00C		
202664-6		11/09/99	10/10/00	12		10/10/00	55	IG 3552	00D		

**Errors on CA125 Analysis File**

12/14/2004  
2:39 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA have blank ship date

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
304265-3	IG 3552 000	06/27/00			XXX1	10/10/00	55		IG 3552 003	304265-3	
304265-3	IG 3552 000	10/21/99				10/10/00	7		IG 3552 004	304265-3	
304265-3	IG 3552 000	11/11/99				10/10/00	5		IG 3552 005	304265-3	
304265-3	IG 3552 000	11/09/99				10/10/00	9		IG 3552 006	304265-3	
304265-3	IG 3552 000	11/09/99				10/10/00	7		IG 3552 007	304265-3	
304265-3	IG 3552 000	08/31/99				10/10/00	9		IG 3552 008	304265-3	
304265-3	IG 3552 000	08/31/99	10/10/00	12	XXX1				IG 3552 009	304265-3	
304265-3	IG 3552 000	03/15/99				10/10/00	55	XXX2	IG 3552 010	304265-3	
304265-3	IG 3552 000	11/09/99				10/10/00	5	XXX3	IG 3552 011	304265-3	

12/14/2004  
2:40 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA show both CA125 and CA125 II  
results

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from Ship BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 028	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 030	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 029	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 031	202664-6	06/07/00	
202664-6		12/29/99	10/10/00	12		10/10/00	55	IG 3552 00C			
202664-6		11/09/99	10/10/00	12		10/10/00	55	IG 3552 00D			
304265-3	IG 3552 000	07/19/00	10/10/00	4		10/10/00	55	IG 3552 002	304265-3	04/08/96	

**Errors on CA125 Analysis File**

12/14/2004  
2:40 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA show both result code and problem  
code

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from Ship BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
304265-3	IG 3552 000	06/27/00			XXX1	10/10/00	55		IG 3552 003	304265-3	
304265-3	IG 3552 000	08/31/99	10/10/00	12	XXX1				IG 3552 009	304265-3	
304265-3	IG 3552 000	03/15/99				10/10/00	55	XXX2	IG 3552 010	304265-3	
304265-3	IG 3552 000	11/09/99				10/10/00	5	XXX3	IG 3552 011	304265-3	

**Errors on CA125 Analysis File**

12/14/2004  
2:40 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA have unexpected problem code

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from Ship BCF/BFF)	Date
			Date	Result	Prob	Date	Result	Prob			
800474-3	UV 0095 000	11/09/99				10/10/00		XXX6	UV 0095 002	800474-3	07/14/99

**Errors on CA125 Analysis File**

12/14/2004  
2:40 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: new analysis date is incompatible with existing BCF analysis date

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 028	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 030	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 029	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 031	202664-6	06/07/00	
304265-3	IG 3552 000	07/19/00	10/10/00	4		10/10/00	55	IG 3552 002	304265-3	04/08/96	
304265-3	IG 3552 000	08/31/99	10/10/00	12	XXX1			IG 3552 009	304265-3		
800474-3	UV 0095 000	11/09/99				10/10/00	XXX6	UV 0095 002	800474-3	07/14/99	

**Errors on CA125 Analysis File**

12/14/2004  
2:40 pm

PLCO CANCER SCREENING TRIAL

Page 1  
SMS 10.0.0

Rejected CA125: records from UCLA show both CA125 and CA125 II dates

\*\*\* Contact Westat and Fax this Report to User Support \*\*\*

PID	Sample ID	Draw Date	CA125			CA125II			Sample ID (Our Vials)	PID (from BCF/BFF)	Ship Date
			Date	Result	Prob	Date	Result	Prob			
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 028	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 030	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 029	202664-6	06/07/00	
202664-6	IZ 1698 000	11/09/99	10/10/00	12		10/10/00	55	IZ 1698 031	202664-6	06/07/00	
202664-6		12/29/99	10/10/00	12		10/10/00	55	IG 3552 00C			
202664-6		11/09/99	10/10/00	12		10/10/00	55	IG 3552 00D			
304265-3	IG 3552 000	07/19/00	10/10/00	4		10/10/00	55	IG 3552 002	304265-3	04/08/96	

## **Appendix B-10-4: UCLA Pre-transmittal Log**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***UCLA Pre-transmittal Log***

**This report shows all blood samples collected, receipted, and stored at the SC, for the previous month before the shipment of samples to UCLA. The report includes the participant ID, draw date, and the Sample ID number. In contrast to the "official" transmittal, this one lists any problems that the blood sample may have. This should be used to resolve any problems prior to shipment. A copy of this report should not be sent to UCLA.**

---

\*\*\*\*\* PRETRANSMITTAL \*\*\*\*\* DO NOT DISTRIBUTE \*\*\*\*\*

7/17/98  
6:40 pm

PLCO CANCER SCREENING TRIAL  
UCLA Transmittal Log

Page 3  
SMS 4.2

Screening Center: Westat / Id#: 08

Shipment Date: 7/17/98

Sample Type: PSA

Box Number: UP1000

PARTICIPANT ID	DRAW DATE	PROBLEM #1	PROBLEM #2	PROBLEM #3	SAMPLE ID
802587-6	5/28/98				IZ 1236 001
802591-5	5/29/98				IZ 1237 001
802595-9	6/01/98				IZ 1238 001
802600-8	5/23/98				IZ 1239 001
802603-6	5/26/98				IZ 1240 001
802604-2	5/30/98				IZ 1242 001
802746-8	6/02/98				IZ 1400 001
802942-2	5/08/98				IZ 1450 001
803140-1	6/19/98				IZ 1639 001

## Appendix B-10-5: Biorepository Pre-transmittal Log

### PLCO Reports - Forms and Specimens Tracking

---

#### ***Biorepository Pre-transmittal Log***

This report shows all blood samples collected, receipted, and stored at the SC, for the previous month before the shipment of samples to the Biorepository. The report includes the participant ID, draw date, and the Sample ID number. In contrast to the "official" transmittal, this one lists any problems that the blood sample may have. This should be used to resolve any problems prior to shipment. A copy of this report should not be sent to the Biorepository.

---

7/17/98  
5:23 pm

\*\*\*\*\* PRETRANSMITTAL \*\*\*\*\* DO NOT DISTRIBUTE \*\*\*\*\*  
PLCO CANCER SCREENING TRIAL  
Biorepository Transmittal Log  
Study ID : PLC

Page 2  
SMS 4.2

ERROR : B1111 box contains mixed vials, T0 and T3

Screening Center : Westat / Id#: 08

Shipment Date : 7/17/98

Box Number : B1111

Study Year : T0                      Total # of Vials : 9                      Total # of PIDs : 1

PARTICIPANT ID	DRAW DATE	MM1	MM2	MM3	SAMPLE ID
-----	-----	---	---	---	-----
810238-1	11/11/95				IY 0020 003 IY 0020 004 IY 0020 005 IY 0020 006 IY 0020 007 IY 0020 008 IY 0020 009 IY 0020 010 IY 0020 011

## **Appendix B-10-6: ESC Directive**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***ESC Directive***

**This report lists all participants who are due to complete the Etiologic Studies Consent Form (ESC). Entries are sorted by PID and list PID, study year, and randomization date. They are also separated by study group and within study group by gender.**

---

Screening Center: University of Pittsburgh / ID# 01

Participants Due for NEW Requests  
Studyyear >= T6

RANDOMIZATION GROUP: I

Gender: F

PID	Study Year	Form Type	Rand Date
800408-2	T9	ESC	3/23/94
800411-5	T9	ESC	3/23/94
800413-7	T9	ESC	3/23/94
800416-5	T9	ESC	3/23/94
800430-9	T9	ESC	3/24/94
800468-2	T9	ESC	3/29/94
800486-0	T9	ESC	4/05/94
800522-0	T9	ESC	4/13/94
800535-3	T9	ESC	4/15/94
800543-6	T9	ESC	4/22/94
800553-1	T9	ESC	4/22/94
800555-3	T9	ESC	4/25/94
800605-2	T9	ESC	5/05/94
800610-7	T9	ESC	5/05/94
800628-0	T9	ESC	5/12/94
800647-4	T9	ESC	5/17/94
800667-4	T9	ESC	5/19/94
800772-3	T9	ESC	6/15/94
800852-7	T9	ESC	7/14/94
800906-0	T9	ESC	8/02/94
802304-0	T8	ESC	3/15/95
802390-1	T8	ESC	3/24/95
802460-0	T8	ESC	3/30/95
802749-6	T8	ESC	5/02/95
803037-4	T8	ESC	6/13/95
803137-8	T8	ESC	6/30/95
803145-1	T8	ESC	6/30/95
803375-4	T8	ESC	7/27/95
805072-0	T7	ESC	3/19/96
805757-8	T7	ESC	6/20/96
805863-3	T7	ESC	7/02/96
805940-9	T7	ESC	7/09/96
808321-0	T6	ESC	6/24/97
808457-5	T6	ESC	7/08/97
800404-8	T9	ESC	3/22/94
800420-4	T9	ESC	3/23/94
800423-2	T9	ESC	3/23/94
800424-8	T9	ESC	3/23/94
800427-6	T9	ESC	3/24/94
800433-7	T9	ESC	3/24/94
800434-3	T9	ESC	3/24/94
800469-8	T9	ESC	3/29/94

## **Appendix B-10-7: Biorepository Blood Collection**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Biorepository Blood Collection***

**on or after 5/4/98 for Participants Who Have Not Signed an Etiologic Studies Consent Form (ESC) (Biorepository Activity without ESC Report)**

**This report identifies those participants who had Biorepository blood drawn after the start date of the BCF3 (May 4, 1998) without a receipted ESC. (Note: A protocol violation report should be submitted for each of these participants.)**

---

PLCO CANCER SCREENING TRIAL  
 Biorepository Blood Collection  
 from 1/01/2001 to 6/01/2001  
 for Participants Who Have Not Signed an  
 Etiologic Consent Form (ESC)

5/09/03  
 2:39 pm

Page 1  
 SMS: 8.1

Pid	StudyYear	Visit	Sample ID	Draw Date	Ship Date
803739-4	T5	1	UZ 1771 038	3/23/01	4/04/01
			UZ 1771 039	3/23/01	4/04/01
			UZ 1771 040	3/23/01	4/04/01
			UZ 1771 041	3/23/01	4/04/01
			UZ 1771 042	3/23/01	4/04/01
			UZ 1771 043	3/23/01	4/04/01
			UZ 1771 044	3/23/01	4/04/01
			UZ 1771 045	3/23/01	4/04/01
			UZ 1771 046	3/23/01	4/04/01
804556-1	T5	1	UV 9818 038	2/21/01	3/07/01
			UV 9818 039	2/21/01	3/07/01
			UV 9818 040	2/21/01	3/07/01
			UV 9818 041	2/21/01	3/07/01
			UV 9818 042	2/21/01	3/07/01
			UV 9818 043	2/21/01	3/07/01
			UV 9818 044	2/21/01	3/07/01
			UV 9818 045	2/21/01	3/07/01
			UV 9818 046	2/21/01	3/07/01
812741-0	T2	1	UV 4438 003	2/01/01	2/07/01
			UV 4438 004	2/01/01	2/07/01
801516-2	T5	1	UV 7195 012	1/17/01	1/17/01
			UV 7195 013	1/17/01	1/17/01
			UV 7195 014	1/17/01	2/07/01
			UV 7195 015	1/17/01	2/07/01
			UV 7195 016	1/17/01	2/07/01
			UV 7195 017	1/17/01	2/07/01
			UV 7195 018	1/17/01	2/07/01
			UV 7195 019	1/17/01	2/07/01
			UV 7195 020	1/17/01	2/07/01
			UV 7195 021	1/17/01	2/07/01
			UV 7195 023	1/17/01	2/07/01

## **Appendix B-10-8: T3 Tubes 12/13 Shipped Late Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***T3 Tubes 12/13 Shipped Late Report***

**This report identifies those participants whose T3 tubes (#012 and #013) were sent to the Processing Lab more than one day after the draw date. (Note: A protocol violation report should be submitted for each of these participants.)**

---

PLCO CANCER SCREENING TRIAL  
T3/Vanguard Blood Tubes 012/013 Shipped Late

5/08/03  
2:38 pm

Page 1  
SMS: 8.1

PID	Study Year	Visit	Sample ID	Vial	Draw Date	Ship Date
801555-6	T5	1	UV 6843 000	012	6/16/00	6/20/00
802485-0	T5	1	UV 6881 000	012	7/18/00	7/20/00

## **Appendix B-11-1: Screening Examination Report - Chest X-Ray**

**PLCO Reports - Forms and Specimens Tracking**

---

### ***Screening Examination Report - Chest X-Ray***

**This is a "decoded" or English version of the Chest X-Ray Screening Examination Form. It may be generated by individual PID, form type, disposition and exam date.**

---

PLCO Cancer Screening Trial  
Screening Examination Report

Exam Type: Chest X-Ray Examination  
Screening Center: Westat  
Participant Name: Zmt. Gwendolyn Jeanette Cianflone Jr  
Date of Examination: 07/21/97  
Study Year: T1  
Visit: 1

Chest X-Ray Examination Findings:

A.1. Number of Attempts: One  
A.2. Adequate Films Obtained: Yes  
A.3. Reason for Inadequate Films:  
A.4. Comments: None  
B.1. Radiographic Abnormality Noted: Yes  
B.2. Information for Each Abnormality:

#	Location of Right Hemithorax	Location of Left Hemithorax	Description of Abnormality
1	Upper 1/3	Upper 1/3	Pleural fibrosis/pleural plaque
2			
3			
4			
5			

Chest X-Ray Examination Results:

C.1. Examination Results: Negative screen - other abnormalities  
C.2. Reason Protocol not Met: Not Applicable  
C.3. Level of Referral: Slight variation from normal, no referral.  
C.4. Comments: None  
C.5. Interpreted by: Sam Petrarca

## **Appendix B-12-1: Screening Examination Report - Digital Rectal Examination**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Screening Examination Report - Digital Rectal Examination***

This is a "decoded" or English version of the Digital Rectal Screening Examination of the Prostate Form. It may be generated by individual PID, form type, disposition and exam date.

---

PLCO Cancer Screening Trial  
Screening Examination Report

Exam Type: Digital Rectal Examination of the Prostate  
Screening Center: Westat  
Participant Name: Judge Orlando Sanford Fix Ph.D  
Date of Examination: 07/21/97  
Study Year: T3  
Visit: 1

Prostate Examination Findings:

A.1. Participant Position: Bent at waist over end of examination table  
A.2. Prostate Palpable?: Yes  
A.3. Approximate Size of Gland: Transverse: 06.0 cm. Sagittal: 06.0 cm.  
A.4. Prostate Symmetry: Symmetrical  
A.5. Consistency of Gland: Induration/nodular  
A.6. Number of Areas of Induration: 1  
A.7. Information on Three Largest Areas of Induration:

---

	Area of Induration #1	Area of Induration #2	Area of Induration #3
Location:	Left apex		
	Left lateral lobe		
Approx. Size:	1.5 cm to 2.0 cm		
Type:	Focal (non-nodular)		
Grade:	Firm		
Extent:	Confined to Prostate		

---

A.8. Additional Findings: Enlargement

Prostate Examination Results:

B.1. Examination Results: Positive screen, referral required  
B.2. Reason Protocol not Met: Not Applicable  
B.3. Level of Referral: Significant abnormality, referral  
B.5. Comments: None

# Appendix B-13-1: Screening Examination Report - Flexible Sigmoidoscopy

## PLCO Reports - Forms and Specimens Tracking

---

### ***Screening Examination Report - Flexible Sigmoidoscopy***

This is a "decoded" or English version of the Flexible Sigmoidoscopy Screening Examination Form. It may be generated by individual PID, form type, disposition and exam date.

---

PLCO Cancer Screening Trial  
Screening Examination Report

Exam Type: Flexible Sigmoidoscopy Examination  
Screening Center: Westat  
Participant Name: Sr. Letitia Leonora Stringert R.M.  
Date of Examination: 07/21/97  
Study Year: T0  
Visit: 1

Flexible Sigmoidoscopy Examination Findings:

A.1. Rectal Examination Findings: None  
B.1. Number of Attempts: One  
B.2. Reason for Repeat Exam:  
B.3. Depth of Sigmoidoscope Insertion: 65 cm.  
B.4. Number of Lesions Seen: Two  
B.5. Information for Largest Four Lesions:

	Lesion 1	Lesion 2	Lesion 3	Lesion 4
Type:	Polyp	Polyp		
Location:	Rectum			
Size:	1.5 cm.	0.2 cm.		
Shape:	Sessile	Sessile		
Biopsy:	No	No		
Video/Photo Documentation:	No	No		

B.6. Other Irregular Findings: None

Flexible Sigmoidoscopy Examination Results:

C.1. Examination Result: Positive screen, referral required  
C.2. Reason Protocol not Met: Not Applicable  
C.3. Level of Referral: Significant abnormality, referral  
C.5. Comments: Yes, on file

## **Appendix B-14-1: Screening Examination Report - Ovarian Palpation**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Screening Examination Report - Ovarian Palpation***

**(Due to the discontinuation of the Ovarian Palpation Exam, this report is no longer available.)**

**This is a "decoded" or English version of the Ovarian Palpation Screening Examination Form. It may be generated by individual PID, form type, disposition and exam date.**

---

# **Appendix B-15-1: Screening Examination Report - Transvaginal Ultrasound**

**PLCO Reports - Forms and Specimens Tracking**

---

## ***Screening Examination Report - Transvaginal Ultrasound***

**This is a "decoded" or English version of the Transvaginal Ultrasound Screening Examination Form. It may be generated by individual PID, form type, disposition and exam date.**

---

PLCO Cancer Screening Trial  
Screening Examination Report

Exam Type: Transvaginal Ultrasound Screening Examination  
 Screening Center: Westat  
 Participant Name: Rev Marianne Kay Sagone CSJ  
 Date of Examination: 07/21/97  
 Study Year: T1  
 Visit: 1

Transvaginal Ultrasound Examination Findings:

A.1. Sonographically Detectable Ovary: Right: Yes Left: Yes  
 A.2. Ovary Size:  
 . Longitudinal Diameter: Right: 01.6 cm. Left: 01.5 cm.  
 . Transverse Diameter: Right: 01.2 cm. Left: 01.4 cm.  
 . Anteroposterior Diameter: Right: 01.1 cm. Left: 01.3 cm.  
 . Volume (Width x Height x Thickness x 0.523): Right: 0001.1 cc. Left: 0001.4 cc.  
 A.3. Morphologic Abnormalities in Adnexal Area: Right: None Left: None  
 A.4. Three Largest Discrete Cysts or Abnormalities:

	Right Adnexal Area			Left Adnexal Area		
	#1	#2	#3	#1	#2	#3
Maximum Diameter						
Volume (**)						
Solid Area						
Septal Structure						
Cyst Outline						
Cyst Wall Thickness						
Echogenicity						

\*\* Volume = (Max. Diam.)<sup>3</sup> \* 0.523

A.5. Other Abnormalities: Notes are on file

Transvaginal Ultrasound Examination Results:

B.1. Examination Result: Negative screen, other abnormalities  
 B.2. Reason Protocol not Met: Not Applicable  
 B.3. Level of Referral: Slight variation from normal, no referral  
 B.4. Photo Documentation: Yes  
 B.6. Comments: None

## **Appendix B-16-1: Pathology Slide Transmittal Log**

**PLCO Reports - Forms and Specimens Tracking**

---

### ***Pathology Slide Transmittal Log***

**This report shows all pathology slides that have been receipted and have not been shipped to the NCI slide repository.**

---

**THIS REPORT HAS NOT BEEN DEVELOPED**

## **Appendix B-17-1: Staff Report**

### **PLCO Reports - System Administration**

---

#### ***Staff Report***

**This report lists the SC staff members and their assigned ID number, satellite center (if applicable), and position. It can be sorted by staff ID, satellite center, name, or position. This report identifies former staff members by placing an X in the "not current" column. In addition, the report can be printed showing only current staff members.**

---

12/14/2004  
2:35 pm

## PLCO CANCER SCREENING TRIAL

### Staff Report University of Pittsburgh Sorted By Staff ID

Page 1  
SMS 10.0.0

All Staff Members (\* = Not Current)

<u>Staff ID</u>	<u>Satellite Center</u>	<u>Staff Name</u>	<u>Username</u>	<u>Staff Position</u>
0	00	westat	WESTAT	
0000	00	Westat	WESTAT2	
0001*	00	J'ane Yo'da T'est Seko'u, ju'n	CADAMO_J	XR'Y E
0002	00	Rachel Cunningham	CUNNIN_R	XRY E
0003	00	Melissa Fitzgerald	FITZGE_M	XRY E
0004	00	Janice Freidel	FREIDE_J	XRY E
0005	00	Janice Gatial	GATIAL_J	XRY E
0006	00	Lisa Halapin	HALAPI_L	XRY E
0007	00	Michelle King	KING_M	XRY E
0008	00	Shirley Lindeman	LINDEM_S	XRY E
0009	00	Jane Longmore	LONGMO_J	XRY E
0010	00	Linda McHugh	MCHUGH_L	XRY E
0011	00	Mary Ann McQuillan	MCQUIL_M	XRY E
0012	00	Adrienne Moeslein	MOESLE_A	XRY E
0013	00	Lisa Mrazek	MRAZEK_L	XRY E
0014	00	Marci Thomas	THOMAS_M	XRY E
0015	00	Cathy Whitehead	WHITEH_C	XRY E
0016	00	Bonnie Williams	WILLIA_B	XRY E
0017	00	Kara Mooney	MOONEY_K	XRY E
0018	00	Susan Restano	RESTAN_S	XRY E
0019	00	Dean Duffner	DUFFNE_D	XRY E
0020	00	Janeen Miller	MILLER_J	XRY E
0021	00	Jennifer Yohe	YOHE_J	XRY E
0022	00	Kami Gavran	GAVRAN_K	XRY E
0023	00	Callie Redmond	REDMON_C	XRY E
0024	00	Lisa Sova	SOVA_L	XRY E
0025	00	Judy Page	PAGE_J	XRY E
0026	00	Lorrie Bemnowski	BEMBNO_L	XRY E
0027	00	Stephanie Simmons	SIMMON_S	XRY E
0028	00	Gia Edwards	EDWARD_G	XRY E
0029	00	Nicole Allegre	ALLEGR_N	XRY E
0030	00	Michaela Fink	FINK_M	XRY E
1000	00	Joel Weissfeld	WEISSF_J	FSG E, DRE E
1001	00	Betsy Gahagan	GAHAGA_B	BLD T, BLD Phl
1002	00	Carol Lucas	LUCAS_C	BLD Phl
1003	00	Mary Alyce Riley, RN	RILEY_M	BLD Phl,BLD Pro
1004	00	Lisa Roth, R.N.	ROTH_L	BLD Phl,BLD Pro

## **Appendix B-17-2: Count/List of MDFs**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Count/List of MDFs***

**This report includes three separate listings: (1) count of receipted Missing Data Forms by form type, (2) list of Missing Data Forms for PIDs specified by the user, and (3) Missing Data Forms for specific forms.**

---

Study/year=T0	Pid	Rand Group	Rcptdate	CompDate	Reason	Ospspecify	Date LastUpd
	800087-0	I	7/17/95	7/12/95	1		7/17/95
	800095-3	I	5/09/95	5/09/95	1		5/09/95
	800125-2	I	5/25/94	5/25/94	4		
	800169-6	I	5/25/94	5/25/94	2		
	800242-8	I	5/25/94	5/25/94	1		
	800291-7	I	5/25/94	5/25/94	1		
	800293-9	I	5/25/94	5/25/94	1		
	800297-3	I	5/25/94	5/25/94	1		
	800354-9	I	5/25/94	5/25/94	1		
	800355-5	I	5/25/94	5/25/94	1		
	800390-5	I	5/25/94	5/25/94	1		
	800400-4	I	5/25/94	5/25/94	1		
	800404-8	I	5/25/94	5/25/94	2		
	800408-2	I	5/25/94	5/25/94	1		
	800423-2	I	6/07/94	6/02/94	1		
	800434-3	I	5/25/94	5/25/94	1		
	800455-9	I	5/25/94	5/25/94	1		
	800479-3	I	7/14/94	7/13/94	1		
	800484-8	I	5/31/94	5/31/94	1		
	800497-1	I	5/25/94	5/25/94	1		
	800515-3	I	6/07/94	6/02/94	1		
	800518-1	I	7/14/94	7/13/94	1		
	800544-2	I	7/22/94	7/22/94	1		
	800507-4	I	7/22/94	7/22/94	1		
	800636-3	I	9/28/94	9/28/94	1		9/28/94
	800647-4	I	9/28/94	9/28/94	3		9/28/94
	800707-8	I	9/28/94	9/28/94	1		9/28/94
	800794-5	I	9/28/94	9/28/94	1		6/23/97
	800818-3	I	9/28/94	9/28/94	1		9/28/94
	800819-9	I	11/22/94	11/22/94	1		11/22/94

Pid	Study Year	F-type	Rand Group	Rcptdate	CompDate	Reason	Ospecify	Date LastUpd
202664-6	T3	FSG	I	11/10/98	11/10/98	3		4/29/03
202664-6	T4	DHQ	I	10/24/00	10/23/00	5		10/24/00
304265-3	T0	DQX	I	2/21/96	2/21/96	8	not needed	2/21/96
304265-3	T1	BCF	I	12/31/96	12/27/96	2		3/12/01
304265-3	T1	OVR	I	12/31/96	12/27/96	2		3/12/01
304265-3	T1	TVU	I	12/31/96	12/27/96	2		3/12/01
304265-3	T1	XRY	I	12/31/96	12/27/96	2		3/12/01
304265-3	T2	BCF	I	2/02/98	1/30/98	2		2/02/98
304265-3	T2	OVR	I	2/02/98	1/30/98	2		2/02/98
304265-3	T2	TVU	I	2/02/98	1/30/98	2		2/02/98
304265-3	T2	XRY	I	2/02/98	1/30/98	2		2/02/98
304265-3	T3	BCF	I	2/11/99	2/10/99	2		2/11/99
304265-3	T3	DHQ	I	2/02/99	2/02/99	8	not needed	2/02/99
304265-3	T3	TVU	I	2/11/99	2/10/99	2		2/11/99
304265-3	T4	AGU	I	1/29/00	1/27/00	1		3/12/01
304265-3	T4	BFF	I	1/29/00	1/27/00	2		1/29/00
304265-3	T4	FLP	I	3/02/00	3/02/00	1		3/12/01
305420-4	T0	DQX	I	7/17/96	7/17/96	8	not needed	7/17/96
305420-4	T1	BCP	I	9/15/97	9/15/97	2		9/16/97
305420-4	T1	OVR	I	9/15/97	9/15/97	2		9/16/97
305420-4	T1	TVU	I	9/15/97	9/15/97	2		9/16/97
305420-4	T1	XRY	I	9/15/97	9/15/97	2		9/16/97
305420-4	T2	BCF	I	8/28/98	8/27/98	2		8/28/98
305420-4	T2	OVR	I	8/28/98	8/27/98	2		8/28/98
305420-4	T2	TVU	I	8/28/98	8/27/98	2		8/28/98
305420-4	T2	XRY	I	8/28/98	8/27/98	2		8/28/98
407632-6	T0	DQX	I	11/17/97	11/17/97	6		11/17/97
407632-6	T2	ASU	I	6/15/99	6/15/99	6		2/15/01
407632-6	T2	BCF	I	10/08/98	9/28/98	1		10/08/98
407632-6	T2	FLP	I	6/15/99	6/15/99	6		2/15/01
407632-6	T2	OVR	I	10/08/98	9/28/98	1		10/08/98

Ftype	CountMDFs
ASU	490
BCF	2549
BFF	780
BLF	2
BQN	4
BUC	181
EEC	102
EBL	30
EEO	32
EEP	157
EHQ	2503
EQX	875
ERE	1363
ESC	68
FLF	442
FSG	1840
HSM	7
HSW	8
CCF	63
CVR	1155
ECC	12
TIL	1
TIP	1
TVU	1819
XRY	2721

## **Appendix B-17-3: Non-Participation Status Summary**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Non-Participation Status Summary***

**This report shows the distribution of non-participants (i.e., participants for whom a Non Response Form has been receipted) by status category within randomization group, age, and gender groups. The report is intended to assist SC's in rapidly identifying and addressing retention issues as they arise.**

---

PLCO CANCER SCREENING TRIAL  
 Non-Participation Status Summary

SC Name: University of Pittsburgh

Page 1  
 SMS 8.1  
 Report Date: 5/13/03  
 Time: 3:28 pm

Distribution by Randomization Group:

Status Category	Control	Intervention	Total
Medical Condition		1	1
Refused further participation	5	5	10
Lost Contact		1	1
Total non-participation	5	7	12
Confirmed Deceased Only	207	203	410
Total Enrolled to Date	8464	8471	16935

Distribution by Age Group:

Status Category	55-59	60-64	65-69	70-74	Total
Medical Condition				1	1
Refused further participation	2	3	4	1	10
Lost Contact		1			1
Total non-participation	2	4	4	2	12
Confirmed Deceased Only	42	99	145	124	410
Total Enrolled to Date	5930	4993	3846	2166	16935

Distribution by Gender:

Status Category	Female	Male	Total
Medical Condition	1		1
Refused further participation	4	6	10
Lost Contact		1	1
Total non-participation	5	7	12
Confirmed Deceased Only	108	302	410
Total Enrolled to Date	8657	8278	16935

## **Appendix B-17-4: Population Profile Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Population Profile Report***

**This report shows the distribution of participants by age, gender, race, and educational level within each randomization group. This report may be used by the SCs in reports to NCI and for comparison to contract commitments. The report may also highlight workload issues. For example, lower average education levels may increase data retrieval. The user may select a range of randomization dates.**

---

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Participants by Age:

Randomization Age	Control	Intervention	Total
Age 55-59	1697	1697	3394
Age 60-64	886	887	1773
Age 65-69	684	688	1372
Age 70-74	403	401	804
Total	3670	3673	7343

Distribution of Participants by Gender:

Gender	Control	Intervention	Total
Female	2169	2173	4342
Male	1501	1500	3001
Total	3670	3673	7343

Distribution of Female Participants by Age:

Randomization Age	Control	Intervention	Total
Age 55-59	956	958	1914
Age 60-64	527	528	1055
Age 65-69	422	425	847
Age 70-74	264	262	526
Total	2169	2173	4342

PLCO CANCER SCREENING TRIAL  
Population Profile Report

12/14/2004  
11:21 am

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Male Participants by Age:

Randomization Age	Control	Intervention	Total
Age 55-59	741	739	1480
Age 60-64	359	359	718
Age 65-69	262	263	525
Age 70-74	139	139	278
Total	1501	1500	3001

Distribution of All Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	26	3	6	107	1	100	91	3160		1001	3394
Age 60-64	7	2		39		34	56	1669		67	1773
Age 65-69	1		1	23		19	38	1308		1	1372
Age 70-74		2		22		15	15	765			804
Total	34	7	7	191	1	168	200	6902		1	7343

Distribution of Female Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	14	3	5	65	1	52	84	1742		133	1914
Age 60-64	1			24		19	53	977		133	1055
Age 65-69			1	15		10	34	797		133	847
Age 70-74		1		17		10	15	493			526
Total	15	4	6	121	1	100	186	4009		400	4342

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Male Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	12		1	42			7	1418			1480
Age 60-64	6	2		15			3	692			718
Age 65-69	1			8			4	511		1	525
Age 70-74		1		5				272			278
Total	19	3	1	70			14	2893		1	3001

Distribution of Female/Control Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	5	2	2	40	1		41	865			956
Age 60-64	1			10			23	493			527
Age 65-69				10			16	396			422
Age 70-74				8			8	248			264
Total	6	2	2	68	1		88	2002			2169

Distribution of Male/Control Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	4			25			2	710			741
Age 60-64	3	1		8			1	346			359
Age 65-69				7			1	253		1	262
Age 70-74								139			139
Total	7	1		40			4	1448		1	1501

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Female/Intervention Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	9	1	3	25			43	877			958
Age 60-64				14			30	484			528
Age 65-69			1	5			18	401			425
Age 70-74		1		9			7	245			262
Total	9	2	4	53			98	2007			2173

Distribution of Male/Intervention Participants by Age/Race:

Randomization Age	AA	AI	BH	BN	BU	PI	WH	WN	WU	Missing	Total
Age 55-59	8		1	17			5	708			739
Age 60-64	3	1		7			2	346			359
Age 65-69	1			1			3	258		1	263
Age 70-74		1		5			0	133			139
Total	12	2	1	30			10	1445			1500

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Participants by Race:

Race	Control	Intervention	Total
White, Not Hispanic	3450	3452	6902
White, Hispanic	92	108	200
Black, Not Hispanic	108	83	191
Black, Hispanic	2	5	7
Black, Hispanic Origin Not Specified	1		1
Asian	13	21	34
American Indian Or Alaskan	3	4	7
Missing	1		1
Total	3670	3673	7343

Distribution of Female Participants by Race:

Race	Control	Intervention	Total
White, Not Hispanic	2002	2007	4009
White, Hispanic	88	98	186
Black, Not Hispanic	68	53	121
Black, Hispanic	2	4	6
Black, Hispanic Origin Not Specified	1		1
Asian	6	9	15
American Indian Or Alaskan	2	2	4
Total	2169	2173	4342

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Male Participants by Race:

Race	Control	Intervention	Total
White, Not Hispanic	1448	1445	2893
White, Hispanic	4	10	14
Black, Not Hispanic	40	30	70
Black, Hispanic	7	1	8
Asian	1	12	13
American Indian Or Alaskan	1	2	3
Missing	1		1
Total	1501	1500	3001

Distribution of Participants by Race/Age:

Race	55 - 59	60 - 64	65 - 69	70 - 74	Total
White, Not Hispanic	3160	1669	1308	765	6902
White, Hispanic	91	56	38	15	200
Black, Not Hispanic	107	39	23	22	191
Black, Hispanic	6		1		7
Black, Hispanic Origin Not Specified	1				1
Asian	26	7	1		34
American Indian Or Alaskan	3	2		2	7
Missing					1
Total	3394	1773	1372	804	7343

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Control Participants by Race/Age:

Race	55 - 59	60 - 64	65 - 69	70 - 74	Total
White, Not Hispanic	1575	839	649	387	3450
White, Hispanic	43	24	17	8	92
Black, Not Hispanic	65	18	17	8	108
Black, Hispanic	2				2
Black, Hispanic Origin Not Specified	1				1
Asian	9	4			13
American Indian Or Alaskan	2	1			3
Missing			1		1
Total	1697	886	684	403	3670

Distribution of Intervention Participants by Race/Age:

Race	55 - 59	60 - 64	65 - 69	70 - 74	Total
White, Not Hispanic	1585	830	659	378	3452
White, Hispanic	48	32	21	7	108
Black, Not Hispanic	42	21	6	14	83
Black, Hispanic	4		1		5
Asian	17	3	1		21
American Indian Or Alaskan	1	1		2	4
Total	1697	887	688	401	3673

For Participants Randomized from 01/01/1998 to 01/01/2003

Distribution of Participants by Education Level:

Education Level	Control	Intervention	Total
Less than 8 years	12	19	31
8 through 11 years	201	172	373
12 years or completed high school	1093	1084	2177
Post high school training other than c	547	559	1106
Some college	736	683	1419
College graduate	497	536	1033
Postgraduate	580	618	1198
Missing	4	2	6
Total	3670	3673	7343

Baseline Questionnaires not received:

Gender	Control	Intervention	Total
Female	1	1	2
Male	1	1	2
Total	2	2	4

## **Appendix B-17-5: Participant Information Sheet**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Participant Information Sheet***

**This report provides a summary of all locator information for a participant. It may be used for regular operational activities such as scheduling, return calls, etc.**

---

\*\* This report contains data protected by the Privacy Act of 1975. \*\*  
\*\* Distribute only to authorized staff and dispose of report in a proper manner. \*\*

PLCO CANCER SCREENING TRIAL  
Participant Information Sheet

Participant ID: 800001-4

Report Date: 5/20/03

Full Name: Damon Gerla Edus  
Maiden Name:  
SSN: 683-76-5763  
Mother's Maiden Name: Ribald

Other Names:  
Place of Birth: Utica NY  
Mother's POB: Las Vegas NV

Date of Birth: 11/18/31      Gender: F      Randomization Date: 11/08/93      Group: C  
Modified Date of Birth:      Date of Death:

CURRENT HOME ADDRESS:  
26132 Montpelier St  
Wheatland PA 16161  
Hphone: (724)428-5412      Wphone: (724)996-9503

VACATION HOME/OTHER RESIDENCE:  
26132 Montpelier St  
Canton OH 44701  
Phone: (330)426-6940  
Time of Year: Varied winter

HOUSEHOLD MEMBERS:      Relationship

PHYSICIANS:      Specialty  
  
Rilye Nona Peatta      Primary Doctor  
1433 Mauney Rd  
Dixonville PA 15734  
Phone: (724)264-1123  
Date Last Updated: 3/02/01

CONTACTS:      Relationship  
  
Eliezer Dull Wim      Parent (Sex unspecified)  
27057 Mcnicol Pl  
Robinson PA 15949  
Phone: (724)864-9055  
  
Tiffani Joscelyn Moulton      Friend  
47035 Woodbyne Building  
Fairfax VA 20151  
Phone: (703)689-7293

## **Appendix B-17-6: Intervention Activities Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Intervention Activities Report***

**This report lists the IDs of intervention participants who are entering, continuing in, leaving their reporting window, and those who are in their delinquency period. It can be produced for any week specified by the user and is sorted by study year. This report may be used for scheduling and for managing the SC workload.**

---

PLCO CANCER SCREENING TRIAL  
Intervention Activities Report

Page 9  
SMS 2.04

SC Name: Westat

Report Date: 7/15/96  
Time: 3:37 pm

Week Beginning: 7/15/96

Study Year: T0

Continuing:

Participant ID

-----

802971-1

802972-7

Delinquent:

Participant ID

-----

802939-9

802940-0

802941-6

802949-4

802950-5

802953-3

802959-9

802960-0

802961-6

802962-2

802964-4

802965-0

802967-2

802968-8

Study Year: T2

Entering:

Participant ID

-----

800997-1

Continuing:

Participant ID

-----

800795-1

800799-5

800801-6

800805-0

## **Appendix B-17-7: Control Activities Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Control Activities Report***

**This report lists the IDs of control participants who are entering, continuing in, leaving their reporting window, and those who are in their delinquency period. It can be produced for any week specified by the user and is sorted by study year. This report may be used for scheduling and for managing the SC workload.**

---

PLCO CANCER SCREENING TRIAL  
Control Activities Report

Page 1  
SMS 2.04

SC Name: Westat

Report Date: 7/15/96  
Time: 3:37 pm

Week Beginning: 7/15/96

Study Year: T0

Continuing:

Participant ID

-----

802973-3

802974-9

Delinquent:

Participant ID

-----

802938-3

802942-2

802943-8

802951-1

802952-7

802954-9

802955-5

802956-1

802957-7

802958-3

802963-8

802966-6

802969-4

802970-5

Study Year: T2

Continuing:

Participant ID

-----

800796-7

800797-3

800798-9

800800-0

800802-2

800803-8

800804-4

800806-6

800807-2

## **Appendix B-17-8: Open Forms/Specimens Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Open Forms/Specimens Report***

**This report shows all delinquent or outstanding forms or specimens for each participant. For participants who are past the delinquency period with no MDF receipted, the report indicates that an MDF is outstanding for the form. The report may be generated for specific form types, specific months of randomization, and for one or both randomization groups. The report may be sorted by PID or latest due date.**

---

PLCO CANCER SCREENING TRIAL  
Open Forms/Specimens Report  
Summary Information

Page 1  
SMS 8.1

SC Name: University of Pittsburgh

Report Date: 5/19/03  
Time: 1:45 pm

Expectations as of: 5/19/2003

Months of Randomization selected : JAN,FEB

Study Year : T1

Form Type	Outstanding	Delinquent	MDF	Total
XRY	0	0	31	31

Study Year : T2

Form Type	Outstanding	Delinquent	MDF	Total
XRY	0	0	198	198

Study Year : T3

Form Type	Outstanding	Delinquent	MDF	Total
XRY	0	13	230	243

All Study Years

Form Type	Outstanding	Delinquent	MDF	Total
XRY	0	13	459	472

PLCO CANCER SCREENING TRIAL  
 Open Forms/Specimens Report  
 Sorted by Participant ID

Page 1  
 SMS 8.1

SC Name: University of Pittsburgh

Report Date: 5/19/03  
 Time: 1:51 pm

Expectations as of: 5/19/2003  
 Months of Randomization selected : JAN,FEB

Participant ID	Random. Date	Random. Group	Form	Latest Due Date	Status
T1 :					
815141-5	1/10/00	I	MDF-XRY	4/10/01	Outstanding
815146-5	1/10/00	I	MDF-XRY	4/10/01	Outstanding
815169-3	1/10/00	I	MDF-XRY	4/10/01	Outstanding
815178-2	1/10/00	I	MDF-XRY	4/10/01	Outstanding
815180-9	1/10/00	I	MDF-XRY	4/10/01	Outstanding
815198-2	1/12/00	I	MDF-XRY	4/12/01	Outstanding
815222-5	1/19/00	I	MDF-XRY	4/19/01	Outstanding
815228-1	1/19/00	I	MDF-XRY	4/19/01	Outstanding
815259-2	1/31/00	I	MDF-XRY	4/30/01	Outstanding
815268-1	1/31/00	I	MDF-XRY	4/30/01	Outstanding
815288-1	2/02/00	I	MDF-XRY	5/02/01	Outstanding
815311-8	2/09/00	I	MDF-XRY	5/09/01	Outstanding
815314-6	2/09/00	I	MDF-XRY	5/09/01	Outstanding
815340-7	2/11/00	I	MDF-XRY	5/11/01	Outstanding
815346-3	2/11/00	I	MDF-XRY	5/11/01	Outstanding
815353-0	2/11/00	I	MDF-XRY	5/11/01	Outstanding
815355-2	2/11/00	I	MDF-XRY	5/11/01	Outstanding
815361-3	2/11/00	I	MDF-XRY	5/11/01	Outstanding
815380-7	2/16/00	I	MDF-XRY	5/16/01	Outstanding
815383-5	2/16/00	I	MDF-XRY	5/16/01	Outstanding
815389-1	2/16/00	I	MDF-XRY	5/16/01	Outstanding

PLCO CANCER SCREENING TRIAL  
 Open Forms/Specimens Report  
 Summary Information

Page 1  
 SMS 9.1

SC Name: Westat

Report Date: 7/07/03  
 Time: 4:04 pm

Expectations as of: 7/07/2003  
 Randomization Date Range : 1/01/99 to 1/08/99

Study Year : T2

Form Type	Outstanding	Delinquent	MDF	Total
DEC	1	0	0	1

Study Year : T3

Form Type	Outstanding	Delinquent	MDF	Total
ASU	0	0	1	1
BCF	0	0	4	4
DEC	1	0	0	1
TVU	0	0	3	3

Study Year : T4

Form Type	Outstanding	Delinquent	MDF	Total
ASU	0	0	22	22
BFF	0	0	9	9
HSW	1	0	0	1
PCC	2	0	0	2

All Study Years

Form Type	Outstanding	Delinquent	MDF	Total
ASU	0	0	23	23
BCF	0	0	4	4
BFF	0	0	9	9
DEC	2	0	0	2
HSW	1	0	0	1
PCC	2	0	0	2
TVU	0	0	3	3

PLCO CANCER SCREENING TRIAL  
 Open Forms/Specimens Report  
 Sorted by Participant ID

SC Name: Westat

Report Date: 7/07/03  
 Time: 4:04 pm

Expectations as of: 7/07/2003  
 Randomization Date Range : 1/01/99 to 1/08/99

Participant ID	Random. Date	Random. Group	Form	Latest Due Date	Status
T2 :					
812497-9	1/06/99	C	DEC		Outstanding
T3 :					
812488-0	1/06/99	I	MDF-BCF	4/06/02	Outstanding
812489-6	1/06/99	I	MDF-BCF MDF-TVU	4/06/02 4/06/02	Outstanding Outstanding
812497-9	1/06/99	C	DEC MDF-ASU	4/06/02	Outstanding Outstanding
812499-1	1/06/99	I	MDF-BCF MDF-TVU	4/06/02 4/06/02	Outstanding Outstanding
812508-4	1/06/99	I	MDF-BCF MDF-TVU	4/06/02 4/06/02	Outstanding Outstanding
T4 :					
812488-0	1/06/99	I	MDF-ASU MDF-BFF PCC	4/06/03 4/06/03 4/06/03	Outstanding Outstanding Outstanding
812489-6	1/06/99	I	MDF-ASU MDF-BFF	4/06/03 4/06/03	Outstanding Outstanding
812490-7	1/06/99	I	MDF-ASU MDF-BFF	4/06/03 4/06/03	Outstanding Outstanding
812491-3	1/06/99	C	MDF-ASU	4/06/03	Outstanding
812492-9	1/06/99	C	MDF-ASU	4/06/03	Outstanding
812493-5	1/06/99	C	MDF-ASU	4/06/03	Outstanding
812494-1	1/06/99	C	MDF-ASU	4/06/03	Outstanding
812495-7	1/06/99	I	MDF-ASU MDF-BFF	4/06/03 4/06/03	Outstanding Outstanding

## Appendix B-17-9: Production Edit Report

### PLCO Reports - Forms and Specimens Tracking

---

#### *Production Edit Report*

There are two versions of this report:

**Intra-Forms Edit Report:** This report prints a list of errors and inconsistencies within a data collection form. The user may run the report for a single form, a category of forms (exams, medical, etc.), or all forms.

**Inter-Forms Edit Report:** This report prints a list of errors and inconsistencies among forms of different types. It compares the data for all forms and specimens for a specific PID or Sample ID. The user may run the report for selected PIDs, a range of PIDs, selected Sample IDs, a range of Sample IDs, and 'ALL'.

---

PLCO CANCER SCREENING TRIAL  
Intra-Forms Edit Report

Page 1  
SMS 8.1

SC Name: University of Pittsburgh

Report Date: 6/02/03  
Time: 1:26 pm

PID	Study Year	Visit	Form	Receipt Date	Error Keys for this record
800853-3	T5	2	PCR	9/21/1999	75
800947-6	T0	1	PCR-TVU	8/30/1994	70 92
805741-7	T0	1	XRY	7/02/1996	54
810159-3	T0	2	PCR-FSG	7/13/1998	61
810642-6	T0	2	PCR-FSG	7/07/1998	61
811774-0	T1	2	PCR-XRY	11/22/1999	61
813383-9	T0	2	PCR-FSG	9/03/1999	61
815506-1	T0	2	PCR-FSG	7/18/2000	61
816596-9	T0	2	PCR-FSG	12/06/2000	61
816675-7	T0	1	XRY	11/03/2000	54

PLCO CANCER SCREENING TRIAL  
Inter-Forms Edit Report

Page 1  
SMS 8.1

SC Name: University of Pittsburgh

Report Date: 6/02/03  
Time: 2:06 pm

PID	Study Year	Visit	Form	Error Keys for this record
202664-6			STATUS	14

6/02/03  
2:02 pm

PLCO CANCER SCREENING TRIAL  
Inter-Forms Edit Report for Sample IDs

Page 1  
SMS 8.1

PID	Sample ID	Error Keys for this ID
-----	-----	-----
202664-6	IF 0936 012	50
202664-6	IF 0936 013	50

## **Appendix B-17-10: Participant Overview Report**

### **PLCO Reports - Forms and Specimens Tracking**

---

#### ***Participant Overview Report***

This report gives a summary of the study information for a participant such as PID, Randomization Date, Randomization group, Participant Name, Gender, Date of Birth, and address. Prior adenoma detection, vital status, cancer status, and medical record abstracting information are also presented as well as forms receipted (including ESC completion status) and exam results. This report can be run for selected PIDs or for a block of participants according to their randomization date.

---

\*\* This report contains data protected by the Privacy Act of 1975.  
 \*\* Distribute only to authorized staff. Store and dispose of properly.

PLCO CANCER SCREENING TRIAL  
 Participant Overview

Page 1  
 SMS 8.1  
 Report Date: 4/24/03  
 Time: 5:39 pm

SC Name: University of Pittsburgh

Participant ID: 202664-6  
 Name: Mr. Waldemar Ceadd Lovie  
 Medical Record #:  
 Study Year: T7 as of: 4/24/2003

Randomization Date: 12/08/95  
 Group: Intervention  
 Gender: Male  
 Date of Birth: 6/29/34

Scheduling Notes: ESC receipted.  
 Smoker - Offer T3 XRY.  
 T0 hyperplastic polyps, but may have had colonoscopy since  
 T2 check before scheduling T5 fsg had a cecal polyp

Participation Status:  
 Transfer Status: Added Participant  
 Vital Status:

Status Date:  
 Transfer Date: 3/07/2000  
 Status Date:  
 Date of Death:  
 NDI Submission:

Modified Date of Birth:  
 ASU No Mail Indicator :

Cancer Status:  
 T0 -Colorectal -Not PLCO Cancer-1/03/96 -FSG  
 T0 -Colorectal -Not PLCO Cancer-1/23/96 -FSG  
 T3 -Prostate -Suspected -1/26/99 -BCF

CURRENT HOME ADDRESS:

VACATION/OTHER ADDRESS:

60497 Creekridge Dr  
 Fairplay, MD 21733  
 Hphone: (301)966-8730 Wphone: (301)913-3798

60497 Creekridgs Dr  
 Middletown MD 21769  
 Time of Year:  
 Vphone: (301)748-2508

PRIMARY CARE PHYSICIAN/CLINIC:  
 Tina Dilbert Hrothberta  
 99534 Ruth Ct  
 Hannibal MO 63401  
 Phone: (573)594-2007

SPECIALITY  
 Primary Doctor

Study Year	Form	Visit	Comp Date	Exam Result	Status	Reason
T0	BCF	1	1/03/96	NG4	Received	
T0	BLF		12/15/95		Received	
T0	BQM		12/30/95		Received	
T0	DQX		12/30/95		Received	
T0	DRE	1	1/03/96	AN3	Received	
T0	EVF				Received	
T0	FSG	1	1/03/96	AS1	Received	

\*\* This report contains data protected by the Privacy Act of 1975.



## **Appendix B-17-11: Summary of Scanned Forms Report**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Summary of Scanned Forms Report***

**This report may be used to determine the cumulative number of a specific form that have been scanned and counts by date scanned.**

---

**PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY**  
**SUMMARY OF FORMS SCANNED REPORT**

12/03/2003  
 06:16 pm

BCF2  
 For records LScan date 10/01/1993 thru 12/03/2003

Page: 1  
 DEES: 9.1

<u>PID</u>	<u>SERIAL</u>	<u>STUDYYR</u>	<u>VISIT</u>	<u>SAMPID</u>	<u>VISIT DATE</u>	<u>FDISP</u>	<u>FSCAN</u>	<u>LSCAN</u>
800002-0	045438	T3	1	IX 7561 000		1	11/15/1996	11/19/1996
800005-8	045594	T3	1	IX 7649 000		1	11/22/1996	12/13/1996
800008-6	045495	T3	1	IX 7576 000		1	11/15/1996	11/21/1996
800009-2	047138	T3	1	IX 7972 000		1	12/24/1996	12/30/1996
800014-7	046966	T3	1	IX 8733 000		1	3/11/1997	3/11/1997
800017-5	045595	T3	1	IX 7651 000		1	11/22/1996	12/13/1996
800018-1	046693	T3	1	IX 7361 000		1	10/30/1996	10/31/1996
800020-8	046351	T2	1	IX 4891 000		1	2/16/1996	2/20/1996
800023-6	046880	T3	1	IX 7476 000		1	11/11/1996	11/13/1996
800024-2	046968	T3	1	IX 7937 000		1	12/19/1996	12/19/1996
.....	.....	..	.	.....		.	.....	.....

## **Appendix B-17-12: Report of DEES Final Disposition**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Report of DEES Final Disposition***

**This report lists forms according to their final disposition (FCM, FIC, ICM). This report will enable SC staff to identify forms that are not yet final and have a disposition of Interim Complete (ICM).**

---

**PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY**  
**FINAL DISPOSITION REPORT**

12/03/2003  
05:58 pm

BCF2, BCF3  
For records LScan date 10/01/1993 thru 12/03/2003

Page: 1  
DEES: 9.1

*with Final Disposition = FCM*

<u>PID</u>	<u>FTYPE</u>	<u>SERIAL</u>	<u>STUDYYR</u>	<u>FDISP</u>	<u>VISIT</u>	<u>FSCAN</u>	<u>LSCAN</u>
413532-2	BC3	146981	T3	1	1	05/03/2001	12/12/2001
800002-0	BC2	045438	T3	1	1	11/15/1996	11/19/1996
800005-8	BC2	045594	T3	1	1	11/22/1996	12/13/1996
800008-6	BC2	045495	T3	1	1	11/15/1996	11/21/1996
800009-2	BC2	047138	T3	1	1	12/24/1996	12/30/1996
800014-7	BC2	046966	T3	1	1	03/11/1997	03/11/1997
800017-5	BC2	045595	T3	1	1	11/22/1996	12/13/1996
800018-1	BC2	046693	T3	1	1	10/30/1996	10/31/1996
800020-8	BC2	046351	T2	1	1	02/16/1996	02/20/1996

## **Appendix B-17-13: Production Edits Report - DEES**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Production Edits Report - DEES***

**This report lists errors and inconsistencies for individual forms that are scanned. For a given form type, the report shows PID, serial number, study year, visit number, completion date, first scanned date, last scanned date, and error descriptions.**

---

**PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY**  
**EDITS REPORT - FORMS WITH ERRORS**

11/19/2001  
 03:28 pm

XRY2  
 Lscan between 10/01/1993 and 11/19/2001

Page: 1  
 DEES: 7.3.0

**\*\* NOTE: ALL ITEMS EXCEPT FORM PROCESSING ITEMS ARE CRITICAL \*\***

PID	SERIAL	STUDY YEAR	VISIT	COMPDATE	FSCAN	LSCAN
811774-0	245675	T2	1	11/08/2000	11/16/2000	05/15/2001
BLANK	XR2.FP3.02					Data Retrieval is blank
BLANK	XR2.FP4.02					Data Entry Of Non-Scannable Items is blank
BLANK	XR2.FP5.02					Final Disposition is blank
ILLEGAL	XR2.A.5.06					Technician Identification not found in SMS Staff ID table
XTRAVRB	XR2.A.3.4.11					Other reason has extra verbatim not expected
XTRAVRB	XR2.A.4.1.11					Comments: (Yes, specify/No) has extra verbatim not expected
XTRAVRB	XR2.C.2.3.11					Reasons for Inadequate Exam: Mark All That Apply (Other, specify) has extra verbatim not expected
XTRAVRB	XR2.C.4.1.11					Comments: has extra verbatim not expected

## **Appendix B-17-14: DEES/SMS Comparison Report**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***DEES/SMS Comparison Report***

**This report compares like data items in SMS and DEES for all OPSCAN forms and prints any discrepancies between the two data sets.**

---

PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY

DEES/SMS DATA COMPARISON REPORT  
Items Where SMS and DEES Data Do Not Match

01/29/2002  
04:35 pm

XRY  
LScan between 10/01/1993 and 01/29/2002

Page: 1  
DEES: 7.3.0

PID: 800005-8	StudyYr: T0	Visit: 1	Serial:	Form: XRY	Fdisp: 1
LABEL		DEES QUES.	DEES Value		SMS Value
DATE OF EXAM		1.	01-21-1994		12-12-1993
RADIOLOGIST ID		C.4	3000		1000
EXAM RESULT		C.1	NG		AS

PID: 800014-7	StudyYr: T3	Visit: 1	Serial:	Form: XRY	Fdisp:
LABEL		DEES QUES.	DEES Value		SMS Value
RADIOLOGIST ID		C.4	1000		3102
EXAM RESULT		C.1	NG		AN

---

End of Report

## **Appendix B-17-15: Key Field Edits Report**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Key Field Edits Report***

**This report identifies OPSCAN forms scanned with a key field error (also available at time of scanning.) For a selected form type, the PID, serial number, study year, final disposition, date first scanned, and date last scanned are listed.**

---

PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY  
KEY FIELD EDITS REPORT

12/14/2004  
02:11 pm

DRE2

Page: 1  
DEES: 10.0.0

<u>PID</u>	<u>SERIAL</u>	<u>STUDYYR</u>	<u>VISIT</u>	<u>FDISP</u>	<u>FSCAN</u>	<u>LSCAN</u>
812811-9	153336	T3	*	1	02/21/2002	04/09/2002

---

Total Number of Records: 1

End of Report

## **Appendix B-17-16: SMS/DEES Synchronization Reports**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***SMS/DEES Synchronization Reports***

**This report identifies forms scanned in DEES but not receipted in SMS or receipted in SMS but not yet scanned in DEES.**

---

**PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY****SMS/DEES Synchronization Report  
Forms Scanned in DEES but not Received in SMS**12/03/2003  
06:08 pmBCF  
Lscan between 10/01/1993 and 12/03/2003Page: 1  
DEES: 9.1

<u>PID</u>	<u>STUDYYR</u>	<u>VISIT</u>	<u>SERIAL</u>	<u>FTYPE</u>	<u>FDISP</u>	<u>LSCAN</u>
304265-3	T5	1	064838	B2F	1	02/08/2002
413532-2	T3	1	146981	BC3	1	12/12/2001
413532-2	T4	1	090190	B2F	1	04/08/2002
800853-3	T5	1	025330	BFF	1	11/27/2001
801225-9	T5	1	091853	BC3	1	10/10/2001
801423-5	T5	1	091701	BC3	1	12/19/2001
801668-3	T1	1	31787	BCF	1	03/01/2002
801724-3	T5	1	091692	BC3	1	11/08/2001
801860-3	T5	1	064635	B2F	2	10/24/2001
801888-1	T5	1	091855	BC3	1	10/10/2001
801894-2	T5	1	092168	BC3	1	12/10/2001
802012-1	T5	1	091696	BC3	1	01/10/2002
802028-2	T5	1	091694	BC3	1	11/19/2001
802039-3	T5	1	091691	BC3	1	11/08/2001
802163-6	T5	1	064641	B2F	2	10/24/2001
802473-3	T5	1	092222	BC3	1	10/10/2001
802474-9	T5	1	092221	BC3	1	10/10/2001
802514-3	T5	1	091697	BC3	1	12/10/2001
802558-7	T5	1	092229	BC3	1	02/22/2002
802671-9	T5	1	091706	BC3	1	02/22/2002
802672-5	T5	1	091705	BC3	1	02/22/2002
802734-1	T5	1	091709	BC3	1	03/19/2002
802767-4	T5	1	091690	BC3	1	04/01/2002
802782-4	T5	1	092414	BC3	1	05/07/2002
802799-1	T5	1	092423	BC3	1	12/11/2001
802849-0	T5	1	091695	BC3	1	11/19/2001
802891-7	T5	1	091707	BC3	1	03/05/2002
803108-9	T5	1	091852	BC3	1	10/10/2001
803138-4	T5	1	091693	BC3	1	11/07/2001
803147-3	T5	1	091699	BC3	1	03/26/2002
803304-3	T5	1	050371	B2F	1	10/17/2001
803334-8	T5	1	064275	B2F	2	10/24/2001
803338-2	T5	1	064159	B2F	2	10/24/2001

PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY

SMS/DEES Synchronization Report  
Forms Received in SMS but not Scanned in DEES

12/03/2003  
06:09 pm

BCF

Page: 1  
DEES: 9.1

<u>PID</u>	<u>STUDYYR</u>	<u>VISIT</u>	<u>FTYPE</u>	<u>COMPDATE</u>	<u>RCPTDATE</u>	<u>DATELASTUPD</u>
202664-6	T0	1	BCF	01/03/1996	01/03/1996	01/03/1996
202664-6	T1	1	BCF	02/13/1997	02/18/1997	02/19/1997
202664-6	T2	1	BCF	12/11/1997	12/17/1997	12/17/1997
202664-6	T3	1	BCF	01/26/1999	01/26/1999	01/26/1999
304265-3	T0	1	BCF	04/02/1996	04/04/1996	04/04/1996
305420-4	T0	1	BCF	09/06/1996	09/09/1996	07/26/1999
305420-4	T3	1	BCF	06/24/1999	06/28/1999	06/29/1999
407632-6	T0	1	BCF	12/07/1996	12/13/1996	12/17/1996
407632-6	T1	1	BCF	11/10/1997	11/17/1997	11/17/1997
413532-2	T0	1	BCF	04/04/1998	04/14/1998	04/14/1998
413532-2	T1	1	BCF	11/21/1998	11/25/1998	11/25/1998
413532-2	T2	1	BCF	01/12/2000	01/18/2000	01/18/2000
800853-3	T5	2	BFF	09/17/1999	09/21/1999	03/29/2001
803291-6	T1	1	BCF	06/26/1996	07/03/1996	07/03/1996
809493-4	T2	2	BCF	05/10/2000	05/16/2000	05/16/2000

---

Total Number of Records: 15

End of Report

## **Appendix B-17-17: Forms Count Report**

**PLCO Reports - Data Entry and Editing System**

---

### ***Forms Count Report***

**This report summarizes the number of forms scanned by date and by form type.**

---

**PROSTATE, LUNG, COLORECTAL, AND OVARIAN CANCER STUDY  
FORMS COUNT REPORT**

09/07/2004  
11:43 am

BCF3

Page: 16  
DEES: 10.0.0

<u>FSCAN</u>	<u>Number of Forms</u>
07/15/1998	99
07/14/1998	42
07/10/1998	1
07/07/1998	25
07/06/1998	18
07/02/1998	6
06/30/1998	44
06/29/1998	186
06/12/1998	60
06/10/1998	43
06/09/1998	26
06/05/1998	7
06/02/1998	46
06/01/1998	21
05/29/1998	41
05/27/1998	12
05/22/1998	63
05/21/1998	3
05/20/1998	27
05/19/1998	5
05/15/1998	106
05/06/1998	1
05/05/1998	14

---

**Total Number of Records: 19,404**

End of Report

## **Appendix B-18-1: Buccal Cell Directive/Late Directive**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Buccal Cell Directive/Late Directive***

The Buccal Cell Directive lists the participants who are eligible for a kit mailing. The Buccal Cell Late Directive lists participants whose sample has not been receipted in SMS. The PIDs are listed in addition to the study year, form type, randomization date and ship date.

---

Screening Center: University of Pittsburgh / ID# 08

Participants Due for NEW Requests

RANDOMIZATION GROUP: C

Gender: F

PID	Study Year	Form Type	Rand Date	Remail
800249-0	T9	BUC	2/01/94	
800283-4	T9	BUC	2/08/94	
800582-0	T9	BUC	4/29/94	
801631-6	T8	BUC	12/01/94	
801851-4	T8	BUC	1/06/95	
801878-6	T8	BUC	1/13/95	
802625-8	T8	BUC	4/18/95	
802702-4	T8	BUC	4/27/95	
802794-1	T8	BUC	5/08/95	
802859-5	T8	BUC	5/11/95	
803308-7	T8	BUC	7/21/95	
803722-7	T7	BUC	9/15/95	
803843-7	T7	BUC	10/03/95	
804571-1	T7	BUC	1/23/96	
804841-8	T7	BUC	2/22/96	
804872-9	T7	BUC	2/26/96	
804874-1	T7	BUC	2/26/96	
805071-4	T7	BUC	3/19/96	
805349-9	T7	BUC	4/29/96	
805370-0	T7	BUC	4/30/96	
805623-5	T7	BUC	6/03/96	
806031-7	T7	BUC	7/25/96	
806940-2	T6	BUC	11/20/96	
807002-1	T6	BUC	12/03/96	
807048-7	T6	BUC	12/04/96	
807091-0	T6	BUC	12/09/96	
807362-3	T6	BUC	1/28/97	
807483-3	T6	BUC	2/12/97	
807682-5	T6	BUC	3/24/97	
808206-6	T6	BUC	6/04/97	

-----  
Total Females (Control) : 30  
-----

Gender: M

PID	Study Year	Form Type	Rand Date	Remail
800588-6	T9	BUC	5/03/94	
800604-6	T9	BUC	5/05/94	
800745-6	T9	BUC	6/09/94	

## **Appendix B-18-2: Buccal Cell Summary Report**

### **PLCO Reports - Data Entry and Editing System**

---

#### ***Buccal Cell Summary Report***

**This report gives summary numbers for the buccal cell collection effort. Listed are the number of forms mailed, received, and shipped to Westat. Counts are also given for the number of outstanding kits, those which have been “followed-up” and the number of MDFs receipted.**

---

FLCO Cancer Screening Trial  
 Buccal Cell Summary Report for Control Participants

Report Date: 4/28/03  
 Time: 1:59 pm

SC Name: University of Pittsburgh

Total #  
 Controls  
 -----  
 8464

# Controls Mailed ESC	167	# Controls with ESC Received	3435	% Controls with Buccal Cell Sample Received at Biorepository	40.50	# Controls with ESC Received	19	% Controls with MDP-ESC Received	.22
-----------------------	-----	------------------------------	------	--	-------	------------------------------	----	----------------------------------	-----

# Controls Shipped Kit	1597	% Controls Shipped Kit	18.87	# Controls with Buccal Cell Sample Received at Biorepository	1302	% Controls with Buccal Cell Sample Received at Biorepository	15.38	# Controls with MDP-BUC Received	80	% Controls with MDP-BUC Received	.95	# Controls with Buccal Cell Sample Outstanding	215	% Controls with Buccal Cell Sample Outstanding	2.54
------------------------	------	------------------------	-------	--	------	--	-------	----------------------------------	----	----------------------------------	-----	--	-----	--	------

## **APPENDIX C**

### **Appendix C: Sample Materials**

**C-2-1**

Sample Recruitment Letter

## PROSTATE, LUNG, COLORECTAL AND OVARIAN CANCER SCREENING TRIAL

### Sample Introductory Letter

(Date)

(Participant Name)

(Participant Address)

(City, State, Zip Code)

Dear (Participant Name):

The National Cancer Institute (NCI) and (Screening Center) are sponsoring a nationwide study of older Americans called the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. The cancers being studied are cancers of the prostate, lung, colon, rectum and ovary. The purpose of the study is to determine whether or not screening for the early detection of these cancers helps reduce the number of people who die from them each year.

We would like to ask for your participation in this important study. Enclosed is a brochure that provides further details about the study and a brief questionnaire which will help us determine whether you are eligible to participate. Please complete the questionnaire and return it to us in the enclosed postage-paid envelope. If you are eligible for the study, we will call you with more information.

Let us assure you that your participation is voluntary, and there are no penalties for not participating, or for withdrawing from the study at any time. Participation will not influence your relationship with (Screening Center), its staff, or with any federal program such as Social Security or Medicare. If you do participate, all of the information you provide will be kept confidential and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. No names or other identifying information will appear in any report of the study. The information will be combined for all study participants and reported as statistical summaries. In addition, study records will be kept for the duration of the study, approximately 16 years, and then destroyed.

For your information, this study is authorized by the Public Health Service Act, Section 412 [42 USC 285 a-1], and your rights as a study participant are protected by the Privacy Act of 1974.

If you would like to learn more about the study, please contact me or my colleague, (Name of Screening Center Coordinator) at (telephone number).

We hope you will consider participating in this important study.

Sincerely,

(Name of Investigator)

Principal Investigator

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6701 Rockledge Drive, MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-xxxx). Do not return the completed form to this address



**C-2-2**

Sample Potential Participant Tracking Log



**C-2-3**

Sample Recruitment Summary Form

**Appendix C-2-3**

**PROSTATE, LUNG, COLORECTAL AND OVARIAN CANCER SCREENING TRIAL**

**Sample Recruitment Summary Form**

**Screening Center:** \_\_\_\_\_

**Report Date:** |\_\_|\_|/|\_\_|\_|/|\_\_|\_|

**SC Coordinator:** \_\_\_\_\_

	Reporting Period	Cumulative
Total Potential Participants Identified	_ _ _ _	_ _ _ _
Total Potential Participants Not Contacted	_ _ _ _	_ _ _ _
Total Potential Participants Uninterested	_ _ _ _	_ _ _ _
Total Potential Participants Ineligible	_ _ _ _	_ _ _ _
01 = Age < 55 or > 74	_ _ _ _	_ _ _ _
02 = Current treatment for cancer	_ _ _ _	_ _ _ _
03 = History of PLCO	_ _ _ _	_ _ _ _
04 = Entire colon, one lung or entire prostate removed	_ _ _ _	_ _ _ _
05 = Other study		
06 = Proscar/Propecia/Finasteride treatment	_ _ _ _	_ _ _ _
07 = Unable/unwilling to sign consent	_ _ _ _	_ _ _ _
08 = More than one PSA blood test in past 3 years	_ _ _ _	_ _ _ _
09 = Colonoscopy, sigmoidoscopy, or barium enema in past 3 years	_ _ _ _	_ _ _ _
Total Nonparticipants - Other Reasons	_ _ _ _	_ _ _ _
Specify reasons:		
1. _____	_ _ _ _	_ _ _ _
2. _____	_ _ _ _	_ _ _ _
3. _____	_ _ _ _	_ _ _ _
Total Eligible	_ _ _ _	_ _ _ _
Total Participants Enrolled	_ _ _ _	_ _ _ _
Total Potential Participants with Eligibility Pending	_ _ _ _	_ _ _ _

**C-3-1**

Prototype Main Consent

## PLCO SCREENING TRIAL

### PROTOTYPE (Main) CONSENT FORM

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

**NAME OF CLINICAL CENTER**

#### **DESCRIPTION OF STUDY**

I have been asked to take part in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial sponsored by the National Cancer Institute, LOCAL CLINICAL CENTER, and nine other centers across the country. The purpose of this study is to determine if certain screening tests can reduce deaths from prostate cancer, lung cancer, ovarian cancer, and cancers of the colon and rectum. [Some doctors believe that screening for these cancers will extend lives, others do not believe that it will. A large, carefully controlled scientific study is necessary to resolve this debate.] Nationwide, this study will enroll 148,000 men and women between the ages of 55 and 74.

Four specific questions to be addressed in this study are:

- Does screening with flexible sigmoidoscopy reduce deaths from cancers of the colon and rectum?
- Does screening with chest x-rays reduce deaths from lung cancer?
- In men, does screening with digital rectal examinations plus a blood test for serum prostate-specific-antigen (PSA) reduce deaths from prostate cancer?
- In women, does screening with transvaginal ultrasound of the ovaries, and testing the blood for CA-125, reduce deaths from ovarian cancer?

The PLCO Trial will also look for factors that may cause these cancers.

#### **STUDY PROCEDURES**

By agreeing to participate in the PLCO Trial, I agree to be assigned by a random statistical process to either a screened group or a usual care group. I understand that I have an equal chance of being in either group.

Regardless of which group I am assigned to, I will be asked questions about my personal and family medical history for these cancers and about my overall risk of developing cancer.

If I am assigned to the usual care group, I will follow my normal health care routine. I will be asked to give information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

If I am assigned to the screened group, the following tests will be carried out on an annual basis for up to 6 years:

Males:           <sup>1</sup>   Digital rectal exam (annually for the first four (4) years)

<sup>2</sup> Serum PSA blood test (annually for six (6) years)

<sup>2</sup> Chest x-ray (annually for the first four (4) years in current and former smokers; first three (3) years in people who never smoked)

Females:       <sup>1</sup>   Transvaginal ultrasound (annually for the first four (4) years except for women without ovaries)

(a tampon-sized probe is inserted into the vagina and images of the ovaries are made using sound waves)

<sup>2</sup> CA-125 blood test (annually for six (6) years except for women without ovaries)

<sup>2</sup> Chest x-ray (annually for first four (4) years in current and former smokers; first three (3) years in people who never smoked)

At the first and sixth screening visit, the following test will be performed on both male and female participants:

<sup>2</sup> Flexible sigmoidoscopy

The flexible sigmoidoscopy involves the insertion to about 20-24 inches of a thin flexible lighted instrument to examine the colon and the rectum. Preparation for this test consists of two Fleets enemas one hour before the test.

The blood draw for the PSA or CA-125 test will include the collection of up to 45-ml (3 tablespoons) of blood from my arm. Blood not used for the PSA or CA-125 will be stored for future research purposes.

By agreeing to participate in this study, I agree to have all of the screening tests performed as required by the study. The examinations that are part of this trial are well-established tests that doctors use frequently to diagnose problems in patients with certain symptoms. Their effectiveness in early detection of cancer is being tested in this study. It is unknown if these tests will provide any benefit to me.

For quality control, some participants will be asked to have a screening test repeated to test the accuracy of certain measures.

I further agree to provide specific information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

## **BENEFITS**

I understand that I will receive free cancer screening tests. I further understand that if I develop prostate, colorectal, lung, or ovarian cancer it is possible that the cancer may be detected at an early stage. Early diagnosis may prolong my life, however, this cannot be guaranteed.

[If this study shows that screening for prostate, lung, colorectal, or ovarian cancer decreases the chances of dying from these cancers, then screening for these cancers will become common practice in the future. If this study shows that the screening tests do not decrease the chances of dying of these cancers, doctors will know not to use them, saving me and others unnecessary inconvenience and expense.]

## **RISKS**

I understand that there are certain risks and discomforts that might be associated with the screening procedures.

- There may be some discomfort from the physical exam of the rectum, or the sigmoidoscopic exam.
- Very rarely a perforation of the bowel occurs during sigmoidoscopy (less than once in every 10,000 to 50,000 examinations). If this would occur, medical treatments consisting of antibiotics and, in a very rare instance, surgical correction could occur.
- A small amount of radiation is received as part of the chest x-ray. This amount is smaller than that of a normal chest x-ray and poses no measurable risk.
- There may be discomfort involved from the transvaginal ultrasound. There is a very rare chance of a vaginal tear with the probe.
- When blood is drawn, there may be local bruising or bleeding at the puncture site. There may also be uneasiness associated with needles.

I understand that it is possible that the cancers detected by these screening tests may be very slow growing. It is possible that diagnosis (and treatment) of cancers detected in this trial may not prolong my life. Additionally, it is possible that the screening tests may falsely suggest that I have cancer. In this case, it is possible that I may suffer pain, anxiety, and expense that could have been avoided if I had never undergone the screening tests.

## **NOTIFICATION AND COSTS**

I understand screening results will be sent to me as soon as they become available. If I have indicated a primary physician, he/she will receive the results. If the results indicate a potential medical problem, I will also be offered a referral to a physician specialist of my choice from whom I can receive further medical evaluation, if I so choose. The costs of diagnostic tests beyond screening will not be covered by the study and must come from insurance or other sources.

If I am diagnosed with cancer, I may be referred to a cancer specialist of my choice, if I so request. The costs of cancer treatment will not be covered by this study.

## **COMPENSATION FOR RESEARCH-RELATED INJURIES**

In the unlikely event of physical injury resulting from my participation in this study, I will be provided with immediate medical treatment. I understand, however, that no payment of medical treatment is available from the National Cancer Institute for any such injury.

## **EXCLUDED PROCEDURES**

This trial includes only the screening tests listed above. Other medical procedures are not part of this trial. ~~This includes a biopsy that might be done if abnormalities are found during the flexible sigmoidoscopy.~~

---

## **INFORMATION ON NEW FINDINGS**

I understand that any significant new findings about screening for these cancers discovered during the term of the study will be given to me if that information will make a difference in my willingness to continue in the study.

**CONFIDENTIALITY**

I understand that information concerning my participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. Personal identifying information such as name, address, and social security number will be used only for the purposes of locating me in future years.

**RIGHT TO WITHDRAW**

I understand that my participation is voluntary and that I may refuse to participate and/or withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

**PERMISSION TO REVIEW MEDICAL RECORDS**

I understand that, by agreeing to participate, I give permission for my doctors and hospitals where I have been seen to release my medical records to the study investigators.

**CERTIFICATION**

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study.

PARTICIPANT'S NAME (PRINT)

PARTICIPANT'S SIGNATURE

DATE

Witness (if necessary)

WITNESS SIGNATURE

[ ] = Optional Phrase

## **C-3-2**

C-3-2: Prototype Protocol Changes Consent (PCC)

## PLCO SCREENING TRIAL

### PROTOTYPE (Addendum) CONSENT FORM

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

**NAME OF CLINICAL CENTER**

#### **DESCRIPTION OF STUDY**

I have been participating in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial sponsored by the National Cancer Institute, LOCAL CLINICAL CENTER, and nine other centers across the country. The purpose of this study is to determine if certain screening tests can reduce deaths from prostate cancer, lung cancer, ovarian cancer, and cancers of the colon and rectum

If I was assigned to the usual care group, I will follow my normal health care routine. I will be asked to give information about my health and factors related to my health (collected by mail or telephone) once a year for 13 years.

If I was already enrolled in the screening group, I understand that there will be 2 additional years of screening exams and 3 additional years of follow-up after all the screening exams have been completed. I agree to the following changes in the study protocol:

- The 4<sup>th</sup> chest x-ray will not be performed on participants who never smoked cigarettes, cigars or a pipe.
- During the 5<sup>th</sup> and 6<sup>th</sup> years (last two years of the study), PSA tests for men and CA125 levels for women will be performed.
- At the last screening visit, year 6, I will receive the second flexible sigmoidoscopy instead of having it at my fourth (4<sup>th</sup>) visit.
- Women will no longer receive the annual physical exam of the ovaries.

I further agree to provide specific information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

#### **BENEFITS**

I understand that I will receive free cancer screening tests. I further understand that if I develop prostate, colorectal, lung, or ovarian cancer it is possible that the cancer may be detected at an early stage. Early diagnosis may prolong my life, however, this cannot be guaranteed.

#### **RISKS**

I understand that the certain risks and discomforts that might be associated with the screening procedures do not differ from the risks and discomforts that have already been performed.

#### **NOTIFICATION AND COSTS**

I understand that I will continue to receive my screening results as soon as they become available. If I have indicated a primary physician, he/she will receive the results.

If I am diagnosed with cancer, I may be referred to a cancer specialist of my choice, if I so request. The costs of cancer treatment will not be covered by this study.

**COMPENSATION FOR RESEARCH-RELATED INJURIES**

In the unlikely event of physical injury resulting from my participation in this study, I will be provided with immediate medical treatment. I understand, however, that no payment of medical treatment is available from the National Cancer Institute for any such injury.

**INFORMATION ON NEW FINDINGS**

I understand that any significant new findings about screening for these cancers discovered during the term of the study will be given to me if that information will make a difference in my willingness to continue in the study.

**CONFIDENTIALITY**

I understand that information concerning my participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. Personal identifying information such as name, address, and social security number will be used only for the purposes of locating me in future years.

**RIGHT TO WITHDRAW**

I understand that my participation is voluntary and that I may refuse to participate and/or withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

**PERMISSION TO REVIEW MEDICAL RECORDS**

I understand that, by agreeing to participate, I give permission for my doctors and hospitals where I have been seen to release my medical records to the study investigators.

**CERTIFICATION**

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study.

\_\_\_\_\_  
PARTICIPANT'S NAME (PRINT)

\_\_\_\_\_  
PARTICIPANT'S SIGNATURE

\_\_\_\_\_  
DATE

Witness (if necessary)  
\_\_\_\_\_  
WITNESS SIGNATURE

**C-3-3**

C-3-3: Prototype Etiologic Studies Consent (ESC)

## PLCO SCREENING TRIAL

### PROTOTYPE RESEARCH ON THE DEVELOPMENT AND CAUSES OF CANCER AND OTHER DISEASES

#### CONSENT FOR PARTICIPATION

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

#### NAME OF CLINICAL CENTER

The purpose of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is to determine if certain screening tests for early detection of prostate, lung, colorectal and ovarian cancers can reduce deaths caused by these cancers. Using questionnaire information, which you provide, studies of the causes of cancer are also carried out. **Your consent to participate in the screening part of the PLCO Trial has been provided in a separate document.**

The PLCO Trial also seeks to develop new biologic markers of early forms of cancer and to study biologic factors that may cause cancer and other conditions that affect your age group. The exact studies that will be performed are not all known at this time but are likely to include studies of early biochemical signs of cancer and studies of inherited traits (genes) and biochemical factors which may influence whether people develop cancer and other diseases and conditions. **In this document, we are requesting your consent to participate in these additional studies.**

#### PROCEDURE

If you are in the PLCO Trial screening group and you volunteer for these additional studies, less than four (4) tablespoons of blood collected at each of the screening exams but not used for the prostate cancer screening test (PSA) or the ovarian cancer screening test (CA-125II) test will be stored and used in future medical research. (If you are a woman without ovaries and will not receive the CA-125II, or a man without a prostate and will not receive the PSA you may still choose to participate in this additional medical research by signing this document.) These future studies will include investigations to determine if genetic (inherited) factors and chemicals in blood, such as dietary nutrients and hormones, are related to the risk of developing cancer and other diseases that occur in your age group.

If you are assigned to the usual care group and you volunteer for these additional studies, you will provide a sample of saliva which will be stored and used in future medical research. Such studies will include investigations to determine if genetic (inherited) factors are related to the risk of developing cancer and other diseases that occur in your age group. Briefly, the collection of saliva requires that, at home, you rinse with a small sample of mouthwash (less than a tablespoon), spit the saliva into a small cup, and then seal the cup tightly. You will be provided with a kit and instructions for the collection and pre-paid return mailing of this sample to the researchers.

If you volunteer for these additional studies and you later have surgery for diagnosis or treatment of cancer or a related condition, the study investigators may then ask your doctors and the hospitals where you were treated to provide a small sample of the surgical material. This material may be used by the study investigators only for medical research about genetic (inherited) factors and

chemical changes that lead to the development of cancer and other diseases that occur in your age group.

These materials will be stored at a National Cancer Institute research storage facility for up to 25 years and used to help scientists learn what causes cancer and how to prevent its progression. It is believed that cancer may be caused by both environmental and genetic factors. Therefore, the samples, which you contribute may be used in biochemical and genetic studies to identify these causes.

### **BENEFITS**

The additional studies will not provide direct benefit to you other than the satisfaction of participating in this research for the possible benefit of future generations. However, your participation in these additional studies will help answer questions related to the health and longevity of persons in your age group and will help establish a scientific understanding of the factors which influence the development and progression of cancer.

### **RISKS**

There are certain risks and discomforts that might be associated with the additional procedures.

When blood is drawn you may feel a little discomfort as the needle goes through the skin. There may be local bruising or bleeding at the puncture site. Pressing hard on the spot for 1 to 2 minutes after the needle is removed will help prevent a bruise. There may also be uneasiness associated with needles. Very rarely, the arm may become infected. The risk is the same as that of having blood drawn at your doctor's office or clinic.

When saliva is collected, (by rinsing with mouthwash) there may be slight irritation or stinging in the mouth from the mouthwash.

### **NOTIFICATION**

We will do many laboratory tests on the biologic samples you give us. The results of these laboratory tests are for research purposes and will not be meaningful for evaluating your health. Results of these laboratory tests will be reported in the scientific literature. This notification will be of results for all participants together. As the study proceeds, we will summarize important scientific advances from these laboratory tests for you in the PLCO Trial newsletter.

### **CONFIDENTIALITY**

Information concerning your participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. As the tests to be carried out are for research purposes only, no results from these tests will be placed in your medical records or linked to your name. In order to protect the confidentiality of your samples, they will be stored and used for medical research by code number only and no one who has access to your name will have access to the coded test results for you. No individual will be identified in any report.

## RIGHT TO WITHDRAW

Your participation in the additional medical research is voluntary and you may refuse to participate and/or withdraw your consent and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may participate in the screening part of the PLCO Trial and yet decline to have biologic samples stored for research purposes. Further, if you initially decide to have your biologic samples stored for research purposes, but later change your mind by written notification to Dr. \_\_\_\_\_ at \_\_\_\_\_ University Medical Center, whatever remains of your biologic samples will then be destroyed. Your decision will not affect your care.

## CERTIFICATION

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study. **My consent to participate in the screening part of the PLCO Trial has been provided in a separate document.**

Please read the two sentences below and circle your responses (Yes/No).

1. By signing this document, I agree to have biologic samples (some of my blood or saliva and possibly surgical tissue) stored for future **research on cancer**.

YES

NO

2. By signing this document, I agree to have biologic samples (some of my blood or saliva and possibly surgical tissue) stored for future research **on diseases and conditions other than cancer** that affect my age group.

YES

NO

---

PARTICIPANT'S NAME (PRINT)

---

PARTICIPANT'S SIGNATURE DATE

Witness (if necessary)

---

WITNESS SIGNATURE

[ ] = Optional Phrase

**C-3-4**

Sample Language for Etiologic Studies Consent  
Cover Letter

## Sample Language For Etiologic Studies Consent (ESC) Cover Letters

The following language, or similar language (with NCI approval) is sufficient for cover letters which accompany an ESC form:

### For Intervention Participants:

*"As part of your participation in the PLCO study, you agreed to have blood drawn at each screening visit for PSA (men) or CA 125 (women). In addition, you also agreed to have blood collected and stored for future research purposes. Because of the large number of participants successfully recruited into the PLCO study, these additional blood samples are becoming one of the major resources in the U.S. for studies of cancer and other diseases that effect your age group. The enclosed consent describes the use of these samples and asks for your signed agreement for their use for 1) research on cancer, and 2) research on other conditions that effect your age group. Although the information obtained from these additional studies will not provide direct benefit to you, it will help answer questions related to the health and longevity of persons in your age group, and may benefit future generations.*

*Your participation in these additional studies is voluntary. You may continue to participate in the PLCO Trial regardless of your decision to consent to these additional studies. We encourage you to participate in these additional studies, so please sign and date the last page of the document (one signature for cancer research, one signature for research on other conditions) and return it to the PLCO Screening Center. If you should have any questions please contact..."*

### For Potential Participants:

*"As part of your participation in the PLCO Trial, for those of you who are randomized into the intervention group, we are asking you to have blood drawn at each screening visit for PSA (men) or CA 125 (women). In addition, we are also asking you to have blood collected and stored for future research purposes. For those of you in the control group, we are asking you to give permission for a future collection of a saliva sample. This sample will also be stored for future research purposes. The enclosed consent for etiologic studies describes the use of these samples and asks for your signed agreement for their use for 1) research on cancer, and 2) research on other conditions that effect your age group. Although the information obtained from these additional studies will not provide direct benefit to you, it will help answer questions related to the health and longevity of persons in your age group, and may benefit future generations.*

*Your participation in these ancillary studies is voluntary. You may choose to participate in the main part of the study, and not choose to participate in these additional studies. We encourage you to participate in these additional studies, so please sign and date the last page of the document (one signature for cancer research , on signature for research on other conditions) and return it to the PLCO Screening Center. If you should have any questions, please contact..."*

**C-3-5**

Prototype Main Consent and Etiologic Studies Consent

## PLCO SCREENING TRIAL

### PROTOTYPE "SCREENING" (Main combined with ESC) CONSENT FORM

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

**NAME OF CLINICAL CENTER**

#### **DESCRIPTION OF STUDY**

I have been asked to take part in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial sponsored by the National Cancer Institute, LOCAL CLINICAL CENTER, and nine other centers across the country. The purpose of this study is to determine if certain screening tests can reduce deaths from prostate cancer, lung cancer, ovarian cancer, and cancers of the colon and rectum. [Some doctors believe that screening for these cancers will extend lives, others do not believe that it will. A large, carefully controlled scientific study is necessary to resolve this debate.] Nationwide, this study will enroll 148,000 men and women between the ages of 55 and 74.

Four specific questions to be addressed in this study are:

- Does screening with flexible sigmoidoscopy reduce deaths from cancers of the colon and rectum?
- Does screening with chest x-rays reduce deaths from lung cancer?
- In men, does screening with digital rectal examinations plus a blood test for serum prostate-specific-antigen (PSA) reduce deaths from prostate cancer?
- In women, does screening with transvaginal ultrasound of the ovaries, and testing the blood for CA-125, reduce deaths from ovarian cancer?

The PLCO Trial will also look for factors that may cause these cancers.

#### **STUDY PROCEDURES**

By agreeing to participate in the PLCO Trial, I agree to be assigned by a random statistical process to either a screened group or a usual care group. I understand that I have an equal chance of being in either group.

Regardless of which group I am assigned to, I will be asked questions about my personal and family medical history for these cancers and about my overall risk of developing cancer.

If I am assigned to the usual care group, I will follow my normal health care routine. I will be asked to give information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

If I am assigned to the screened group, the following tests will be carried out on an annual basis for up to 6 years:

Males:

- Digital rectal exam (annually for the first four (4) years)
- Serum PSA blood test (annually for six (6) years)

- Chest x-ray (annually for the first four (4) years in current and former smokers; first three (3) years in people who never smoked)

Females:

- Transvaginal ultrasound (annually for the first four (4) years except for women without ovaries)
- (a tampon-sized probe is inserted into the vagina and images of the ovaries are made using sound waves)
- CA-125 blood test (annually for six (6) years)
- Chest x-ray (annually for first four (4) years in current and former smokers; first three (3) years in people who never smoked)

At the first and sixth screening visit, the following test will be performed on both male and female participants:

- Flexible sigmoidoscopy

The flexible sigmoidoscopy involves the insertion to about 20-24 inches of a thin flexible lighted instrument to examine the colon and the rectum. Preparation for this test consists of two Fleets enemas one hour before the test.

The blood draw for the PSA or CA-125 test will include the collection of up to 45-ml (3 table-spoons) of blood from my arm. Blood not used for the PSA or CA-125 will be stored for future research purposes.

By agreeing to participate in this study, I agree to have all of the screening tests performed as required by the study. The examinations that are part of this trial are well-established tests that doctors use frequently to diagnose problems in patients with certain symptoms. Their effectiveness in early detection of cancer is being tested in this study. It is unknown if these tests will provide any benefit to me.

For quality control, some participants will be asked to have a screening test repeated to test the accuracy of certain measures.

I further agree to provide specific information about my health and factors related to my health (collected by mail or telephone) once a year for at least 13 years.

In addition to evaluating screening tests, the PLCO Trial also seeks to study factors that may cause these cancers to develop and progress. Additional research on cancer and other diseases that occur in your age group will be carried out among PLCO participants who volunteer for these additional studies. We are requesting your consent to participate in these additional studies of cancer and other diseases that occur in you age group.

#### **ADDITIONAL STUDY PROCEDURES**

If I am selected to be in the screened group and I volunteer for these additional studies, blood not used for the prostate cancer screening test (PSA) or the ovarian cancer screening test (CA-125II) test will be stored and used in future medical research. (If I am a woman without ovaries and will not receive the CA-125II, or a man without a prostate and will not receive the PSA I may still choose to participate in this additional medical research by signing this document.) These future studies will include investigations to determine if genetic (inherited) factors and chemicals in blood, such as dietary nutrients and hormones, are related to the risk of developing cancer and other diseases that occur in your age group.

If I am assigned to the usual care group and I volunteer for these additional studies, I will provide a sample of saliva which will be stored and used in future medical research. Such studies will include investigations to determine if genetic (inherited) factors are related to the risk of developing cancer and other diseases that occur in your age group. Briefly, the collection of saliva requires that, at home, I rinse with a small sample of mouthwash (less than a tablespoon), spit the saliva into a small cup, and then seal the cup tightly. I will be provided with a kit and instructions for the collection and pre-paid return mailing of this sample to the researchers.

If I volunteer for these additional studies and I later have surgery for diagnosis or treatment of cancer or a related condition, the study investigators may then ask my doctors and the hospitals where I was treated to provide a small sample of the surgical material. This material may be used by the study investigators only for medical research about genetic (inherited) factors and chemical changes that lead to the development of cancer and other diseases that occur in my age group.

These materials will be stored at a National Cancer Institute research storage facility for up to 25 years and used to help scientists learn what causes cancer and how to prevent its progression. It is believed that cancer may be caused by both environmental and genetic factors. Therefore, the samples, which I contribute, may be used in biochemical and genetic studies to identify these causes.

## **BENEFITS**

I understand that I will receive free cancer screening tests. I further understand that if I develop prostate, colorectal, lung, or ovarian cancer it is possible that the cancer may be detected at an early stage. Early diagnosis may prolong my life, however, this cannot be guaranteed.

[If this study shows that screening for prostate, lung, colorectal, or ovarian cancer decreases the chances of dying from these cancers, then screening for these cancers will become common practice in the future. If this study shows that the screening tests do not decrease the chances of dying of these cancers, doctors will know not to use them, saving me and others unnecessary inconvenience and expense.]

## **BENEFITS OF ADDITIONAL STUDIES**

The additional studies will not provide direct benefit to me other than the satisfaction of participating in this research for the possible benefit of future generations. However, my participation in these additional studies will help answer questions related to the health and longevity of persons in my age group and will help establish a scientific understanding of the factors, which influence the development, and progression of cancer.

## **RISKS**

I understand that there are certain risks and discomforts that might be associated with the screening procedures.

There may be some discomfort from the physical exam of the rectum, or the sigmoidoscopic exam.

- Very rarely a perforation of the bowel occurs during sigmoidoscopy (less than once in every 10,000 to 50,000 examinations). If this would occur, medical treatments consisting of antibiotics and, in a very rare instance, surgical correction could occur.

- A small amount of radiation is received as part of the chest x-ray. This amount is smaller than that of a normal chest x-ray and poses no measurable risk.
- There may be discomfort involved from the transvaginal ultrasound. There is a very rare chance of a vaginal tear with the probe.
- When blood is drawn, there may be local bruising or bleeding at the puncture site. There may also be uneasiness associated with needles.

I understand that it is possible that the cancers detected by these screening tests may be very slow growing. It is possible that diagnosis (and treatment) of cancers detected in this trial may not prolong my life. Additionally, it is possible that the screening tests may falsely suggest that I have cancer. In this case, it is possible that I may suffer pain, anxiety, and expense that could have been avoided if I had never undergone the screening tests.

### **RISKS OF ADDITIONAL STUDIES**

There are certain risks and discomforts that might be associated with the additional procedures.

When blood is drawn I may feel a little discomfort as the needle goes through the skin. There may be local bruising or bleeding at the puncture site. Pressing hard on the spot for 1 to 2 minutes after the needle is removed will help prevent a bruise. There may also be uneasiness associated with needles. Very rarely, the arm may become infected. The risk is the same as that of having blood drawn at my doctor's office or clinic.

- When saliva is collected, (by rinsing with mouthwash) there may be slight irritation or stinging in the mouth from the mouthwash.

### **NOTIFICATION AND COSTS**

I understand screening results will be sent to me as soon as they become available. If I have indicated a primary physician, he/she will receive the results. If the results indicate a potential medical problem, I will also be offered a referral to a physician specialist of my choice from whom I can receive further medical evaluation, if I so choose. The costs of diagnostic tests beyond screening will not be covered by the study and must come from insurance or other sources.

If I am diagnosed with cancer, I may be referred to a cancer specialist of my choice, if I so request. The costs of cancer treatment will not be covered by this study.

The additional biologic samples are for medical research only and the research results are not suitable for use as clinical tests for my medical care. The scientific studies require only looking at all lab results together. Therefore, the results of these additional studies will not be available to me.

### **COMPENSATION FOR RESEARCH-RELATED INJURIES**

In the unlikely event of physical injury resulting from my participation in this study, I will be provided with immediate medical treatment. I understand, however, that no payment of medical treatment is available from the National Cancer Institute for any such injury.

### **EXCLUDED PROCEDURES**

This trial includes only the screening tests listed above. Other medical procedures are not part of this trial. This includes a biopsy that might be done if abnormalities are found during the flexible sigmoidoscopy.

## **INFORMATION ON NEW FINDINGS**

I understand that any significant new findings about screening for these cancers discovered during the term of the study will be given to me if that information will make a difference in my willingness to continue in the study.

## **CONFIDENTIALITY**

Information concerning my participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. As the tests to be carried are for research purposes only, no results from these tests will be placed in my medical records or linked to my name. In order to protect the confidentiality of my samples, they will be stored and used for medical research by code number only and no one who has access to my name will have access to the coded test results for me. No individual will be identified in any report.

## **RIGHT TO WITHDRAW**

My participation in the additional medical research is voluntary and I may refuse to participate and/or withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I may participate in the screening part of the PLCO Trial and yet decline to have biologic samples stored for research purposes. Further, if I initially decide to have my biologic samples stored for research purposes, but later change my mind by written notification of Dr. \_\_\_\_\_ at \_\_\_\_\_ University Medical Center, whatever remains of my biologic samples will then be destroyed. My decision will not affect my care.

## **PERMISSION TO REVIEW MEDICAL RECORDS**

I understand that, by agreeing to participate, I give permission for my doctors and hospitals where I have been seen to release my medical records to the study investigators.

## **CERTIFICATION**

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study.

Please read the two sentences below and circle your responses (Yes/No).

By signing this document, I agree to have biologic samples (some of my blood or saliva and possibly surgical tissue) stored for future research on cancer.

**YES**

**NO**

By signing this document, I agree to have biologic samples (some of my blood or saliva and possibly surgical tissue) stored for future research **on diseases and conditions other than cancer** that affect my age group.

**YES**

**NO**

---

PARTICIPANT'S NAME (PRINT)

---

PARTICIPANT'S SIGNATURE

DATE

Witness (if necessary)

---

WITNESS SIGNATURE

[ ] = Optional Phrase

**C-6-1**

Sample Participant Results Letter

**[DATE]**

**[PARTICIPANT NAME]**

**[PARTICIPANT ADDRESS]**

Dear **[PARTICIPANT NAME]**,

Recently you participated in a series of voluntary screening tests as part of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. The result of one or more of your screening tests was found to be abnormal. The attached report gives you the results of your tests.

We cannot be certain whether these abnormal results represent illness or not. The examination involved a number of screening tests and was not intended to be a complete physical examination or a substitute for a visit to a doctor. We recommend that you make an appointment to have these results fully evaluated. If you do not have a physician or would like us to recommend one, we would be happy to consult with you.

A copy of these results has been mailed to your physician if you listed one at the time you started in the study, or at the time of this last screening. Please contact us to let us know whether you plan to see your own doctor or if you need a referral.

We appreciate your cooperation in this program. If you have any questions about these test results or any other aspect of the PLCO Trial, please do not hesitate to call Nurse Hatchet, R.N, PLCO Project Coordinator at (704) 555-1212.

Sincerely,

Dr. Quinn, M.D.

Principal Investigator. PLCO Trial

**C-6-2**

Sample Physician Results Letter

[DATE]

[PHYSICIAN NAME]

[PHYSICIAN ADDRESS]

RE: PLCO Participant Name: [PARTICIPANT NAME]

Date of Birth: [DATE OF BIRTH]

Date of Examination:[ DATE OF EXAM]

Dear Doctor [ PHYSICIAN NAME] ,

Recently [PARTICIPANT NAME] participated in a series of voluntary screening tests as part of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. This is an NCI sponsored scientific study designed to evaluate screening tests for the above cancers.

One or more of [PARTICIPANT NAME]'s screening tests was found to be abnormal. At the participant's request, we are sending you the attached form, documenting the results of the examination.

The examination involved a number of screening tests and was not intended to be a complete physical examination or a substitute for a visit to a doctor. We have contacted [PARTICIPANT NAME] and recommended that he/she contact you to discuss these findings and we encourage you to see [PARTICIPANT NAME] for any diagnostic follow-up you deem necessary. If you would like additional information regarding the diagnosis and treatment of prostate, lung, colorectal or ovarian cancer, please contact the Screening Center. Since the participant is enrolled in an NCI sponsored trial, it is important that we receive follow-up information. We may be contacting your office at a later date to obtain information on the participant's status.

We appreciate your cooperation in this important program. If you have any questions about these test results or any other aspect of the PLCO Trial, please do not hesitate to call Nurse Hatchet, R.N, PLCO Project Coordinator at (704) 555-1212.

Sincerely,

Dr. Quinn, M.D.

Principal Investigator. PLCO Trial

**C-6-3**

Sample Cover Letter for Diet History Questionnaire  
(alone)

**NOTE: The SCs may want to customize this letter depending upon the participant's study year or study group.**

[DATE]

[PARTICIPANT NAME AND ADDRESS]

Dear participant,

Thank you for your continued participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. Enclosed is the **Diet History Questionnaire**. Your answers will provide us with important information regarding your diet, cooking practices, and use of vitamin and herbal supplements.

The questionnaire is designed for automated data processing so it is necessary to use a soft #2 pencil when completing it. Further instructions are provided on the cover of the booklet. We would appreciate it if you would complete the questionnaire and return it in the enclosed postage-paid envelope as soon as possible. If you are unable to complete the form, please contact the study office or have a member of your household contact the study office to advise us of your situation.

Please be assured that all information you give us will be kept confidential. Your name or other identifying information will not appear on any report of the study. All study results will be reported as statistical summaries only.

Please do not hesitate to call the study office at [SC PHONE NUMBER] if you have any questions about this form or any aspect of the PLCO Trial. Your participation represents a valuable contribution to the outcome of the study, and we thank you again for your cooperation.

Sincerely yours,

[NAME OF SC PI OR COORDINATOR]

[TITLE]

**C-7-1**

Sample Cover Letter for Annual Study Update

# PROSTATE, LUNG, COLORECTAL AND OVARIAN CANCER SCREENING TRIAL

## Sample Cover Letter for Annual Study Update and Follow-up Locator Form

*(Date)*

*(Participant Name)*

*(Participant Address)*

*(City, State, Zip Code)*

Dear *(Participant Name)*:

Thank you for your continued participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. As you may recall, once a year we will be asking you for information about your medical care during the year.

Enclosed are two questionnaires: an **Annual Study Update** and a **Follow-up Locator Form**. The Annual Study Update asks about your recent medical care and the Follow-up Locator Form asks for identifying information, such as your address, phone number, doctor's name, etc. Please take a few moments to complete these questionnaires and return them in the postage-paid envelope provided.

If you are unable to complete these forms, please contact the Screening Center or have a member of your household contact the Screening Center to advise us of your situation.

Please be assured that all information you give will be kept confidential and will not be disclosed to anyone but the researchers conducting this study, except otherwise allowed by law.

Again, we thank you for your cooperation. Your participation represents a valuable contribution to the outcome of the study, and ultimately may help reduce the number of deaths each year from cancer.

If you have any questions about these forms or about any aspect of the PLCO trial, please do not hesitate to contact me or *(Coordinator Name)* at *(telephone number)*.

Sincerely yours,

*(Name of Investigator)*

Principal Investigator

**C-7-2**

Sample Cover Letter for Health Status Questionnaire

# PROSTATE, LUNG, COLORECTAL AND OVARIAN CANCER SCREENING TRIAL

## Sample Cover Letter for the Health Status Questionnaire

(Date)

(Participant Name)  
(Participant Address)  
(City, State, Zip Code)

Dear (Participant Name):

We at the **(Screening Center)** \_\_\_\_\_ want to thank you for your continued commitment to the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO). The health information you have provided us in the past has contributed to the success of this important national study.

Your ongoing participation is very important. Once again, we would like you to provide us with some valuable information. Please take a few minutes to complete the enclosed **Health Status Questionnaire** and return it to us in the envelope provided for your convenience. No postage is required. **If you are unsure of how to best answer the questions or whether you have had a particular exam, please call your physician's office or health care provider.** Typically, this information can be given to you over the phone in a matter of minutes.

Please remember, all information you give us will be kept confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law. Your name or other identifying information will not appear in any report of the study.

If you have any questions about this form, please contact **(name of staff member), (title), at (site phone number)**. Thank you for your time in completing the questionnaire. We look forward to your prompt reply.

Sincerely,

(Name of investigator)  
Principal Investigator

**C-7-3**

Sample Health Status Questionnaire Call Record





**C-7-4**

Sample Cover Letter for Annual Study Update and  
Diet History Questionnaire (combined)

**NOTE: The SCs may want to customize this letter depending upon the participant's study year or study group.**

[DATE]

[PARTICIPANT NAME AND ADDRESS]

Dear participant,

Thank you for your continued participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. As you may recall, once a year we will be asking you for information about your medical care during the year. Enclosed are three questionnaires, the **Annual Study Update Form**, the **Follow-up Locator Form**, and the **Diet History Questionnaire**. The Annual Study Update Form asks about your recent medical care and the Follow-up Locator Form asks for identifying information such as your address, your phone number, your doctor's name, etc. The Diet History Questionnaire asks about your diet, cooking practices, and use of vitamin and herbal supplements.

The Diet History Questionnaire is designed for automated data processing so it is necessary to use a soft #2 pencil when completing it. Further instructions are provided on the cover of the booklet. We would appreciate it if you would complete the questionnaires and return them in the enclosed postage-paid envelope as soon as possible. If you are unable to complete these forms, please contact the study office or have a member of your household contact the study office to advise us of your situation.

Please be assured that all information you give us will be kept confidential. Your name or other identifying information will not appear on any report of the study. All study results will be reported as statistical summaries only.

Please do not hesitate to call the study office at [SC PHONE NUMBER] if you have any questions about these forms or any aspect of the PLCO Trial. Your participation represents a valuable contribution to the outcome of the study, and we thank you again for your cooperation.

Sincerely yours,

[NAME OF SC PI OR COORDINATOR]

[TITLE]

**C-7-5**

Post Office Address Correction Request (POA)

TO: POSTMASTER

ADDRESS INFORMATION REQUEST

Please furnish this agency with the new address, if available, for the following individual or verify whether or not the address given below is one at which mail for this individual is currently being delivered. If the following address is a post office box, please furnish the street address as recorded on the boxholder's application form.

As part of our official duties, we conduct a variety of health studies across the nation. This person has been selected to participate in one of these studies. I certify that the address information for this individual is required for the performance of this agency's official duties. **Per the January 21, 1994 directive, we understand that address information may continue to be researched and provided at no charge for requests from government agencies.**

Christine Berg, Ph.D.  
Chief, Early Detection Branch  
National Cancer Institute

FOR POST OFFICE USE ONLY

MAIL IS DELIVERED TO ADDRESS GIVEN

NEW ADDRESS

NOT KNOWN AT ADDRESS GIVEN

MOVED, LEFT NO FORWARDING ADDRESS

NO SUCH ADDRESS

BOXHOLDER'S STREET ADDRESS

OTHER (SPECIFY):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Agency return address

National Institutes of Health  
c/o PLCO

Postmark/Date Stamp

**C-8-1**

Sample Medical Authorization Release Form

## LETTERHEAD OF SCREENING CENTER

ASSURANCE OF CONFIDENTIALITY - All information which would provide identification of the individual will be held in confidence, will be used only for study purposes, and will not be disclosed or released to other than the study team, unless required by law.

### AUTHORIZATION TO OBTAIN INFORMATION FROM MEDICAL RECORDS

I, \_\_\_\_\_ hereby authorize the release of information from medical records and staff of a health care facility where I have been seen. This information will be used for a cancer screening trial being conducted by NAME OF SCREENING CENTER and the National Cancer Institute. I understand that I may revoke this consent at any time except to the extent that action has already been taken. I also understand that this authorization expires one year from the date of signature. I further understand that all information obtained will be held confidential, and will not be disclosed to anyone but the researchers conducting this study, except as otherwise required by law.

---

Signature of Subject

---

Print Name

---

Date

**C-8-2**

Sample Cover Letter to Request Medical Records



National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

Early Detection Res Group, DCP, NCI  
Executive Plaza North/3100  
6130 Executive Blvd. MSC 7340  
Bethesda, MD 20892-7340  
Telephone: (301) 496-8544  
FAX: (301) 402-0816

TO: Medical Records Personnel  
FROM: Christine D. Berg, M.D.  
PLCO Project Officer  
Early Detection Research Group  
Division of Cancer Prevention, NCI  
DATE: September 1, 2004

The National Cancer Institute (NCI) is conducting the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. This is a large randomized trial to determine whether screening and early detection of these cancers can reduce cancer-related deaths. All PLCO participants sign an Authorization to Obtain Information from Medical Records when they join the trial and again at the time of annual screening exams.

A crucial element in the PLCO Trial is obtaining clinical follow-up information on procedures related to a positive or suspicious screening trial examination result as well as death related medical records. Your efforts in providing PLCO staff with individual clinical information is essential in obtaining answers from the trial that may have important public health implications.

On behalf of NCI and PLCO, I want to thank you for your continued assistance in providing medical record information on our participants.

Please refer to the attached document(s) for the specific medical records that are being requested.  
**Mail the requested medical records to the following address:**

(SC Specific Address)

**C-9-1**

Summary of PLCO Protocol

# Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial

## PROTOCOL SUMMARY

The primary goal of a major 22-year randomized trial of screening for prostate, lung, colorectal, and ovarian (PLCO) cancers funded by the National Cancer Institute (NCI), Division of Cancer Prevention is to determine the effects of screening on cancer-specific mortality.

Lung and colorectal cancers are among the most common cancers in American men and women, accounting for 46 percent of cancer deaths. Prostate cancers account for another 11 percent of cancer deaths among men, and ovarian cancers account for an additional 5 percent of cancer deaths among women. Successful screening programs for these cancers could have a major impact on overall cancer mortality in the United States; however, uncertainty regarding the value of screening for these cancers has resulted in conflicting positions in the medical community and confusion among populations at risk for these diseases.

Ten screening centers (SCs) across the United States are enrolling approximately 75,000 women and 75,000 men, aged 55 to 74, and randomizing subjects to an experimental (screening) group or a control group. Men and women in the control group follow their usual routine of health care. Baseline information on demographic characteristics, known risk factors for the cancers under study, and screening history is collected from all participants. Participants in the screening group receive the following screening exams:

- Men and women receive a chest x-ray screen for lung cancer at baseline and annually for 2 additional years. Only current and former smokers receive a chest x-ray examination at their fourth screening visit.
- Men and women receive a flexible sigmoidoscopy exam for colon cancer at baseline and again at their 6th screening visit.
- Men are screened for prostate cancer by digital rectal exam and a prostate-specific antigen (PSA) blood test. The digital rectal examination is administered at baseline and annually for 3 additional years. The PSA is administered at baseline and annually for 5 additional years.
- Women are screened for ovarian cancer by transvaginal ultrasound and a CA-125 blood test. The transvaginal ultrasound is administered at baseline and annually for 3 additional years and the CA-125 blood test is administered at baseline and annually for 5 additional years.

Diagnostic and treatment information is collected for all participants diagnosed with prostate, lung, colorectal or ovarian cancer during the course of the trial. All participants are followed for at least 13 years after randomization for cancer incidence and disease specific mortality. Cancer incidence is determined through annual administration of a health survey and matching the information against tumor registries.

The trial was initiated in October 1992 with completion of a pilot phase in September 1994. The study is now in its ninth year (2000/2001), with recruitment, screening and followup activities being conducted at 10 screening centers. More than 148,000 participants have been enrolled and recruitment has been extended to the year 2001.

The National Death Index will be used to determine the vital status of the study participants. The individual screening centers will obtain the death certificates. All identifiers will be removed from the death certificate, which will then be shipped to Westat. Westat codes the underlying causes of death appearing on each death certificate. Using the coded causes of death and other medical information, a computer algorithm determines if a particular death needs to be reviewed by an independent death review committee. The committee reviews medical documentation surrounding the death to determine if the death was due to a PLCO cancer.

**C-9-2**

Sample Cover Letter for Collection of HOM Informa-  
tion

*(Date)*

*(Physician Name)*

*(Physician Address)*

*(City, State, Zip Code)*

Dear *(Physician Name)*:

*(Participant Name)* was a participant in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial at *(Screening Center)* and our records indicate that you were involved in his/her medical care.

The National Cancer Institute (NCI) and *(Screening Center)* are sponsoring this nationwide study of older Americans. The purpose of the study is to determine whether or not screening for the early detection of cancers in the prostate, lung, colon, rectum and ovary, helps reduce the number of people who die from them each year

*(In the past, you provided us with information about participant's \_\_\_\_\_ cancer. Thank you for that information. We would now like to confirm whether or not there were any additional cancer diagnoses in participant). We would appreciate your cooperation in completing the enclosed questionnaire. Also enclosed is an authorization for release of information signed by (Participant)'s (relationship, e.g., brother, wife, etc.).*

By completing this questionnaire, you will be making an important contribution to this project. We have enclosed a self-addressed, stamped envelope for your convenience. If you have any questions, please contact me at *(PI phone number)*. Thank you for your help.

Sincerely,

*(Name of Investigator)*

Principal Investigator

**C-18-1**

Sample ESC Cover Letter

# Your help is needed!

(Date)

(Participant Name)

(Participant Address)

(City, State Zip code)

Dear (Participant Name):

Your participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is important in answering questions about cancer. The PLCO Trial is starting an exciting new project that will investigate biologic causes of cancer and other diseases, including genetic factors and we would like you to participate. Please review the enclosed brochure for more information about the new project and to find out how easy it is to participate.

Also enclosed, you will find two identical consent forms and a postage-paid envelope. The consent form explains in detail your rights as a participant in the project. **Please indicate your willingness to participate by completing the following steps:**

- Step 1:** On the last page of the consent form questions **1** and **2** are about participation in this project, please answer by circling “yes” or “no.”
- Step 2:** Print your **name**, **sign** and **date** the form.
- Step 3:** Return one **signed copy** to us in the addressed, postage-paid envelope. (Keep the other form for your records.)

Your participation in the Usual Care group of the PLCO Trial is a valuable contribution. We hope you will join in this new project to help us learn more about the causes of cancer and other diseases. If you have any questions about the consent form or any other part of the PLCO Trial, please call me or (Coordinator Name) at (###) ###-####.

Sincerely,

Principal Investigator

**C-18-2**

Prototype ESC for Previously Enrolled Controls

# Prototype Etiologic Studies Consent Form for Previously Enrolled Controls

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

## Name of Screening Center

The purpose of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is to determine if certain screening tests for early detection of prostate, lung, colorectal and ovarian cancer can reduce deaths caused by these cancers. Using questionnaire information which you provide, studies of the causes of cancer are also carried out. **Your consent to participate in the PLCO Trial has been provided in a separate document.**

The PLCO Trial also seeks to develop new biologic markers of early forms of cancer and to study biologic factors that may cause cancer and other conditions that affect your age group. The exact studies that will be performed are not all known at this time but are likely to include studies of early biochemical signs of cancer and studies of inherited traits (genes) and biochemical factors which may influence whether people develop cancer and other diseases and conditions. **In this document, we are requesting you consent to participate in these additional studies.**

## PROCEDURE

If you volunteer for these additional studies, you will provide a sample of saliva which will be stored and used in future medical research. Such studies will include investigations to determine if genetic (inherited) factors are related to the risk of developing cancer and other disease that occur in your age group. Briefly, the collection of saliva requires that, at home, you rinse with a small sample of mouthwash (less than a tablespoon), spit the saliva into a small cup, and then seal the cup tightly. You will be provided with a kit and instructions for the collection and pre-paid return mailing of this sample to the researchers.

If you volunteer for these additional studies and you later have surgery for diagnosis or treatment of cancer or a related condition, the study investigators may then ask your doctors and the hospitals where you were treated to provide a small sample of the surgical material. This material may be used by the study investigators only for medical research about genetic (inherited) factors and chemical changes that lead to the development of cancer and other diseases that occur in your age group.

These materials will be stored at a National Cancer Institute research storage facility for up to 25 years and used to help scientists learn what causes cancer and how to prevent its progression. It is believed that cancer may be caused by both environmental and genetic factors. Therefore, the samples which you contribute may be used in biochemical and genetic studies to identify these causes.

## **BENEFITS**

The additional studies will not provide direct benefit to you other than the satisfaction of participating in this research for the possible benefit of future generations. However, your participation in these additional studies will help answer questions related to the health and longevity of persons in your age group and will help establish a scientific understanding of the factors which influence the development and progression of cancer.

## **RISKS**

There are certain risks and discomforts that might be associated with the additional procedures.

- \* When saliva is collected, (by rinsing with mouthwash) there may be slight irritation or stinging in the mouth from the mouthwash.

## **NOTIFICATION**

Results of these additional studies will be reported in the scientific literature. This notification will be of results for all participants together. No individual results will be provided from these additional studies. As the study proceeds, we will summarize important scientific advances from these additional studies for you in the PLCO Trial newsletter.

## **CONFIDENTIALITY**

Information concerning your participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. As the tests to be carried out are for research purposes only, no results from these tests will be placed in your medical records or linked to your name. In order to protect the confidentiality of your samples, they will be stored and used for medical research by code number only and no one who has access to your name will have access to the coded test results for you. No individual will be identified in any report

## **RIGHT TO WITHDRAW**

Your participation in the additional medical research is voluntary and you may refuse to participate and/or withdraw your consent and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may participate in the PLCO Trial and yet decline to have biologic samples stored for research purposes. Further, if you initially decide to have your biologic samples stored for research purposes, but later change your mind by written

notification of Dr. \_\_\_\_\_ at \_\_\_\_\_ University Medical Center, whatever remains of my biologic samples will then be destroyed. Your decision will not affect your care.

CERTIFICATION

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in these additional studies. **My consent to participate in the PLCO Trial has been provided in a separate document.**

Please read the two sentences below and circle your responses (Yes/No)

1. By signing this document, I agree to have biologic samples (some of my saliva and possibly surgical tissue) stored for future **research on cancer**.

**YES**

**NO**

2. By signing this document, I agree to have biologic samples (some of my saliva and possibly surgical tissue) stored for future research **on diseases and conditions other than cancer** that affect my age group.

**YES**

**NO**

---

PARTICIPANT'S NAME (PRINT)

---

PARTICIPANT'S SIGNATURE

DATE

Witness (if necessary)

---

WITNESS SIGNATURE

**C-18-3**

Sample Buccal Cell Kit Cover Letter

## *Sample Cover Letter for PLCO Buccal Cell Collection Kit*

(Date)

(Participant Name)  
(Participant Address)  
(City, State, Zip Code)

Dear (Participant Name):

Sometime ago, we told you that the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial is expanding to include new studies with the National Cancer Institute to investigate the causes of cancer and other diseases. We would like to thank you for agreeing to participate in these new studies.

For this new research, we ask that you provide our research laboratory at the National Cancer Institute with a small sample of loose cells from your mouth for the analysis of inherited (genetic) traits. These added studies will not provide clinical test results for you, but participation by you and others will help us to learn about causes of disease.

This mailing contains all the items needed for you to collect and mail a sample of loose cells from your mouth. Please follow the Directions for Collecting the Sample (blue sheet), and mail the sample in the envelope provided to the National Cancer Institute laboratory at the Frederick, Maryland address.

Thank you for your continued participation in the PLCO trial and for taking the time to provide this valuable sample. If you have any questions about this sample collection or any aspect of the PLCO trial, please contact me or (Coordinator Name) at (telephone #).

Sincerely,

(Name of P.I.)  
Principal Investigator

Enclosure: Collection Kit

## **APPENDIX D**

**Appendix D: PLCO Brochure and Logo**

**D-1-1**

PLCO Logo

**NATIONAL CANCER INSTITUTE**



**Prostate, Lung, Colorectal, & Ovarian  
CANCER SCREENING TRIAL**

**D-2-1**

PLCO Recruitment Brochure

*You* can contribute  
to this important study.  
Do this for yourself and  
for future generations.



For answers to your questions about  
cancer, or studies like the PLCO  
Cancer Screening Trial, call the  
National Cancer Institute's toll-free  
Cancer Information Service at:

**1-800-4-CANCER (1-800-422-6237)**

**TTY: 1-800-332-8615**

PLCO web site:  
<http://deq.nci.nih.gov/PLCO>



ARC 05 098



SCHOOL OF  
MEDICINE

Department of Medicine  
Division of Preventive Medicine  
Birmingham, AL 35294-4410

NON-PROFIT ORG.  
U.S. POSTAGE  
PAID  
Birmingham, AL  
Permit No. 1256



**WE**

**NEED YOU**

**TO MAKE**

**A DIFFERENCE**

Prostate, Lung,  
Colorectal,  
& Ovarian  
Cancer  
Screening Trial



## What is the PLCO Cancer Screening Trial?

PLCO refers to four organs in the body—the Prostate, Lung, Colorectum, and Ovary. The PLCO Cancer Screening Trial is a scientific health study sponsored by the National Cancer Institute, an agency of the U.S. Public Health Service. It will involve 150,000 Americans nationwide, 55 but not yet 75 years of age.

- Half of the people who agree to be in the study will be selected by chance to receive screening tests. The other half will not receive the tests. Both groups will provide information about their health every year for up to 14 years.
- The screening tests being studied are for prostate cancer, lung cancer, and ovarian cancer.
- A screening test is a medical examination used to look for a disease before any symptoms are present.

## Why is this study being conducted?

Each year over 250,000 men and women die from prostate, lung, colon, rectal, and ovarian cancers. This trial is designed to find out if screening tests which detect these cancers at an early stage will be able to reduce the number of deaths from them. The trial will also help researchers learn more about the causes of these cancers and how to prevent them in the future.

## Who can participate?

Women and men can participate if they are at least 55 but not yet 75 years old.

*You may be able to join the study if:*

- You are willing to come in for cancer screening tests;
- You are not currently being treated for any cancer;
- You have not had cancer of the prostate, lungs, colon, rectum, or ovaries; and
- You are not taking the drugs Proscar (finasteride) or Nolvadex (tamoxifen).



## What will I be asked to do if I decide to join?

If you are eligible to take part in the PLCO trial, you will be asked to fill out a questionnaire once a year, for up to 14 years. You may also be selected, by chance, to receive cancer screening tests once a year, for 4 years. These tests will be at no cost and should take about 2 hours.

## How do I learn more about the study?

If you are interested in joining and need more information, please complete and return the attached reply card, or call our medical center at the phone number provided on the back of this brochure.

If you are eligible, you will be given detailed information about what is involved in participating in this trial. You will be able to decide freely whether or not you want to take part in the study. All information collected will be kept confidential.

## **APPENDIX E**

### **Appendix E: PLCO Protocol**

## APPENDIX E: PLCO PROTOCOL 2001

## DESIGN OF THE PROSTATE, LUNG, COLORECTAL AND OVARIAN (PLCO) CANCER SCREENING TRIAL

Philip C. Prorok, PhD, Gerald L. Andriole, MD, Robert S. Bresalier, MD, Sandra S. Buys, MD, David Chia, PhD, E. David Crawford, MD, Ronald Fogel, MD, Edward P. Gelmann, MD, Fred Gilbert, MD\*, Marsha A. Hasson, MS, Richard B. Hayes, PhD, Christine Cole Johnson, PhD, MPH, Jack S. Mandel, PhD, MPH, Albert Oberman, MD, MPH, Barbara O'Brien, MPH, Martin M. Oken, MD, Sameer Rafla, MD, PhD, Douglas Reding, MD, MPH, Wilmer Rutt, MD\*\*, Joel L. Weissfeld, MD, MPH, Lance Yokochi, MD, MPH, and John K. Gohagan, PhD, FACE for the PLCO Project Team\*\*\*

\* Deceased

\*\* Retired

\*\*\* A roster of the project team appears in the lead paper of this supplement. Other participants in early design considerations for this trial included former National Cancer Institute investigators David P. Byar (deceased) and Charles R. Smart (retired).

Division of Cancer Prevention (P.C.P., J.K.G.) and Division of Cancer Epidemiology and Genetics (R.B.H.), National Cancer Institute, Bethesda, Maryland; Washington University School of Medicine, St. Louis, Missouri (G.L.A.); Henry Ford Health System, Detroit, Michigan (R.S.B., R.F., C.C.J., W.R.); University of Utah Health Sciences Center, Salt Lake City, Utah (S.S.B.); UCLA Tissue Typing Laboratory, Los Angeles, California (D.C.); University of Colorado Health Sciences Center, Denver, Colorado (E.D.C.); Georgetown University, Washington, DC (E.P.G.); Pacific Health Research Institute, Honolulu, Hawaii (F.G., L.Y.); Westat, Inc., Rockville, Maryland (M.A.H., B.O.); University of Minnesota, Minneapolis, Minnesota (J.S.M.); University of Alabama at Birmingham, Birmingham, Alabama (A.O.); Virginia Piper Cancer Center, Minneapolis, Minnesota (M.M.O.); Cancer Institute of Brooklyn, Brooklyn, New York (S.R.); Marshfield Medical Research and Education Foundation, Marshfield, Wisconsin (D.R.); and University of Pittsburgh Cancer Institute, Pittsburgh, Pennsylvania (J.L.W.)

RUNNING TITLE: Design of the PLCO Trial

KEY WORDS: *Randomized trial, screening, design, prostate cancer, colorectal cancer, lung cancer, ovarian cancer*

Address reprint requests to: Dorothy Sullivan, Early Detection Research Group, Division of Cancer Prevention, National Cancer Institute, EPN 330, 6130 Executive Blvd., Bethesda, MD 20892-7346.

### ABSTRACT

The objectives of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial are to determine in screenees ages 55-74 at entry whether screening with flexible sigmoidoscopy (60-cm sigmoidoscope) can reduce mortality from colorectal cancer, screening with chest x-ray can reduce mortality from lung cancer, screening men with digital rectal examination (DRE) plus serum prostate-specific antigen (PSA) can reduce mortality from prostate cancer, and screening women with CA125 and transvaginal ultrasound (TVU) can reduce mortality from ovarian cancer. Secondary objectives are to assess screening variables other than mortality for each of the interventions including sensitivity, specificity, and positive predictive value; to assess incidence, stage, and survival of cancer cases; and to investigate biologic and/or prognostic characterizations of tumor tissue and biochemical products as intermediate endpoints.

The design is a multicenter, two-armed, randomized trial with 37,000 females and 37,000 males in each of the two arms. In the intervention arm, the PSA and CA125 tests are per-

formed at entry, then annually for 5 years. The DRE, TVU, and chest x-ray exams are performed at entry and then annually for 3 years. Sigmoidoscopy is performed at entry and then at the 5-year point. Participants in the control arm follow their usual medical care practices. Participants will be followed for at least 13 years from randomization to ascertain all cancers of the prostate, lung, colorectum, and ovary, as well as deaths from all causes. A pilot phase was undertaken to assess the randomization, screening, and data collection procedures of the trial and to estimate design parameters such as compliance and contamination levels. This paper describes eligibility, consent, and other design features of the trial, randomization and screening procedures, and an outline of the follow-up procedures. Sample-size calculations are reported, and a data analysis plan is presented.

## INTRODUCTION

Lung and colorectal cancers, the most common cancers in Americans, accounted for 46% of cancer deaths in males and 34% of cancer deaths in females in 1989 when this trial was being considered [1]. In males, prostate cancer was the third leading cause of cancer mortality and accounted for 11% of cancer deaths. In females, ovarian cancer accounted for 5% of cancer deaths. Mortality statistics for these cancers are similar today. In 2000, there will be an estimated 28,500 deaths among women and 27,800 deaths among men from colorectal cancer and, respectively, 67,600 and 89,300 deaths from lung cancer. About 14,000 women will die from ovarian cancer and 31,900 men from prostate cancer [2].

The death rate for prostate cancer has increased somewhat over time, while the rate for colorectal cancer has dropped, especially for females. The death rate for lung cancer has risen rapidly in both sexes, with a recent downturn for males [2]. Successful screening programs for these three cancers could have a major impact on overall cancer mortality. The death rate for ovarian cancer has remained relatively stable. Nearly 70% of ovarian cancers present as advanced disease with a poor prognosis, while localized disease has a 90% survival rate [3]. Successful screening might substantially reduce ovarian cancer mortality.

Uncertainty regarding the value of screening for these cancers has resulted in conflicting positions in the medical community and confusion in populations at risk. A randomized, controlled trial is necessary to determine the effects of screening on disease-specific mortality. The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is a 23-year randomized trial in which 37,000 men will be screened for prostate, lung, and colorectal cancers and 37,000 women will be screened for lung, colorectal, and ovarian cancers. Prostate-specific antigen (PSA) and digital rectal examination (DRE) (for prostate), chest x-ray (for lung), 60-cm flexible sigmoidoscopy (for colorectal), and CA125 blood test and transvaginal ultrasound (TVU) (for ovary) are being investigated as screening modalities. Equal numbers of men and women will be followed with routine medical care as controls. There will be a follow-up period of at least 13 years from randomization for both intervention and control participants to determine the effects of screening on cause-specific mortality.

This paper describes the design of this trial at the completion of protocol development (just prior to the initiation of the pilot-phase recruitment) and protocol modifications which have occurred since. Included are the specific rationale for each cancer site, overall design features, screening and follow-up procedures, sample-size considerations, and data analysis plans. Recruitment into the pilot phase began November 16, 1993, with main-phase recruitment commencing September 30, 1994.

## TRIAL RATIONALE

### Prostate Cancer Screening

The DRE, the most common screening test for prostate cancer screening prior to 1990, has never been completely evaluated. Observational studies have examined sensitivity and case survival data, but without appropriate controls and with no adjustment for lead-time and length biases [4, 5].

In 1984, Chodak and Schoenberg [6] reported on 811 patients from 50-80 years of age who underwent rectal examination and follow-up. Thirty-eight of 43 patients with a palpable abnormality in the prostate agreed to undergo biopsy. The positive predictive value for prostate cancer was 29%. Forty-five percent of the cases were stage B, 6% stage C, and 18% stage D. More recent results from the same investigators revealed a 25% positive predictive value with 68% of the detected tumors clinically localized [7]. Others also reported a high proportion of localized disease when prostate cancer is detected by routine rectal examination [8-11]. In contrast, Wajzman and Chu [12] among others have reported that even with annual rectal examination, only 20% of cases are localized at diagnosis. Thompson and

Zeidman [13] reported that 25% of men presenting with metastatic disease had a normal prostate exam.

A summary of the data on DRE for detection of prostate cancer concluded the following: sensitivity is 55-69%, specificity is 89-97%, positive predictive value is 11-26%, and negative predictive value is 85-96% [14]. Further, the rectal examination depends on the skill and experience of the examiner and the presence of a cancer in the posterior prostate. However, DRE is inexpensive, relatively noninvasive, nonmorbid, and can be taught to nonprofessional health workers. What remains to be determined is whether routine annual screening by rectal examination reduces prostate cancer mortality. A case-control study involving 139 men with metastatic prostate cancer and matched controls found the relative risk of metastatic prostate cancer to be 0.9 for men with one or more rectal examinations compared with men with none. The 95% confidence interval was 0.5-1.7, suggesting that screening by routine DRE appears to have little effect in detecting and treating prostate cancer before it becomes metastatic [15].

Prostatic imaging by ultrasound, computerized tomography, and magnetic resonance imaging has also been suggested for prostate cancer screening. Each modality has relative advantages and disadvantages. Transrectal ultrasound has received the most attention [8, 16-22]. In a summary, Waterhouse and Resnick [23] reported that the sensitivity and specificity of ultrasound are too low for the procedure to be a valuable screening tool. Sensitivity ranged from 71-92% for prostate cancer and 60-85% for subclinical disease. Specificity ranged from 41-79%, and positive predictive values in the 30% range have been reported. The sensitivity and positive predictive value of ultrasound may be better than those of DRE when each is used as a single test. However, the relatively low specificity along with the invasiveness and cost of the procedure preclude routine screening for prostate cancer by transrectal ultrasound.

Serum PSA has been examined in several observational settings, both for initial diagnosis of disease and as a tool to detect recurrence after initial therapy [8, 20, 24-27]. Parameter estimates for this test include sensitivity near 70% and positive predictive values of 17-28%, although these estimates of predictive value are strongly dependent upon the disease prevalence in the populations studied [28]. The potential value of PSA lies in its simplicity, objectivity, reproducibility, lack of invasiveness, and lower cost relative to ultrasound. The test has increased the detection rate of early stage cancers, many of which may be curable by local therapy [9, 29, 30]. However, the test must be carefully evaluated because false positives in the form of benign prostatic lesions are common, requiring biopsies and added expense, and PSA testing cannot distinguish between latent or biologically irrelevant versus aggressive tumors.

The use of serial tests to assess the rate of change of PSA has been evaluated as a method to improve the specificity of the test [31]. The combination of PSA and ultrasound has been used to determine PSA density indexed to prostate size [32-34]. In one study, volume-adjusted PSA identified a population at higher risk of carcinoma [35], but another study of intermediate levels of PSA found no advantage to volume-adjusted PSA levels for screening [36]. Ratios of free to complexed PSA can amplify the differences in PSA levels for individuals with prostate cancer versus prostatic hyperplasia [37, 38]. No statistical advantage has been established for using the ratio of free to total PSA compared to total PSA alone in a screened population [39]; however, the free to total PSA ratio did improve specificity in other studies [40].

In a study by Cooner et al. [41] to resolve questions surrounding the relative merits of the three tests, all subjects had a rectal examination, PSA determination (Hybritech assay), and a 7 mHz ultrasound examination. Most of the participants with positive results on ultrasound plus a few other individuals were biopsied. The pertinent findings of this study and a similar study by Lee et al. [20] are given in Table 1. Both studies demonstrate that the rate of can-

cer among subjects with positive results on ultrasonography in whom the rectal and PSA exams are normal is extremely low. Hence, ultrasound was not included as one of the screening tests in this trial.

**Table 1:** Effect of Rectal and Prostate-Specific Antigen Examinations On Cancer Rate in Patients with Abnormal Rectal Ultrasound

	Cooner Study			Lee Study		
	Biopsies	Cancer	Rate	Biopsies	Cancer	Rate
Rectal +PSA +	235	151	0.64	89	63	0.71
Rectal + PSA -	166	23	0.14	23	6	0.26
Rectal - PSA +	134	41	0.31	92	31	0.34
Rectal - PSA -	177	12	0.07	44	2	0.05

PSA = Prostate-specific antigen

Careful evaluation of prostate cancer screening is mandatory because the natural history of the disease is variable and appropriate treatment is not clearly defined [28, 42, 43]. The incidence of prostate cancer found at autopsy steadily increases for each decade after age 50, and most of these lesions are clinically latent. Some progress has been made in predicting the biologic behavior of these tumors, but despite improved understanding of the relationship among histologic grade, tumor volume, and biologic behavior, it is difficult to determine appropriate therapy for any given tumor [44]. A meta-analysis indicated that patients with low-grade prostate cancer can experience long-term survival with deferred therapy [45]. Decision analyses produce indeterminate results because of uncertainty regarding treatment efficacy and metastatic rates for prostate cancer [46-48]. On the other hand, a review of 60,000 cases of prostate cancer diagnosed between 1983 and 1992 showed that men with poorly or moderately differentiated cancer had improved survival if treated rather than followed [49].

Screening and treatment of a large population of males could entail substantial risks and morbidity, which include urinary incontinence, urethral strictures, sexual impotence, rectal injury, and a small probability of treatment-related mortality [44, 50]. Given these circumstances, careful evaluation of prostate cancer screening is needed. Currently, there is insufficient evidence with which to decide the efficacy or effectiveness of screening asymptomatic men [44, 47]. In addition to the PLCO trial, randomized trials are underway in other countries to address these issues [51, 52].

### Lung Cancer Screening

Evaluations of chest x-ray and sputum cytology, the most common screening tests for lung cancer, were first reported nearly 30 years ago. The early studies include the Philadelphia Pulmonary Neoplasm Research Project [53], a nonrandomized, uncontrolled study begun in 1951; the Veterans Administration study [54], a nonrandomized, uncontrolled study performed from 1958 to 1961; the South London Lung Cancer Study [55], a nonrandomized, uncontrolled study done in 1955 to 1963; the North London Cancer Study [56, 57], a randomized study with industrial firms randomized between screening and no screening done in the early 1960s; and the Kaiser Foundation Health Plan multiphasic screening trial [58, 59], a controlled trial with annual chest x-ray, spirometry, and medical questionnaire as part of the multiphasic screening begun in 1964. None of these studies demonstrated a significant impact of screening on lung cancer mortality. The South London study, for example, showed an increase in the survival of screen-detected cases compared with other cases found in the

same geographical region, but without adjustment for self-selection bias, lead-time bias, overdiagnosis bias, or length bias [60, 61]. These studies typically were small, and for most, follow-up was short, so that any small to moderate size effect or any long-term effect was not likely to be demonstrated.

More recent studies include a randomized trial in Czechoslovakia [62, 63], a case-control study in the former German Democratic Republic [64], and a case-control study in Japan [65]. As with some earlier studies, the randomized groups in the Czechoslovakian study were screened with x-ray and cytology at two frequencies, semiannual versus every 3 years, so that there was no unscreened control group. There was no difference in mortality between the two groups. The German case-control study evaluated chest x-rays originally used for control of tuberculosis. The Japanese case-control study considered x-ray histories among deceased lung cancer cases and matched controls. In contrast to the German study, the odds ratio of dying from lung cancer for those screened within 12 months versus those not screened was 0.72, suggesting some benefit from the screening.

Three other randomized controlled trials have been conducted. One trial, the Mayo Lung Project, was initiated in 1971 for males 45 years or older who were heavy smokers [66-68]. Participants free of lung cancer on initial screening were randomized either to a group offered screening with sputum cytology and chest x-ray every 4 months or to a group not offered screening but advised to seek it annually. In the studies at the Johns Hopkins University Hospital [69-72] and at Memorial-Sloan Kettering Cancer Center [73, 74], intervention and control groups were offered annual chest x-ray, while the intervention group was also offered sputum cytology every 4 months. In the Mayo Clinic study, cases found in the screened arm were diagnosed in earlier stages than those in the control arm. However, there was no significant reduction in lung cancer mortality between the screened group and the control group in any of these trials.

Therefore, at this point there is no solid evidence that screening for lung cancer can reduce lung cancer mortality. Sputum cytology has not been shown to be effective as an adjunct to annual chest x-ray. There is evidence that screening with chest x-ray plus sputum cytology does improve stage at diagnosis and case survival rate relative to cases diagnosed through usual care, but despite this there was no reduction in lung cancer mortality. However, modeling using data from these trials suggests that there may have been as much as an 18% mortality reduction in these trials [75-77].

The Mayo study is the only one of the three which is pertinent to studying annual x-ray in the present trial because the use of screening x-rays differed in the two arms. However, several reservations can be noted about the Mayo study finding. First, the study was designed to detect a 50% reduction in lung cancer mortality and was too small to demonstrate a lesser but important reduction of 10-15%. Second, at the time the study was terminated there were still 40 excess cases of lung cancer in the screened group. Whether these cases represent overdiagnosis or a screening benefit which would only be seen with longer follow-up is not known. Third, about 50% of the men in the control group received an annual chest x-ray [68]. Thus, the level of contamination may have been sufficient to obscure any small to moderate benefit. Finally, when prevalence cases were detected at the first screen, they were followed separately and were not part of the randomized comparison. Hence, any effect of x-ray on reducing lung cancer mortality among these cases could not have been determined. It can also be argued that therapeutic advances may render early detection more effective today than at the time of the Mayo trial.

The concern about insufficient size of previous studies of chest x-ray screening is illustrated in Table 2. The uncertainty in interpretation of results from completed studies have led to differences of opinion regarding the value of the annual chest x-ray. Whether a small but important benefit exists can be demonstrated only by a properly designed randomized trial.

**Table 2:** Power to Detect Various Screening Effects in Previous Studies of Chest X-Ray Screening for Lung Cancer (based on actual deaths observed)

Study	Mortality Reduction (%)				
	10	20	30	40	50
Philadelphia	0.14	0.32	0.59	0.85	0.98
VA	0.16	0.38	0.69	0.92	0.99
South London	0.14	0.31	0.57	0.83	0.97
North London	0.16	0.39	0.70	0.93	0.995
Kaiser	0.12	0.27	0.50	0.76	0.94
Czechoslovakia	0.16	0.39	0.71	0.93	0.996

### Colorectal Cancer Screening

DRE, sigmoidoscopy, and fecal occult blood testing have each been suggested for colorectal cancer screening. However, only the fecal occult blood test has been proven to be beneficial.

Several uncontrolled studies suggesting that the fecal occult blood test leads to early detection have been reported [78-80] as have two case-control studies of the effect of occult blood testing on colorectal cancer mortality. In one study, the screening histories of fatal colorectal cancer cases and matched controls were compared, resulting in an odds ratio of 0.69 for exposure to at least one occult blood test over a 5-year period. The wide confidence interval (0.52-0.91) suggested a benefit from the screening but also the need for further data [81]. In the second study, cases were less likely to have ever been screened than controls, the odds ratio being 0.7 with a 95% confidence interval of 0.5-1.0, consistent with a screening benefit [82].

Five prospective, controlled studies of fecal occult blood testing have also been conducted. The Strang Clinic of New York undertook a nonrandomized study involving some 12,000 screenees and 7000 controls designed to test the effect of combining the stool guaiac test with annual sigmoidoscopy. Individuals were allocated to the study arms by calendar periods. A reduction in colorectal cancer mortality of borderline significance was reported [83].

A randomized trial of the stool guaiac test began in 1974 at the University of Minnesota, where nearly 47,000 persons ages 50-80 were randomized into three groups: a control group, an annually screened group, and a biennially screened group. The preponderance of test slides were rehydrated. Recent results provided the first definitive evidence that annual testing for occult blood in the stool can reduce the death rate from colorectal cancer. The 13-year cumulative mortality from colorectal cancer was reduced by 33% (mortality ratio 0.67 with 95% confidence interval 0.50-0.87) [84].

A controlled trial in Nottingham, United Kingdom randomized approximately 76,000 individuals to each of two arms using lists of family practitioners. Fecal occult blood testing every 2 years using nonrehydrated slides was offered to the screened arm for three to six rounds of screening. A 15% reduction in colorectal cancer mortality was reported after a median follow-up time of 7.8 years [85].

Two additional randomized trials of occult blood screening were initiated more recently. A trial in Sweden targeted individuals in the narrow age range of 60-64 years [86]. A Danish trial randomized about 31,000 individuals ages 45-75 into two arms. Participants in the

screened arm were offered nonrehydrated fecal occult blood tests every 2 years for five rounds over a 10-year period [87, 88]. This trial demonstrated an 18% reduction in colorectal cancer mortality [89].

In summary, testing for occult blood in the stool as a colorectal cancer screening maneuver has been studied in several trials, and a mortality reduction has been demonstrated. The focus of the PLCO trial is therefore flexible sigmoidoscopy.

DRE and rigid sigmoidoscopy were both part of the multiphasic screening program carried out by the Kaiser-Permanente Foundation, and some considered the results of this study to be evidence of the effectiveness of these tests [90]. Approximately 5000 individuals were allocated to a study group urged to receive an annual multiphasic checkup, and a comparable number served as controls. After 11 years, the screened group experienced a colorectal cancer death rate of 1.0 per 1000 participants entered compared to a rate of 3.3 per 1000 in the control group [58, 59]. The observed decrease in colorectal cancer mortality in this study could be a real effect resulting from screening. However, this conclusion has been questioned for several reasons [91]. Some cancers were detected in an investigation of anemia resulting from the multiphasic examination as well as by the two tests. Further, in a reanalysis the investigators found that rates of sigmoidoscopy were low in both groups (control: 25%; screened: 30%), that there was only a slight excess of exposure to sigmoidoscopy in the study group compared to the control group, and that there was not an appreciable difference in removal of colorectal polyps between groups. They concluded that this study should not be used as evidence either for or against sigmoidoscopy screening [92]. DRE made a minor contribution. In addition, a case-control study found no statistically significant mortality reduction from distal rectal cancer using DRE [93].

Two additional observational cohort studies of sigmoidoscopy have been reported. One involved 21,000 participants in Minnesota who underwent an annual physical examination that included sigmoidoscopy [94, 95]. Polyps discovered during screening were removed, and the number of sigmoid cancers ultimately found was only 15% of the number expected. All of the 13 cancers found were localized, and none of the patients had died as of 1979. The second study followed 26,000 men and women in New York [96]. In 50 cancer patients identified by screening and followed over 15 years, the 5-year survival rate was reported to be 90%. The interpretation that screening was of benefit in these two studies can be questioned on several grounds. Both studies are likely to be affected by self-selection bias of participants and by exclusion of certain individuals from the follow-up process. In the New York study, seven people with a history of symptoms and eight with previously diagnosed lesions were excluded, thereby lowering the observed incidence and mortality rates. In the Minnesota study, cases found at the initial examination were excluded from the observed incidence, and only individuals without gastrointestinal symptoms were allowed to participate. Thus, the data cannot be validly compared with the general population [91]. In addition, the reported survival data from both studies are affected by lead-time and length biases, but no adjustment for these biases was attempted.

Flexible sigmoidoscopy has been shown to be more acceptable to screenees than rigid endoscopy, and the test appears to be very sensitive and highly specific for cancer [97, 98]. The test can discover a high proportion of polyps, and evidence suggests that removal of adenomas decreases the risk of colorectal cancer [99]. The need to address the impact of flexible sigmoidoscopy screening on colorectal cancer mortality has been discussed by several investigators [97, 100, 101]. Encouraging reports of the potential impact of this test come from two case-control studies and from the modeling work of Eddy [102, 103], which suggests a potential mortality reduction of 25-40%. Both case-control studies were conducted in prepaid health plans and used colorectal cancer deaths as cases, with matched controls. Exposure to sigmoidoscopy in cases and controls was compared [104, 105]. Rigid sigmoidoscopy was used in one study, while a majority of the screening was by flexible sigmoidoscopy in the other study. Both studies suggested a strong effect of sigmoidoscopy in reducing col-

orectal cancer mortality, with unadjusted odds ratios of 0.30 and 0.21. The modeling conclusions and the case-control studies are subject to the assumptions and biases in the methodologies, so that conclusive results will only be obtained from a randomized trial.

### **Ovarian Cancer Screening**

Traditionally, the pelvic examination has been relied on to detect ovarian cancer, but it is insensitive to early disease and small tumors [106]. Thus, most ovarian cancers present as late-stage disease. Two new technologies may be useful as screening tools: CA125 and TVU.

CA125 is an antigenic determinant on a high molecular weight glycoprotein recognized by a monoclonal antibody (OC 125) using an ovarian cell line as an immunogen. The test is performed on peripheral blood. In mostly small (50-150 patients) preoperative studies of women with ovarian masses, serum CA125 levels were elevated (typically above 35 U/ml) in 68-100% of cases averaged over all stages and in 40-50% of stage I disease. Serum CA125 may also be elevated with pregnancy, endometriosis, menstruation, benign ovarian tumors, and with breast, colon, pancreatic, lung, gastric, and liver cancers [107]. CA125 was reported to have high specificity in postmenopausal women in two prospective trials. Among 1010 postmenopausal women undergoing both pelvic examination and CA125, the only malignancy diagnosed was detected by CA125 [107]. The specificity was 94.3%. In a study in Sweden among 5550 women over 40 years of age, nine cancers were detected, six of the nine by CA125 [108]. Specificity was 98.5% using a threshold of 35 U/ml in women 50 years of age and older. The sensitivity of CA125 was estimated in two nested case-control studies using sera available from two serum banks [109, 110]. The sensitivity for a level of at least 35 U/ml ranged from 20-57% for cases occurring within the first 3 years of follow-up. These two studies also reported a specificity of 95%.

These preoperative and prospective studies together suggest early detection potential for CA125. However, no studies have been conducted to measure sensitivity and specificity in a large screened population, and no randomized trials have been initiated to assess the impact of screening with CA125 on ovarian cancer mortality.

TVU has been proposed for ovarian cancer screening [111], but experience with this modality is limited. In a series of 1017 tumors, 0.3% of ovarian tumors unilocular on ultrasound were malignant, while 8% of those that were multilocular and 39% of those that were solid were malignant [106]. Van Nagell et al. [111, 112] have been using TVU for screening women over the age of 40 since 1987. Using 8 cm<sup>3</sup> as the upper limit of normal ovarian volume, 31 abnormal ultrasonograms (in 1000 women) were obtained; 24 of these women underwent laparotomy. TVU identified all three of the cancers detected.

Estimates of yield and false positivity of ultrasound are available from several studies of women offered periodic screening. In a cohort of 801 women ages 40-70 who had one or more risk factors for ovarian cancer, 163 had an abnormal abdominal ultrasound. Surgery was performed in 30 cases, and one borderline ovarian tumor was found [113]. In another study of abdominal ultrasound, 5479 asymptomatic women underwent periodic screening. Of 326 participants who had a positive test and went on to surgery, five women were diagnosed with stage IA or IB ovarian cancer, and four were diagnosed with metastatic ovarian cancer [114]. TVU was also used in a study of 3220 asymptomatic, postmenopausal women. An abnormal exam led to exploratory laparotomy in 44 women. Three primary ovarian carcinomas were found, two with stage IA cancer [115]. Finally, both transvaginal and transabdominal ultrasound were used to screen 1601 women with a first- or second-degree relative who had ovarian cancer. There were 61 positive tests, leading to six ovarian cancers, five stage I. There were five additional cancers, three ovarian and two peritoneal, reported 2-44 months after the last test [116].

The available evidence is not sufficient to determine if the sensitivity and specificity of any single ovarian cancer screening test is adequate for routine application. The modalities may

be complementary when used together. The cost of a test such as TVU, as well as the risks and costs associated with surgical evaluation of any positive test result, are potential impediments to general screening. Prospective screening trials to evaluate these modalities are required.

**DESIGN FEATURES**

**Objectives and Global Design**

The PLCO trial is designed to determine, in screenees ages 55-74 at entry, whether:

*In females and males*

- screening with flexible sigmoidoscopy (60-cm sigmoidoscope) can reduce mortality from colorectal cancer, and
- screening with chest x-ray can reduce mortality from lung cancer;

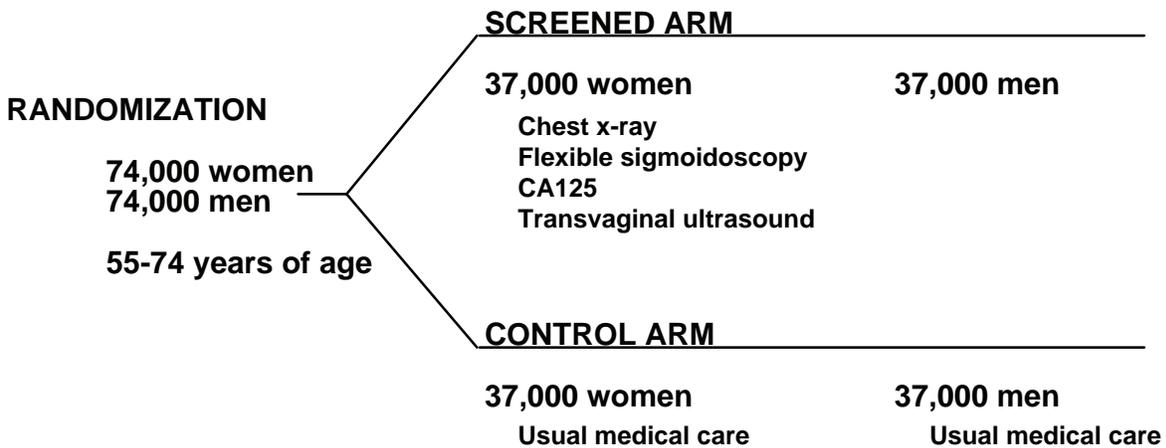
*In males*

- screening with DRE plus serum PSA can reduce mortality from prostate cancer;

*In females*

- screening with CA125 and TVU can reduce mortality from ovarian cancer.

The secondary objectives are: (1) to assess screening variables other than mortality for each of the interventions including sensitivity, specificity, and positive predictive value; (2) to assess the incidence, stage, and survival of cancer cases; (3) to investigate the mortality predictive value of biologic and/or prognostic characterizations of tumor tissue as intermediate endpoints; and (4) to conduct biomolecular and genetic research into factors associated with cancer carcinogenesis and promotion, as well as the early detection of these factors.



**Figure 1:** Schematic of the PLCO Trial Design

The design is a two-armed, randomized, controlled trial with 37,000 females and 37,000 males, ages 55-74 at entry, in each of the two arms. Ten screening centers (SCs) will each recruit approximately 5000 to 30,000 individuals to reach the total of 74,000 females and 74,000 males. Minority representation in the aggregate participant population is sought in appropriate numbers. Participants in the control arm receive their usual medical care. In the intervention arm, men are screened for prostate, lung, and colorectal cancers, and women are screened for ovarian, lung, and colorectal cancers. (See Figure 1.) The PSA and CA125 screening tests are performed at the initial visit at entry to the trial, then annually for 5 years. The DRE, TVU, and chest x-ray exams are performed at entry and then annually for 3

years, except that there are only two annual repeat exams for participants who never smoked. Sigmoidoscopy is performed at entry and then at the 5-year point. All participants will be followed for at least 13 years from randomization.

### **Design Options Considered**

A major design issue was whether to undertake separate trials for each of the cancer sites and corresponding screening modalities or combine them in some way. After a detailed examination of the costs of separate trials and various combinations of cancer sites, it was concluded that the most efficient use of resources would be to evaluate screening for the four cancers in one trial, thereby taking advantage of the efficiency of using one common administrative structure and one coordinating center (CC). It was also decided to use combinations of the screening tests deemed ready for evaluation, as described above, rather than evaluating each test individually. So, for example, DRE and PSA are used together rather than doing a separate trial for each. There were two main reasons for this approach: cost constraints and the ability to evaluate the combined, more-intensive interventions first to see if the combination works. If it does not, then testing the individual procedures is not warranted. If it does, then the individual tests can be evaluated subsequently.

Several overall designs were then considered [117]. The two primary competitors were the reciprocal control design and the all-versus-none design. The reciprocal control design would have had three arms: one devoted to screening for prostate or ovarian cancer, the second to colorectal cancer screening, and the third to lung cancer screening. Since screening would be undertaken for only one cancer site per gender in any given arm, the other arms would serve as controls. It was ultimately decided that this design would not be feasible because of the cost of bringing all participants in for screening and the anticipated substantial levels of contamination, because all participants would be coming in for screening and be aware that participants in the other arms were receiving other screening tests which they would then request. The all-versus-none design was thus chosen in which participants would be randomized to one of two arms. One arm would serve as a control, while screening for all cancers would be done in the other arm, in the spirit of a multiphasic screening endeavor. Use of the all-versus-none design makes the reasonable assumptions for the cancers and screening tests under study that the tests for each cancer do not detect any of the other cancers, and that the endpoints—death from each of the four cancers—are not related.

Within this design it was further decided to employ the so-called “stop screen” approach in which screening is performed for a fixed number of years or screening rounds and then stopped, but follow-up continues to ascertain endpoints [118]. This approach was chosen primarily because it had been used successfully in screening trials for breast and colorectal cancers and because it is the only design that allows a direct assessment of overdiagnosis, a topic of considerable concern for prostate cancer screening in particular.

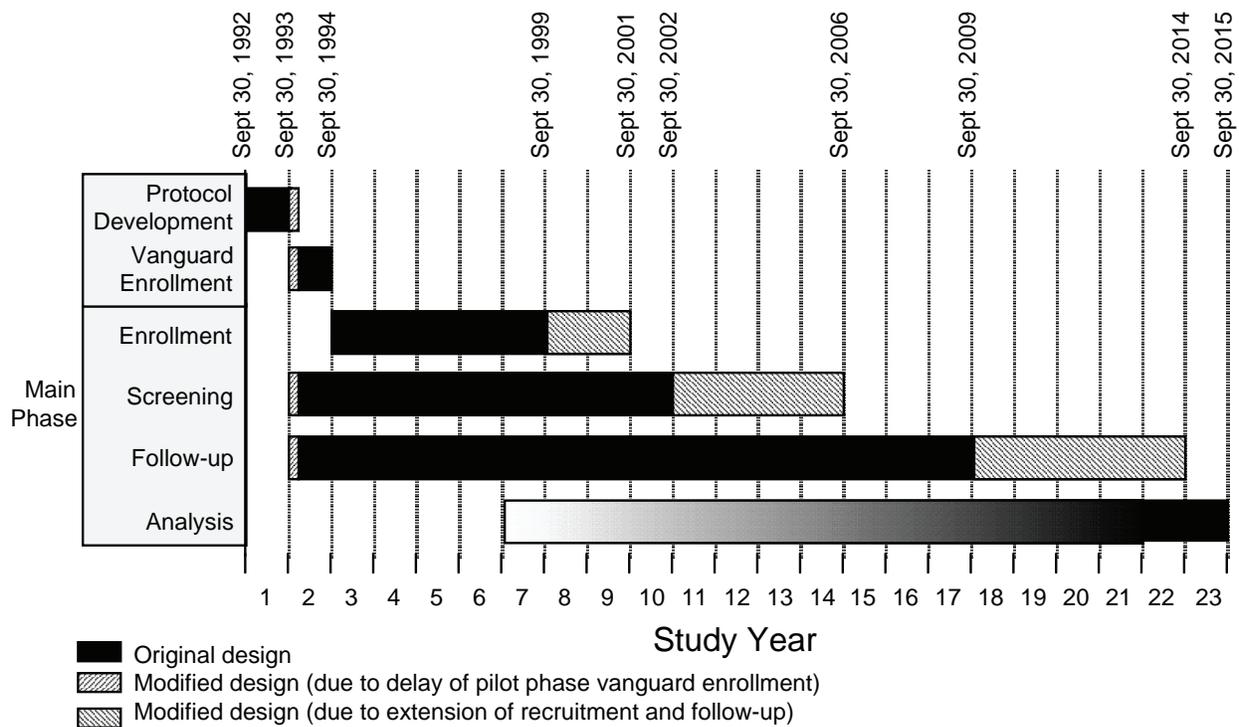
### **Specific Design Choices**

The initial choice of four annual screens, at baseline (T0) plus three annual re-examinations (T1, T2, T3), later expanded to six screens (T0-T5) for PSA and CA125, was a trade-off between enough screens to produce an effect and resources. Three or four screening rounds were sufficient in breast cancer screening trials [119, 120]. This also allowed sigmoidoscopy initially to be scheduled at the beginning and end of screening at a 3-year interval as suggested by many at the time the trial began. The annual interval between screens was chosen as the most-frequent yet practical interval if screening is shown to be effective. Compared to less-frequent screening, an annual interval also increases the likelihood of detection of a broad spectrum of the preclinical conditions in the natural history of the cancers under study. A longer interval might allow some rapidly growing lesions, which might be a source of mortality but which could be cured if found early, to escape detection. A minimum of 10 years of follow-up was initially decided upon to allow sufficient time for any mortality reduction from

screening to emerge. Follow-up intervals of 7 years or more were typically required in breast cancer screening trials [119, 120], and it was assumed that the longer natural history of prostate cancer, and perhaps other cancers under study, warranted a longer follow-up period. It was recognized that these and other design parameter choices were based on the best information at the time and may be subject to change as a result of data gathered during the trial and other information.

The original age range at entry was 60-74 years. Prostate cancer screening was the driving force for the trial, and the lower age limit was based on the sharp increases in prostate cancer mortality beginning about age 60. The upper age limit was based on a combination of increasing mortality from other causes and anticipated reduction in compliance above age 80. Enrollment of individuals in the 55-59 age group began in January 1996 on the advice of the trial's Monitoring and Advisory Panel (MAP). The MAP based its recommendation on prostate cancer, considering trade-offs between younger and older ages and recognizing the natural history of untreated disease and the prognostic importance of age at diagnosis. While the importance of prostate cancer increases with age, so does the competing mortality. It is reasonable to expect that the optimal upper age to initiate screening is not above 75 years, given the relatively slow natural history of screen-detected prostate cancer, the decreasing proportion of patients over 75 who undergo surgery, and the high competing mortality. Many believe a somewhat lower age range, with a lower age limit of 50 or 55 years, is preferred for detecting progressive but curable prostate cancers in men with longer life expectancy. The impact of this change in age range on the trial's sample size is discussed below.

The timeline for this trial is shown in Figure 2. This includes the 2-year pilot phase for protocol development and vanguard recruitment and screening followed by a main phase that comprises recruitment and initial screening of participants in years 3-9, follow-up and additional screening through year 14, final follow-up through year 22, and data analysis through year 23. This time frame represents an experience-based extension of the original target to allow sufficient time to recruit the very large population required for this trial and follow this population for relevant cancer and mortality endpoints.



**Figure 2:** The PLCO Timeline

## Pilot Phase

### *Protocol Development*

During the first 6 months of the pilot phase, the trial investigators addressed the following components of the trial protocol:

1. 1.eligibility requirements for participants entering the trial;
2. mechanism for notifying trial participants of screening results and encouraging them to seek further work-up of suspicious or positive results;
3. work-up of participants with suspicious or positive screens, including discussion of what further tests are required and in what sequence;
4. mechanism for providing appropriate therapy for cancer (or other lesions) detected by the screening program;
5. procedures for establishing and monitoring quality control of screening examinations;
6. procedures for follow-up of all randomized participants, monitoring of compliance with screening, determining cancer incidence, ascertaining cause of death, and correlating biological and tumor characteristics with mortality;
7. educational materials for controls and for screened participants.

A number of these topics are discussed further below. The details of these and other protocol components, such as the questionnaires used in this trial, reside in the manual of operations and procedures.

#### *Pilot Enrollment Period*

Certain pilot studies were planned for the first 2 years of the trial. Decisions on the long-term commitment to the trial were based on these studies. The major activities carried out during the pilot recruitment period are summarized below:

1. Test and evaluate recruitment and randomization procedures by enrolling participants at each SC. Ten SCs enrolled 12,000 participants during the pilot phase.
2. Work out the detailed logistics by actually performing the screening examinations on the pilot-phase participants allocated to the screened arm. It was expected that all screening would take place during a single visit to an SC lasting no longer than 2 hours.
3. Assess background level of usage (contamination) of each screening modality among the participants actually randomized at each SC.
4. Assess compliance for each of the screening modalities at each SC.
5. Test in actual practice all of the data forms and procedures developed during the first year of the pilot phase.
6. Establish procedures to collect, ship, and analyze blood for PSA and CA125 assays and to collect and ship blood and tissue samples for the biorepository.

Each SC identified recruitment sources and strategies appropriate to the local situation. Randomization and enrollment of participants, initially scheduled to begin in September 1993, began in November 1993 when the protocol was completed and the screening procedures set up. During the pilot phase, representatives of the CC attended all meetings of the investigators and were responsible for documenting all decisions reached and compiling the trial protocol as it developed. In addition, the CC was responsible for developing appropriate trial forms, setting up data entry and editing systems, and writing a manual of operations for all procedures to be used in the trial. During this phase, efforts were made to standardize all examinations to the extent deemed feasible in the trial settings. Efforts were made to monitor performance at each SC and correct any deficiencies so as to maintain adequate recruitment for the main phase of the trial. Participants randomized during the pilot phase are treated as a vanguard group and are included with the participants recruited later in the main phase.

#### **Main Phase**

Pilot-phase activities were concluded satisfactorily, and full-scale recruitment to the main phase of the trial began on September 30, 1994. Each SC is randomizing approximately 5000 to 30,000 participants into the trial during years 3-9 of the trial. After recruitment is complete, further screening is required for 5 years and annual determination of cancer incidence and of deaths among trial participants is needed for the remaining years of the trial.

#### **Trial Population and Exclusion Criteria**

Proposals were solicited from all groups nationwide capable of assembling the necessary staff and facilities to recruit participants, conduct the screening, and follow all randomized participants for at least 10 years after entry into the trial. Proposals were peer reviewed. Selection was competitive. The population under study therefore comprises volunteer participants recruited from a variety of organizations. Characteristics of the enrolled population are ascer-

tained via a baseline questionnaire. Potential participants are excluded for the following reasons:

1. men and women who at the time of randomization are <55 or >74 years of age;
2. individuals currently undergoing treatment for cancer, excluding basal cell and squamous cell skin cancer;
3. individuals with known prior cancer of the prostate, lung, colon, rectum, or ovary;
4. individuals with previous surgical removal of the entire prostate, one lung, or the entire colon;
5. individuals who are participating in another cancer screening or cancer primary prevention trial;
6. males who have taken Proscar (Finasteride) in the past 6 months;
7. males who have had more than one PSA blood test in the past 3 years;
8. individuals who have had a colonoscopy, sigmoidoscopy, or barium enema in the past 3 years;
9. 9.individuals who are unwilling or unable to sign the consent form.

The intent of exclusion criteria 7 and 8 is to exclude individuals who might be undergoing the screening tests being studied in this trial. These criteria were implemented on April 15, 1995 on the advice of the trial's MAP in order to minimize contamination in the trial population. During protocol deliberations, it was recognized that the level of contamination by participants already receiving one or more of the trial interventions was a very important parameter about which there was considerable uncertainty. It was therefore decided to allow a more open recruitment at the start so as to measure directly the contamination levels, with the option of making adjustments in the main phase of the trial. That adjustment was made on April 15, 1995 after data revealed that the level of PSA testing among trial participants was nearly double that anticipated prior to the initiation of recruitment.

Prior to October 1996, women with previous surgical removal of both ovaries were excluded from the trial. However, enrollment of women proved more difficult than for men, and the MAP recommended that the trial enter all women, regardless of ovary status, in order to increase enrollment of women and thereby enhance the trial's ability to reach a valid scientific conclusion regarding the colorectal and lung cancer endpoints. Thus, beginning in October 1996, women without ovaries were no longer excluded.

### **Consent**

At the outset, each SC had the option of using one of two informed consent procedures. Pre-randomization consent requires informed consent from participants before randomization into the trial. It was believed that this consent, covering all aspects of participation including screening and data collection, could lead to greater contamination, but could also lead to greater compliance. Dual consent randomization consisted of an initial consent from all participants for administration of the baseline questionnaire and follow-up for cancer incidence and vital status. A second consent was then obtained only from participants randomized to screening, the purpose of which was to obtain consent to conduct the screening tests. This approach could reduce contamination, but could also lead to lowered compliance. Three of the initial ten SCs chose the dual consent approach. However, after several years of recruit-

ment, all centers were directed to switch to a single consent because the extra complexities of the dual consent were impeding enrollment and compliance with screening.

A prototype consent form was designed using standard language across SCs describing the randomized design of the trial, the obligations of the participants, the nature of the screening tests being studied, and the potential risks and benefits of participation. Discomforts associated with the screening procedures were listed, including the possibility of discomfort from the physical examination of the ovaries, the DRE, the sigmoidoscopic examination, and the TVU. Risks mentioned included the very rare perforation of the bowel during sigmoidoscopy, the very slight chance of a vaginal tear from the ultrasound probe, and the small amount of radiation received as part of the chest x-ray. The possibility of local bruising or bleeding at the puncture site of the blood draw was also noted. The consent form indicated that diagnosis (and treatment) of cancers detected in this trial might not prolong life and that the screening tests might falsely suggest that a person has cancer. Consequently, some participants might suffer pain, anxiety, and expense that would not have occurred if the individuals had never undergone the screening tests.

The consent form was reviewed and approved by the National Cancer Institute (NCI), the National Institutes of Health (NIH) Office of Protection from Research Risks, and the U.S. Office of Management and Budget. The prototype is part of the PLCO manual of operations and procedures. Individualized versions, possibly involving minor revisions, were approved by the Institutional Review Boards of each SC. Consent is also sought for use of biologic samples. Consent issues are discussed elsewhere in this supplement [121].

### **Randomization**

Individuals who meet the eligibility criteria are randomized individually into intervention and control arms. The randomization scheme uses blocks of random permutations of varying lengths and is stratified by SC, gender, and age. Random assignment is implemented using compiled software and encrypted files loaded on SC microcomputers. As each person is successfully randomized into the trial, data including name, gender, date of birth, and study arm are automatically stored in encrypted data tables. At the same time, a second protected set of synchronized tables, stored on a backup device, are also updated. This device also carries all of the randomization software. In the event that the system crashes, randomization can be performed directly from the backup device linked to another computer.

### **Screening Procedures**

Whenever possible, screening examinations are conducted in a central screening facility to promote efficiency, accelerate the examination process, eliminate confusion and anxiety among screenees, facilitate patient education, and enhance compliance. The goal is to complete screens for all cancer sites within a 2-hour period for each screenee. The trial protocol specifies examiner qualifications, experience, and training; equipment requirements; examination procedures; and definitions of positive tests. To enhance acceptability of the screening process by screenees, the protocol recommends but does not require that technologists of the same gender as the screenee perform digital rectal and sigmoidoscopic examinations, as well as palpation and TVU examinations of the ovaries.

The blood draw for the PSA or CA125 test is usually performed first (for males blood is drawn prior to the DRE) and includes the collection of up to 45 ml of blood. The specimens are centrifuged, and the serum is separated from the clot and frozen within 2-4 hours of blood collection. Samples are stored at -70°C or colder and shipped weekly overnight on dry ice to the central laboratory (LAB) at UCLA for PSA or CA125 assay. Blood not used for the PSA or CA125 test is stored in a central repository at -70°C for future research. The biorepository is discussed in another paper in this supplement [122]. The LAB transmits assay results electronically to the SCs. A PSA result >4 ng/mL is considered positive, while a CA125 result >35 units/mL is considered positive.

A postero-anterior chest x-ray is taken by a qualified technologist and interpreted by a radiologist. The x-ray is taken using dedicated high-kV equipment (approximately 110-140 kV) at a tube-to-film distance of 6-10 feet. A wide latitude film with a 12:1 standard grid or higher is used. The exam is considered negative if evaluation reveals midline structure and heart to be of normal size and not displaced or enlarged, and pulmonary parenchyma reveals no abnormality suspicious for cancer. The exam is positive (suspicious) for lung cancer if evaluation reveals any of the following pulmonary abnormalities: nodule, mass, hilar or mediastinal lymph node enlargement, major atelectasis/lobar collapse, infiltrate/consolidation/alveolar opacity, or pleural mass.

The DRE is performed by a qualified medical examiner. The participant may bend at the waist over the end of the examination table, kneel in the knees-to-chest position, or lie in the lateral decubitus position with knees pulled up to chest. The examiner applies a lubricated gloved index finger at the 6 o'clock position to relax the sphincter and then introduces the finger into the anal area to palpate the prostate. The examiner explores the anterior portion of the rectal vault, i.e., the base, apex, and lateral lobes of the prostate. The exam is considered negative if the prostate is symmetric, soft, and non-nodular. The result is positive (suspicious) if there is nodularity or induration of the prostate gland or if the examiner judges the prostate to be suspicious based on other criteria such as asymmetry or loss of anatomic landmarks.

Preparation for the ovarian palpation examination requires the participant to empty her bladder within 30 minutes of the examination. The participant is placed in the dorsal recumbent position, in stirrups and draped. The qualified examiner notes right and left adnexa and ovaries separately, and a rectovaginal examination is performed. The cervix is not visualized. The examiner notes if there is blood on the glove after examination. The examiner is blinded to the results of the TVU examination. Findings are considered negative if an adequate examination is completed and no ovarian masses or other abnormalities are detected. For obese participants with nonpalpable ovaries, the examination is considered negative. A positive (suspicious) result is defined as a palpable ovarian mass or cul-de-sac nodularity.

The TVU examination is performed prior to the flexible sigmoidoscopy. It is performed by a qualified sonographer using a 5-7 MHz transvaginal probe. The sonographer images both the left and right ovaries in the transverse and longitudinal planes. The examiner searches for no less than 5 minutes per ovary for each ovary to ensure an adequate search for the ovaries; however, if the iliac vessels are visualized and no ovaries are visualized, the examiner may conclude the search for the ovaries. The examiner is blinded to the results of the ovarian palpation examination.

Using calipers, the sonographer takes measurements on the image along the major and minor axes in both transverse and longitudinal planes. A negative examination is one which clearly defines the ovaries with no abnormalities found. If one or both ovaries cannot be visualized, the examination is also considered negative, provided no other abnormalities are found. The prolate ellipsoid formula (width x height x thickness x 0.523) is used to calculate the volume of each ovary and/or cyst. A finding positive (suspicious) for ovarian cancer consists of one or more of the following features: any ovary or cyst greater than 10 cc in volume, any solid area or papillary projection extending into the cavity of a cystic ovarian tumor of any size, or any mixed (solid/cystic) component within a cystic ovarian tumor.

Sigmoidoscopy is performed by a qualified examiner using a 60-cm flexible sigmoidoscope. Bowel preparation includes a Fleet enema, repeated once or twice if necessary, on the morning of the exam. A brief medical history is obtained before sigmoidoscopy, and vital signs are measured before and after the procedure. After a DRE, the examiner introduces the lubricated scope and visualizes the rectum and the colon as the scope is advanced. Air for inflation or exposure is used at the discretion of the examiner. Once the scope is fully advanced, the examiner withdraws the scope and visualizes the colon and the rectum as the scope is

withdrawn. The examination is considered negative if the examiner is able to advance the scope at least 50 cm, there is adequate bowel preparation, and no abnormalities are seen. A finding that is positive (suspicious) for colorectal cancer or neoplastic lesion is defined as visible (or palpable from rectal exam) evidence of a mucosal abnormality including rectal nodule(s), rectal and colon mass(es), or rectal and colon polyp(s).

The examination procedures used in this trial also identify benign abnormalities such as colon diverticuli seen on flexible sigmoidoscopy or heart enlargement seen on chest x-ray. These are reported to the participants and their physicians. Training and qualifications of the examiners and documentation, reporting, and quality assurance procedures for each screening test are described in detail in the relevant chapters of the trial's manual of operations and procedures. Details of the quality assurance procedures for the trial appear in another paper in this supplement [123].

### **Rescreening Protocol**

For individuals with negative screens, a scheduling and tracking procedure was implemented at each SC to ensure regular attendance at repeat screens. A similar procedure was established for individuals with findings that are considered suspicious or positive by screening, but for whom subsequent diagnostic evaluations do not reveal a prostate, lung, colorectal, or ovarian cancer.

### **Diagnostic and Therapeutic Follow-up**

As described above, a major part of the PLCO trial protocol is an active screening intervention aimed at achieving high compliance and high quality examinations. If participants are found to have an abnormality suspicious for cancer on any one of the screening tests, they are notified of their test results within about 3 weeks. These individuals are referred to a physician of their choice for appropriate diagnostic workup and treatment. The directing role of the SCs ceases after screening, communication of findings, and referral. The trial has no direct control over diagnostic and therapeutic procedures.

The trial is designed to have adequate statistical power for detecting decreases in mortality separately for each cancer site. Therefore, participants with positive screening tests must undergo appropriate diagnostic and therapeutic procedures in order for the screening process to produce an effect. An attempt was made to develop uniform diagnostic and treatment protocols for each organ during the protocol development phase. However, after lengthy discussion it was decided that the trial could not dictate medical practice. In addition, by design, the PLCO trial aims to measure the independent effects of screening and early cancer detection. The investigators wanted to avoid activities which might unfairly bias the type of cancer therapy received by participants in the screened arm. For this reason, the investigators decided not to promulgate treatment guidelines for participants with screen-detected cancers. Further, the funding agency could not pay for diagnostic and therapeutic procedures. Thus, there are no PLCO-prescribed protocols for diagnosis and therapy.

Individuals with positive findings, or with symptoms not arising as a result of a PLCO-initiated screening test, undergo diagnostic procedures determined within their own medical care environment. If requested, referral physicians are provided with standard-of-practice guidelines for diagnostic procedures by the local PLCO SC. All sequelae to screening tests and/or subsequent diagnostic procedures are identified and recorded. These include any morbid or medical events potentially associated with a positive or negative screen or a diagnostic procedure subsequent to a positive screen. Individuals diagnosed with prostate, lung, colorectal, or ovarian cancer as a result of a trial-initiated screening test are referred to qualified medical personnel for appropriate therapy. Treatment is expected to be in accordance with current accepted practice for appropriate stage of disease, age, and medical condition of the participant. Physicians are referred to published references such as those listed in the NIH's Physician's Data Query (PDQ) system for treatment guidelines, if requested.

Data pertaining to diagnosis and (at least initial) treatment of all PLCO cancers are collected in both the screened and control arms of the trial to enable uniform staging and other prognostic criteria to be applied. In addition, the SCs actively track participants with screening test abnormalities and actively seek, collect, assemble, organize, and abstract medical record information related to diagnostic follow-up and treatment. These data collection activities may, and probably do, stimulate contact with physicians and diagnostic follow-up among intervention arm participants who have screening test abnormalities.

## **Endpoints**

Cause-specific mortality for each of the PLCO cancers is the primary endpoint. In addition, cancer incidence, stage shift, and case survival data will be collected and monitored as secondary endpoints to help understand and explain the results. Biologic and/or basic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Collection of endpoint data will involve several processes to ensure as far as possible complete and unbiased ascertainment of endpoints. These include both active and passive follow-up activities, as well as cause of death review procedures.

All prevalent and incident PLCO cancers and all deaths which occur among participants during the trial will be ascertained, primarily by means of an active follow-up process involving a mailed annual study update (ASU) questionnaire. The ASU asks about type and date of cancer diagnosed in the previous year. This is accompanied by a follow-up locator form approximately every other year that updates the participant's mailing address and personal contacts. Participants who do not return the ASU are contacted by repeat mailing and/or telephone. Compliance with the ASU is expected to be about 95%. SCs that are located in regions having population-based cancer registries also make use of these resources for follow-up.

The ASU activity will be supplemented by linkage to the National Death Index (NDI) to enhance completeness of endpoint ascertainment. Each SC collects and retains the information necessary to search the NDI files: name, social security number, and date of birth. Other useful information is state of birth, last known state of residence, race, and marital status. Procedures for and timing of NDI searches will be determined as the trial progresses. Although one could expect substantially complete endpoint identification using the NDI, the PLCO trial uses an active approach as the primary follow-up process in order to obtain more timely information and to promote contact with participants so as to enhance acquiring consent and clinical follow-up information should a participant develop cancer or die.

Underlying cause of death is determined for all participants who die during the trial. Since the true underlying cause may not always be evident or accurately portrayed on the death certificate, the trial will employ a death review process in order to assess cause of death in a uniform and unbiased manner. Each SC collects and makes available for the death review process all documents needed for ascertaining the underlying cause of death, including death certificates, pathology and other medical forms, available autopsy reports, and pathology slides as necessary. These documents will be reviewed by a panel of individuals with appropriate expertise who are not otherwise affiliated with the trial and who will be blinded as to the randomized arm of the deceased participants [124].

## **Etiologic and Early Marker Studies**

To support these objectives, the PLCO collects and archives (1) baseline and supplemental demographic and risk factor information on all participants, and (2) specifically-processed blood products and other tissue samples for molecular/genetic research. Serial, prospective collection of biologic samples (serum, plasma, red blood cells, and buffy coat) from screened participants will make future studies to evaluate new early detection markers of PLCO cancers inexpensive and rapid. It will also make possible molecular epidemiologic and etiologic

risk assessment studies of the highest scientific quality. A full discussion of the biorepository appears in a companion paper in this supplement [122].

### Sample-Size Calculations

Sample size was calculated using the method suggested by Taylor [125], modified to allow for arbitrary magnitude of screening impact, arbitrary sample-size ratio between screened and control arms, and arbitrary levels of compliance in the screened and control arms. Let  $N_C$  be the number of individuals randomized to the control arm and  $N_S$  be the number randomized to the screened arm, with  $N_S = f N_C$ , where  $f$  is a proportionality constant. For  $0 < r < 1$ , assume the trial is designed to detect a  $(1-r) \times 100\%$  reduction in the cumulative disease-specific death rate over the duration of the trial. Also let  $P_C$  be the proportion of individuals in the control arm who comply with the usual-care protocol and  $P_S$  be the proportion of individuals in the screened group who comply with the screening protocol. The total number of disease-specific deaths needed for a one-sided  $\alpha$ -level significance test with power  $1-\beta$  is then

$$D = \frac{\{(Q_C + f Q_S) Z_{1-\alpha} - \sqrt{Q_C Q_S (1+f)} Z_\beta\}^2}{f (Q_C - Q_S)^2}$$

where  $Q_C = r + (1-r)P_C$  and  $Q_S = 1 - (1-r)P_S$ . The number of participants required in the control arm is

$$N_C = \frac{D}{(Q_C + f Q_S) R_C Y}$$

where  $Y$  is the duration of the trial from entry to end of follow-up in years and  $R_C$  is the average annual disease-specific death rate in the control arm expressed in deaths per person per year.

A one-sided hypothesis testing approach to sample-size calculation was employed based on the nature of the question being addressed. The PLCO trial is intended to provide definitive evidence of the effect of screening on cause-specific mortality compared to usual medical care, analogous to phase III placebo-controlled trials in the therapeutic setting. The focal question for each of the four cancers is whether screening reduces mortality. This is inherently a one-sided research question, implying a one-sided design and analysis approach. The question is not whether screening reduces *or* increases mortality. Determining whether screening increases mortality is not an objective of this trial. Furthermore, if the screening intervention has no effect or if it is harmful, the consequences in terms of a public health decision are the same—screening is not recommended. This further dictates a one-sided approach [126].

**Table 3a:** Cancer Mortality Rates per Person per Year (x 10<sup>-5</sup>) for Males, Estimated Using 1983-1987 Data ProstateColorectalLung

	Prostate	Colorectal	Lung

**Table 3a:** Cancer Mortality Rates per Person per Year (x 10-5) for Males, Estimated Using 1983-1987 Data ProstateColorectalLung

Age	White Males	Black Males	White Males <sup>a</sup>	White Males <sup>b</sup>
50-54	3.5	11.1	20.8	88.4
55-59	11.5	31.9	39.6	165.4
60-64	30.4	80.4	64.6	252.6
65-69	71.1	174.1	104.4	367.6
70-74	137.8	332.3	156.1	470.2
75-79	244.8	515.7	216.0	543.9
80-84	402.8	838.7	296.0	555.0
85+	606.3	937.1	378.6	441.3

<sup>a</sup> Rates for black males are very similar.

<sup>b</sup> Average rate for black males in age group 65-79 is about 13% higher.

**Table 3b:** Cancer Mortality Rates per Person per Year (x 10-5) for Females, Estimated Using 1983-1987 Data

Age	Ovarian		Colorectal	Lung
	White Females	Black Females	White Females <sup>a</sup>	White Females <sup>b</sup>
50-54	14.2	10.4	16.5	46.5
55-59	20.3	15.3	28.1	75.3
60-64	27.5	23.3	43.9	104.9
65-69	35.3	27.4	67.9	138.0
70-74	41.5	33.8	100.1	152.9
75-79	45.2	34.5	141.9	143.8
80-84	49.8	41.1	200.5	127.2
85+	44.7	35.0	289.2	103.5

<sup>a</sup> Rates for black females in age group 65-79 are about 15% higher.

<sup>b</sup> Average rate for black females in age group 65-79 is about 20% lower.

The estimation procedure is illustrated for prostate cancer for white males. Prostate cancer screening was the impetus for the trial and is the primary focus for sample-size calculations. Similar calculations can be done for the other sites using the data in Table 3. This illustration is based upon calculations done for the original design prior to the pilot phase, when the eligible age range was 60-74 years and the trial duration was 10 years from randomization for each participant.

Calculation of  $N_C$  requires an estimate of  $R_C$ . It was assumed that the trial would enroll equal numbers of participants in each of three age strata: 60-64, 65-69, and 70-74 years. Because

individuals recruited for screening trials are expected to be healthier than the general population, the usual cancer mortality rate obtained from national or registry data will overestimate the mortality rate of the participants, at least for the early part of the trial. Therefore, for a 10-year prostate cancer screening trial with men entered between the ages of 60-74, it was assumed that for the first 2 years the mortality rate in the control arm is 25% of the usual rate, for the next 3 years it is 50% of the usual rate, and for the last 5 years it equals the usual rate. The usual mortality rate was estimated by the unweighted average prostate cancer mortality rate for men ages 65-79 years. This age range was used to adjust for aging over the 10 years of the trial. The usual mortality rates from national data are shown in Table 3 [127]. The estimated rate for this example is  $R_C = 103.763 \times 10^{-5}$ .

Results of sample-size calculations for the trial are given in Table 4. These calculations assume a 10-year trial using a one-sided, 0.05-level test,  $P_C=P_S=1$ , and possible mortality reductions as shown in a screened group compared to an equal-sized, usual care group ( $f=1$ ). The sample sizes are based on mortality rates for whites. Including blacks in the trial does not substantially alter sample size. A sample size of 37,000 (rounded up from 36,221 in Table 4) screened and 37,000 controls of each gender was chosen on the following basis. A high power of at least 90% is mandatory to yield a meaningful negative result, should that happen, and to achieve a high level of scientific validity because a trial of this magnitude addressing these questions is not likely to be repeated. In addition, it was felt that for an effect of prostate cancer screening to be of public health importance, it must be at least 20% or greater, similarly for colorectal cancer screening. Given the magnitude of the lung cancer problem, it was felt that a screening effect of 10% or greater would be very important. To estimate whether a 20% effect for prostate cancer screening was realistic, two calculations were performed. The first used plausible stage shifts due to screening and survival by stage to project possible improved outcome for screen-detected cancers. The second used projections from a computer model [128]. Both gave mortality reduction estimates in the range of 25% with perfect compliance.

Power calculations are displayed in Table 5. With 37,000 men and women in each arm, the trial has power of 91% to detect a 20% mortality reduction in prostate cancer mortality and 89% power to detect a 10% lung cancer mortality reduction. The power is nearly 90% to detect a 15% colorectal cancer mortality reduction and 99% for a 20% effect. For ovarian cancer, the power is nearly 90% to detect a 35% mortality reduction.

**Table 4:** Number of Participants Ages 60-74 at Entry Needed in Each Arm of the Trial Mortality Reduction (%)

Site	Power	Mortality Reduction (%)		
		10	20	35
Prostate	0.9	153,577	36,221	15,078

**Table 4:** Number of Participants Ages 60-74 at Entry Needed in Each Arm of the Trial Mortality Reduction (%)

(males)	0.8	110,906	26,182	10,920		
Lung	0.9	76,721	18,095			
(males and females)	0.8	55,404	13,080			
Colorectum	0.9	177,208	41,794	17,397		
(males and females)	0.8	127,971	30,211	12,600		
Ovary	0.9		134,697	56,069	39,733	
(females)	0.8		97,365	40,606	28,817	

**Table 5:** Power by Percent Reduction in Mortality with 37,000 Men and 37,000 Women in Each Arm Mortality Reduction (%)

Site	Gender	Mortality Reduction (%)						
		5	10	15	20	25	30	35
Prostate	male	--	--	0.71	0.91	0.98	--	--
Lung	both genders	0.41	0.89	0.997	--	--	--	--
	female	0.17	0.41	0.69	--	--	--	--
	male	0.34	0.81	0.985	--	--	--	--
Colon/rectum	both genders	--	--	0.89	0.99	0.999	--	--
	female	--	--	0.56	0.79	0.93	--	--
	male	--	--	0.72	0.92	0.99	--	--
Ovary	female	--	--	--	0.45	0.62	0.77	0.88

It was recognized that compliance will not be perfect in either randomized group. Contamination or drop-in will occur in the control arm ( $P_C < 1$ ) and noncompliance or dropout is to be anticipated in the screened arm ( $P_S < 1$ ). The target mortality reductions of 20% for prostate and colorectal cancers and 10% for lung cancer are therefore to be interpreted as effects which the trial seeks to detect in the presence of whatever noncompliance and contamination exist in the populations. This implies that if there were perfect compliance, the mortality reductions would be greater since they would not be diminished by noncompliance.

One can assess the relationship between true effect size and level of noncompliance during the screening period by examining Table 6, which shows what the mortality reductions with perfect compliance would have to be in order to realize a 20% mortality reduction for various levels of noncompliance in the screened and control groups. For example, if 90% of participants in the screened group undergo a PSA test ( $P_S = 0.9$ ) while 20% of controls are so screened ( $P_C = 0.8$ ), then the prostate cancer mortality reduction from such screening would have to be 27% with perfect compliance for there to be a 20% effect in the presence of noncompliance. The 27% figure corresponds very closely to the modeling estimate. Thus, compliance of at least 90% and contamination of no greater than 20% for prostate cancer screening, particularly with PSA, were chosen as the target values for these parameters.

Inquiries into potential screening compliance and screening contamination for the four cancer sites being studied in this trial indicated that the ranges of reasonable target values at the time of initiation of recruitment were as shown in Table 7. In addition to direct contact with health maintenance organizations and existing SCs, published data from the 1987 National Health Interview Survey were used to gauge these effects [129, 130]. These numbers were necessarily somewhat subjective. Additional estimates were obtained directly from the trial population during the pilot phase, and further assessment will occur as the trial progresses, possibly leading to sample-size adjustment.

**Table 6:** Percent Mortality Reduction Required When Compliance Is 100% in Both Groups, Based on a Mortality Reduction of 20% in the Presence of Noncompliance, as a Function of PS and PC

Compliance in the Control Group (Pc)	Compliance in the Screened Group (PS )					
	0.5	0.6	0.7	0.8	0.9	1.0
0.5	--	100	67	50	40	33
0.6	90	71	53	42	34	29
0.7	77	56	43	36	30	26
0.8	59	45	37	31	27	24
0.9	48	39	32	28	24	22
1.0	40	33	29	25	22	20

**Table 7:** Design Comtamination and Compliance Ranges Projected by Modality

	Compliance	Contamination
Digital rectal exam	> 90%	< 20%
Prostate-specific antigen	> 90%	< 20%
CA125	> 90%	< 10%
Ovarian palpation	> 85%	< 10%
Transvaginal ultrasound	> 85%	< 10%
Sigmoidoscopy	> 85%	< 15%
Chest x-ray	> 85%	< 40%

In the context of these levels of contamination and compliance, the required true levels of mortality effect (effect size) with perfect compliance are, approximately, lung 20%, colon 25%, and prostate 25%. These requirements are consistent with expected effects based on modeling efforts [74, 75, 103].

Regarding the ovarian cancer objectives of this trial, if the mortality reduction from screening for ovarian cancer were 35%, this design would have almost a 90% power to demonstrate

this effect. However, if the mortality effect were only 25%, 84,000 screened women and an equal number of controls would be required to achieve 90% power. Thus, the ovarian component of this trial is to be viewed as a two-step process. Near the end of the screening phase of the trial, sufficient cases of ovarian cancer should accrue to provide good estimates of sensitivity for each screening modality. Specificity and predictive value can also be estimated. If as a result any one or combination of the tests appears sufficiently promising to justify a full mortality study, the female population base of this trial could be supplemented or a meta-analysis of data from this trial and other relevant studies could be done to increase power.

As noted above, in January 1996 the lower age limit for trial participation was reduced from 60 to 55 years. Given the lower mortality rates in the 55-59 age stratum, this would ordinarily imply the need for an increase in the sample size. However, this protocol change took place after the April 1995 eligibility criterion change, also noted above, to exclude men who had prior repeat PSA screening, thereby reducing the contamination level. Sample-size estimates for prostate cancer screening for the age range 55-74 years are shown in Table 8. For compliance of 90% and a revised estimate of contamination of 10-15%, a sample of 37,000 men (and therefore 37,000 women) in each trial arm is still appropriate. A similar conclusion holds for the other cancer sites as well. As mentioned, this estimate is monitored regularly during the enrollment phase of the trial to determine if adjustment is required.

**Table 8:** Number of Males Required in Each Arm to Achieve 90% Power with Age at Entry Range 55-74, as a Function of PS and PC

P <sub>C</sub>	P <sub>S</sub>		
	0.85	0.90	0.95
0.80	53,057	45,338	39,134
0.85	46,087	39,787	34,650
0.90	40,440	35,225	30,918

Based upon the monitoring of design parameters, further protocol modifications were adopted in December 1998. These were to change from a 3-year to a 5-year interval for flexible sigmoidoscopy for individuals who had not yet had their second exam, and at the same time add year 4 and 5 PSA and CA125 tests. Also, the remaining third annual chest x-ray exams are offered only to current or former smokers, and follow-up is extended 3 years, so that all participants will be followed at least 13 years from randomization. A final change was that the ovarian palpation exam, which had been part of the original protocol, was eliminated.

The interval between flexible sigmoidoscopy was lengthened to coincide with recommendations in the community and based upon preliminary information suggesting that sigmoidoscopy at 3 years finds polyps, but very few are likely to be of any significance. A delay of 2 years was expected to yield more polyps and cancers, leading to a greater potential for mortality reduction. The addition of 2 extra years of PSA and CA125 blood tests and at least 3 additional years of follow-up were adopted to provide assurance of sufficient screening effect and statistical power in the event that initial design assumptions were incorrect. The final round of chest x-ray testing for individuals who never smoked was eliminated because of the very low yield of this exam. Finally, the ovarian palpation exam was deleted because of very low yield and the fact that a very high proportion of women participating in the trial regularly underwent pelvic examination, thereby diluting any possible effect of the palpation exam.

## Data Reporting

The data management system for the trial has the following operational requirements: ability for the NCI and the CC to access SCs remotely, synchronization of databases on multiple platforms, preparation of high quality analysis datasets, secure backup and archiving of data, and robust configuration management. Data are exchanged via a distributed data entry system and are transmitted among collaborators via common carrier service using modems, with transmission to the NIH mainframe on a regular basis. A detailed description of the system is provided in a companion manuscript in this supplement [131].

Various forms were developed for collection of information in this trial. Included are eligibility and consent forms, male and female versions of the baseline questionnaire, a dietary questionnaire, examination forms for each screening procedure, diagnostic evaluation and treatment forms, and a questionnaire for regular follow-up of participants. Additional forms are developed as needed as the trial progresses. Most forms are scanned into the data system. All trial forms are catalogued in the trial's manual of operations and procedures.

Pertinent data items include but are not necessarily restricted to the following:

1. participant trial identification number;
2. participant demographic and risk factor information;
3. participant randomized group, date of birth, and date of entry into the trial;
4. date and result of each screening test for each screened group participant;
5. sufficient information regarding diagnostic procedures performed as a result of a positive or suspicious screening test to allow determination of whether a cancer was or was not diagnosed as a result of screening;
6. for all screening tests, detailed physical findings and any complications or morbid events possibly associated with the test, and description of any diagnostic procedures subsequent to a positive test;
7. for every PLCO cancer diagnosed during the trial in both randomized groups, date of diagnosis, histology and stage at diagnosis, and initial therapy;
8. for every death which occurs during the trial in both randomized groups, date of death and cause of death as noted on the death certificate, coded using the ICD-9-CM classification.

### **Data Analysis Plan**

Analytical methods used will include standard descriptive statistics and techniques such as regression, analysis of variance and covariance, analysis of rates and proportions, contingency table methods, and analysis of survival data. New methods of analysis or modeling will be developed and applied as needed.

Topics addressed in the pilot phase included recruitment progress and problems, evaluation of randomization and the delivery of screening, participant follow-up, compliance, contamination, assessment of quality assurance practices, evaluation of the distributed data entry system, evaluation of data forms processing and information flow, and operation of the biorepository. Intra- and intercenter comparisons in the above mentioned areas are conducted using descriptive statistics to monitor progress and practices. Compliance and contamination are examined, and quality assurance is monitored using summary statistics on screening results and comparing screening exams with quality assurance exams.

Topics to be addressed in the main phase include the following:

1. quality assurance, recruitment, delivery of screening, follow-up, compliance, contamination, and information system evaluation—all continued from the pilot phase;
2. characteristics of the enrolled population;
3. determination of screening test operating characteristics including sensitivity, specificity, and predictive value;
4. prevalence and incidence;
5. characteristics of the four PLCO cancers including stage, histology, survival, prognostic variables, and interval versus screen-detected cases;
6. .lead-time estimation and modeling;
7. incidence rates of interval cancers and advanced stage disease;
8. cause-specific and all-cause mortality;
9. therapy of cancer cases;
10. complications of interventions;
11. surrogate endpoints;
12. cost variables;
13. quality of life.

Each of these areas will be examined for the trial overall, and variability among SCs will be investigated. Cancer site-specific mortality rates for each of the four PLCO cancers will be calculated and compared between the screened arm and the control arm on an intent-to-treat basis as the primary analyses in this trial. These mortality rates are calculated as the number of cause-specific deaths per 1000 person-years at risk among all individuals randomized to a given arm of the trial. In addition, the death rates from other causes and total mortality will be scrutinized to assess the comparability of the randomized populations. The rates will be calculated from time of entry, yearly and cumulatively, by age group at entry and for all ages combined, and by gender and for both genders combined where appropriate. These rates will be compared using Poisson tests, Poisson regression analysis, and the log-rank test. Stratification will be taken into account. Since it is likely that the mortality or hazard rates in the screened and control arms of this trial will not be proportional throughout the trial, statistical methods which apply to this situation will also be considered.

Sensitivity, specificity, and predictive value will be estimated for each screening test and test combination for each cancer site for each screen. After the completion of screening, overall estimation of these parameters will be undertaken. In addition to the standard calculation of sensitivity as the ratio of screen-detected cases to all cases found through some interval after a screen, usually 1 year, a second method will be employed which uses the proportion of expected incidence in time periods after a negative screen [132]. Prevalence will be calculated as the number of cancers detected per 1000 individuals screened on the first screen for each cancer site and SC, and pooled to indicate overall prevalence. Incidence will be similarly calculated as the number of cancers per 1000 person-years at risk. Incidence rates will be calculated yearly and cumulatively over the course of the trial. The ratio of prevalence to incidence will be used as an estimate of the mean duration of preclinical disease.

For cancer case characteristics such as stage and histology that carry prognostic implications, the distribution of each characteristic will be calculated for each cancer site among usual care group cases, all screened group cases, screen-detected cases, and interval cases. The distributions can be compared using chi-square tests. Survival distributions will also be calculated for the same subsets of cancer cases using the Kaplan-Meier method and compared using the log-rank test and Cox proportional hazards regression methods. These distributions will be calculated cumulatively through each successive year of the trial to assess whether there is some suggestion of screening benefit. However, these intermediate endpoints cannot be relied upon for definitive evaluation because they are subject to lead-time and length biases.

Estimation of lead time is important as an intermediate indicator of the early detection capability of the screening procedures in the trial. Average lead time will initially be estimated using the prevalence-to-incidence ratio under the assumption of an exponential distribution of preclinical duration. After screening has been completed, other modeling approaches will be employed. These include the Day-Walter model [133, 134], which allows estimation of the lead-time distribution, and newer approaches that examine differences in long-term case survival rates to estimate mean lead time [135, 136].

The specific therapy used for each PLCO cancer will be collected in the screened and control populations within each disease stage. These data will be examined to assess whether, within each stage of disease, therapy is comparable between randomized groups in order to eliminate any confounding effect of therapy in assessing the impact of the screening protocol. Treatment distributions can be compared using chi-square procedures. In addition, there will be consideration of alternative endpoints which can act as a surrogate for mortality, but which can be ascertained sooner, perhaps at reduced cost. Possible surrogates include advanced stage rate [137], functions of stage or other cancer case characteristics, or functions of lead time.

Complications of the screening, diagnostic, and treatment procedures administered to trial participants will be monitored. These include any medical complications or risks and any mortality potentially related to trial procedures, particularly the more-invasive procedures such as colonoscopy or laparotomy which might follow a positive colorectal screen or ovarian screen, respectively. These will be examined for each cancer site and each SC at least for each month up to 1 year after a screening episode. Cancer incidence will also be tracked carefully to alert the investigators to the possibility of substantial overdiagnosis of one of the cancers being studied. This is thought to be a problem particularly for prostate cancer. Guidelines for termination in the event of adverse effects of the screening process will also be developed by the MAP.

Sequential monitoring will be an integral part of this trial and will be conducted separately for each PLCO cancer site. Statistical monitoring guidelines have been established by the trial investigators and the MAP to use in periodic examinations of the emerging data from the trial to decide on continuation or termination. Beginning in study year 9, the accruing mortality data and secondary endpoints will be examined annually by the MAP, which will determine if and when a protocol change is warranted that would result in an early decision about screening for one or more of the cancer sites. The data will be analyzed in two ways—one addressing the prospect of termination due to a significantly large effect, and one focusing on early termination due to a negligible effect. For early termination with a large effect, a variant of the O'Brien-Fleming boundary arising from Method 1 of Lan and DeMets [138] will be used. The test statistic will be a weighted log-rank statistic with weights linear in cumulative mortality. Choice of this combination of boundary and weights was based on power computation conducted using simulation methods. For early termination with a negligible effect, the stochastic curtailment procedure on Lin, Yao, and Ying [139] will be implemented. This procedure makes allowance for nonproportional hazards, frequently encountered in a screening trial.

## DISCUSSION

The PLCO trial represents a major commitment of resources and personnel designed to evaluate early detection procedures that have great potential to reduce the burden of cancer in the population of the United States as well as other countries. The four cancers targeted for intervention are among the major sources of cancer incidence and mortality in the United States in the targeted age group. Within the constraints of the design assumptions, the sample size is sufficient to ensure scientifically valid assessment of the impact of the screening tests on cause-specific mortality. In addition, the trial will investigate secondary endpoints and disease natural history questions, and will provide data that can be used to address relationships among costs, risks, and benefits.

The screening tests being examined in this trial have been in use for many years, if not decades, but until now none has been rigorously evaluated in a proper scientific trial. The prospective randomized design was chosen for this undertaking because of the uncertainty in interpretation of observational studies of cancer screening due to selection bias and the difficulty in understanding the reasons for changes over time in population cancer rates. Furthermore, it was decided to assess intervention for four cancers in one trial to take advantage of the cost savings achieved by having one administrative structure and one CC, as well as to mimic to some extent the multiphasic nature of screening in the community.

The PLCO timetable calls for recruitment to be completed in the year 2001 with follow-up continuing for another 13 years. The accruing data will be monitored on a regular basis, so that any findings on the main mortality outcome endpoints which occur sooner can be reported promptly. For any of the four cancer sites being studied, if the findings are positive, the trial will provide a quantitative estimate of the effect which will be used in cost-effectiveness planning for public health purposes. Negative findings will provide scientific evidence for abandoning a test and shifting resources elsewhere.

## REFERENCES

1. Silverberg E, Lubera JA. Cancer statistics, 1989. *CA Cancer J Clin* 1989;39(1):3-20.
2. Cancer Facts & Figures-2000. Pub 00-300M-No.5008.00 Atlanta: American Cancer Society; 2000.
3. Gallion HH, van Nagell JR, Donaldson ES, et al. Adjuvant oral alkylating chemotherapy in patients with stage I epithelial ovarian cancer. *Cancer* 1989;63(6):1070-1073.
4. Gilbertsen VA. Cancer of the prostate gland. Results of early diagnosis and therapy undertaken for cure of the disease. *JAMA* 1971;215(1):81-84.
5. Jenson CB, Shahon DB, Wangenstein OH. Evaluation of annual examinations in the detection of cancer. *JAMA* 1960;174(14):1783-1788.
6. Chodak GW, Schoenberg HW. Early detection of prostate cancer by routine screening. *JAMA* 1984;252(23):3261-3264.
7. Chodak GW, Keller P, Schoenberg HW. Assessment of screening for prostate cancer using the digital rectal examination. *J Urol* 1989;141(5):1136-1138.
8. Cooner WH, Mosley BR, Rutherford CL Jr, et al. Clinical application of transrectal ultrasonography and prostate specific antigen in the search for prostate cancer. *J Urol* 1988;139(4):758-761.
9. Babaian RJ, Mettlin C, Kane R, et al. The relationship of prostate-specific antigen to digital rectal examination and transrectal ultrasonography. Findings of the American Cancer Society National Prostate Cancer Detection Project. *Cancer* 1992;69(5):1195-1200.
10. Thompson IM, Ernst JJ, Gangai MP, et al. Adenocarcinoma of the prostate: results of routine urological screening. *J Urol* 1984;132(4):690-692.
11. Thompson IM, Rounder JB, Teague JL, et al. Impact of routine screening for adenocarcinoma of the prostate on stage distribution. *J Urol* 1987;137(3):424-426.
12. Wajsman Z, Chu TM. Detection and diagnosis of prostatic cancer. In: Murphy GP, ed. *Prostatic Cancer*. Littleton, Massachusetts: PSG Publishing; 1979.
13. Thompson IM, Zeidman EJ. Presentation and clinical course of patients ultimately succumbing to carcinoma of the prostate. *Scand J Urol Nephrol* 1991;25(2):111-114.
14. Resnick MI. Editorial comment. In: Rattiff TL, Catalona WJ, eds. *Genitourinary Cancer*. Boston: Martinus Nijhoff Publishers; 1987:94-99.
15. Friedman GD, Hiatt RA, Quesenberry CP Jr, et al. Case-control study of screening for prostatic cancer by digital rectal examinations. *Lancet* 1991;337(8756):1526-1529.
16. Chodak GW, Schoenberg HW. Progress and problems in screening for carcinoma of the prostate. *World J Surg* 1989;13(1):60-64.

17. Chodak GW, Wald V, Parmer E, et al. Comparison of digital examination and transrectal ultrasonography for the diagnosis of prostatic cancer. *J Urol* 1986;135(5):951-954.
18. Clements R, Griffiths GJ, Peeling WB, et al. How accurate is the index finger? A comparison of digital and ultrasound examination of the prostatic nodule. *Clin Radiol* 1988;39(1):87-89.
19. Lee F, Littrup PJ, Torp-Pedersen ST, et al. Prostate cancer: comparison of transrectal US and digital rectal examination for screening. *Radiology* 1988;168(2):389-394.
20. Lee F, Torp-Pedersen S, Littrup PJ, et al. Hypoechoic lesions of the prostate: clinical relevance of tumor size, digital rectal examination, and prostate-specific antigen. *Radiology* 1989;170(1 pt 1):29-32.
21. McClennan BL. Transrectal US of the prostate: is the technology leading the science? *Radiology* 1988;168(2):571-575.
22. Torp-Pedersen ST, Littrup PJ, Lee F, et al. Early prostate cancer: diagnostic costs of screening transrectal US and digital rectal examination. *Radiology* 1988;169(2):351-354.
23. Waterhouse RL, Resnick MI. The use of transrectal prostatic ultrasonography in the evaluation of patients with prostatic carcinoma. *J Urol* 1989;141(2):233-239.
24. Lange PH, Ercole CJ, Lightner DJ, et al. The value of serum prostate specific antigen determinations before and after radical prostatectomy. *J Urol* 1989;141(4):873-879.
25. Oesterling JE, Chan DW, Epstein JI, et al. Prostate specific antigen in the preoperative and postoperative evaluation of localized prostatic cancer treated with radical prostatectomy. *J Urol* 1988;139(4):766-772.
26. Stamey TA, Yang N, Hay AR, et al. Prostate-specific antigen as a serum marker for adenocarcinoma of the prostate. *N Engl J Med* 1987;317(15):909-916.
27. Partin AW, Oesterling JE. The clinical usefulness of prostate specific antigen: update 1994. *J Urol* 1994;152(5 pt 2):1358-1368.
28. Coley CM, Barry MJ, Fleming C, et al. Early detection of prostate cancer. Part I: Prior probability and effectiveness of tests. The American College of Physicians. *Ann Intern Med* 1997;126(5):394-406.
29. Brawer MK, Chetner MP, Beatie J, et al. Screening for prostatic carcinoma with prostate specific antigen. *J Urol* 1992;147(3 pt 2):841-845.
30. Catalona WJ, Smith DS, Ratliff TL, et al. Measurement of prostate-specific antigen in serum as a screening test for prostate cancer. *New Engl J Med* 1991;324(17):1156-1161.
31. Carter HB, Pearson JD, Metter EJ, et al. Longitudinal evaluation of prostate-specific antigen levels in men with and without prostate disease. *JAMA* 1992;267(16):2215-2220.

32. Benson MC, Whang IS, Pantuck A, et al. Prostate specific antigen density: a means of distinguishing benign prostatic hypertrophy and prostate cancer. *J Urol* 1992;147(3 pt 2):815-816.
33. Kane RA, Littrup PJ, Babaian R, et al. Prostate-specific antigen levels in 1695 men without evidence of prostate cancer. Findings of the American Cancer Society National Prostate Cancer Detection Project. *Cancer* 1992;69(5):1201-1207.
34. Oesterling JE. Prostate-specific antigen: improving its ability to diagnose early prostate cancer. *JAMA* 1992;267(16):2236-2238.
35. Lee F, Littrup PJ, Loft-Christensen L, et al. Predicted prostate specific antigen results using transrectal ultrasound gland volume. Differentiation of benign prostatic hyperplasia and prostate cancer. *Cancer* 1992;70(1 suppl):211-220.
36. Bangma CH, Grobbee DE, Schroder FH. Volume adjustment for intermediate prostate-specific antigen values in a screening population. *Eur J Cancer* 1995;31A(1):12-14.
37. Demura T, Watarai Y, Togashi M, et al. Measurement of prostate specific antigen and gamma-seminoprotein ratio: a new means of distinguishing benign prostatic hyperplasia and prostate cancer. *J Urol* 1993;150(5 pt 2):1740-1745.
38. Lilja H. Significance of different molecular forms of serum PSA. The free, noncomplexed form of PSA versus that complexed to alpha 1-antichymotrypsin. *Urol Clin North Am* 1993;20(4):681-686.
39. Bangma CH, Kranse R, Blijenberg BG, et al. The value of screening tests in the detection of prostate cancer. Part I: Results of a retrospective evaluation of 1726 men. *Urology* 1995;46(6):773-778.
40. Vashi AR, Wojno KJ, Henricks W, et al. Determination of the "reflex range" and appropriate cutpoints for percent free prostate-specific antigen in 413 men referred for prostatic evaluation using the AxSYM system. *Urology* 1997;49(1):19-27.
41. Cooner WH, Mosley BR, Rutherford CL Jr, et al. Prostate cancer detection in a clinical urological practice by ultrasonography, digital rectal examination and prostate specific antigen. *J Urol* 1990;143(6):1146-1154.
42. Johansson JE, Adami HO, Andersson SO, et al. Natural history of localised prostatic cancer. A population-based study in 223 untreated patients. *Lancet* 1989;1(8642):799-803.
43. Miller GJ. Histopathology of prostate cancer: prediction of malignant behavior and correlation with ultrasonography. *Urology* 1989;33(6 suppl):18-26.
44. Kramer BS, Brown ML, Prorok PC, et al. Prostate cancer screening: what we know and what we need to know. *Ann Intern Med* 1993;119(9):914-923.
45. Chodak GW, Thisted RA, Gerber GS, et al. Results of conservative management of clinically localized prostate cancer. *New Engl J Med* 1994;330(4):242-248.

46. Fleming C, Wasson JH, Albertsen PC, et al. A decision analysis of alternative treatment strategies for clinically localized prostate cancer. Prostate Patient Outcomes Research Team. *JAMA* 1993;269(20):2650-2658.
47. Barry MJ, Fleming C, Coley CM, et al. Should Medicare provide reimbursement for prostate-specific antigen testing for early detection of prostate cancer? Part IV: Estimating the risks and benefits of an early detection program. *Urology* 1995;46(4):445-461.
48. Beck JR, Kattan MW, Miles BJ. A critique of the decision analysis for clinically localized prostate cancer. *J Urol* 1994;152(5 pt 2):1894-1899.
49. Lu-Yao GL, Yao S. Population-based study of long-term survival in patients with clinically localised prostate cancer. *Lancet* 1997;349(9056):906-910.
50. Prestigiacomo AF, Stamey TA. Physiological variation of serum prostate specific antigen in the 4.0 to 10.0 ng./ml. range in male volunteers. *J Urol* 1996;155(6):1977-1980.
51. Schroder FH, Bangma CH. The European randomized study of screening for prostate cancer (ERSPC). *Br J Urol* 1997;79(suppl 1):68-71.
52. Auvinen A, Rietbergen JB, Denis LJ, et al. Prospective evaluation plan for randomized trials of prostate cancer screening. The International Prostate Cancer Screening Trial Evaluation Group. *J Med Screen* 1996;3(2):97-104.
53. Boucot KR, Weiss W. Is curable lung cancer detected by semiannual screening? *JAMA* 1973;224(10):1361-1365.
54. Lilienfeld A, Archer PG, Burnett CH, et al. An evaluation of radiologic and cytologic screening for the early detection of lung cancer: a cooperative pilot study of the American Cancer Society and the Veterans Administration. *Cancer Res* 1966;26(10):2083-2121.
55. Nash FA, Morgan JM, Tomkins JG. South London lung cancer study. *Br Med J* 1968;2(607):715-721.
56. Brett GZ. The value of lung cancer detection by six-monthly chest radiographs. *Thorax* 1968;23(4):414-420.
57. Brett GZ. Earlier diagnosis and survival in lung cancer. *Br Med J* 1969;4(678):260-262.
58. Dales LG, Friedman GD, Collen MF. Evaluating periodic multiphasic health checkups: a controlled trial. *J Chronic Dis* 1979;32(5):385-404.
59. Friedman GD, Collen MF, Fireman BH. Multiphasic health checkup evaluation: a 16-year follow-up. *J Chronic Dis* 1986;39(6):453-463.
60. Cole P, Morrison AS. Basic issues in population screening for cancer. *J Natl Cancer Inst* 1980;64(5):1263-1272.
61. Prorok PC, Connor RJ. Screening for the early detection of cancer. *Cancer Invest* 1986;4(3):225-238.

62. Kubik A, Polak J. Lung cancer detection. Results of a randomized prospective study in Czechoslovakia. *Cancer* 1986;57(12):2427-2437.
63. Kubik A, Parkin DM, Khlát M, et al. Lack of benefit from semi-annual screening for cancer of the lung: follow-up report of a randomized controlled trial on a population of high-risk males in Czechoslovakia. *Int J Cancer* 1990;45(1):26-33.
64. Ebeling K, Nischan P. Screening for lung cancer—results from a case-control study. *Int J Cancer* 1987;40(2):141-144.
65. Sobue T, Suzuki T, Naruke T. A case-control study for evaluating lung-cancer screening in Japan. Japanese Lung-Cancer Screening Group. *Int J Cancer* 1992;50(2):230-237.
66. Fontana RS. Early detection of lung cancer: the Mayo Lung Project. In: Prorok PC, Miller AB, eds. *Screening for Cancer. I - General Principles on Evaluation of Screening for Cancer and Screening for Lung, Bladder and Oral Cancer*; vol 78. Geneva: UICC Technical Report Series; 1984:107-122.
67. Fontana RS. Screening for lung cancer. In: Miller AB, ed. *Screening for Cancer*. New York: Academic Press; 1985:377-395.
68. Fontana RS. Screening for lung cancer: recent experience in the United States. In: Hansen HH, ed. *Lung Cancer: Basic and Clinical Aspects*. Boston: Martinus Nijhoff Publishers; 1986:91-111.
69. Levin ML, Tockman MS, Frost JK, et al. Lung cancer mortality in males screened by chest X-ray and cytologic sputum examination: a preliminary report. *Recent Results Cancer Res* 1982;82:138-146.
70. Stitik FP, Tockman MS. Radiographic screening in the early detection of lung cancer. *Radiol Clin North Am* 1978;16(3):347-366.
71. Stitik FP, Tockman MS, Khouri NF. Chest radiology. In: Miller AB, ed. *Screening for Cancer*. New York: Academic Press; 1985:163-191.
72. Tockman MS, Frost JK, Stitik FP, et al. Screening and detection of lung cancer. In: Aisner J, ed. *Lung Cancer*. New York: Churchill Livingstone; 1985:25-39.
73. Melamed MR, Flehinger BJ, Zaman MB, et al. Detection of true pathologic stage I lung cancer in a screening program and the effect on survival. *Cancer* 1981;47(5 suppl):1182-1187.
74. Melamed MR, Flehinger BJ, Zaman MB, et al. Screening for early lung cancer. Results of the Memorial Sloan-Kettering study in New York. *Chest* 1984(1):44-53.
75. Flehinger BJ, Kimmel M. The natural history of lung cancer in a periodically screened population. *Biometrics* 1987;43(1):127-144.
76. Flehinger BJ, Kimmel M, Melamed MR. Natural history of adenocarcinoma-large cell carcinoma of the lung: conclusions from screening programs in New York and Baltimore. *J Natl Cancer Inst* 1988;80(5):337-344.

77. Shukla R, Deddens JA, Buncher CR. Survival benefits of x-ray screening for lung cancer after bias adjustments. *Computers and Mathematics with Applications* 1989;18:937-948.
78. Frühmorgen P, Demling L. Early detection of colorectal cancer with a modified guaiac test - a screening examination of 6,000 humans. In: Winawer S, Schottenfeld D, Sherlock P, eds. *Progress in Cancer Research and Therapy*, vol 13. *Colorectal Cancer: Prevention, Epidemiology, and Screening*. New York: Raven Press; 1980:311-315.
79. Winawer SJ, Andrews M, Flehinger B, et al. Progress report on controlled trial of fecal occult blood testing for the detection of colorectal neoplasia. *Cancer* 1980;45(12):2959-2964.
80. Winawer SJ, Fath RB Jr, Schottenfeld D, et al. Screening for colorectal cancer. In: Miller AB, ed. *Screening for Cancer*. New York: Academic Press; 1985:347-366.
81. Selby JV, Friedman GD, Quesenberry CP Jr, et al. Effect of fecal occult blood testing on mortality from colorectal cancer. A case-control study. *Ann Intern Med* 1993;118(1):1-6.
82. Lazovich D, Weiss NS, Stevens NG, et al. A case-control study to evaluate efficacy of screening for faecal occult blood. *J Med Screen* 1995;2(2):84-89.
83. Winawer SJ, Flehinger BJ, Schottenfeld D, et al. Screening for colorectal cancer with fecal occult blood testing and sigmoidoscopy. *J Natl Cancer Inst* 1993;85(16):1311-1318.
84. Mandel JS, Bond JH, Church TR, et al. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. *N Eng J Med* 1993;328(19):1365-1371.
85. Hardcastle JD, Chamberlain JO, Robinson MH, et al. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. *Lancet* 1996;348(9040):1472-1477.
86. Kewenter J, Bjork S, Haglind E, et al. Screening and rescreening for colorectal cancer. A controlled trial of fecal occult blood testing in 27,700 subjects. *Cancer* 1988;62(3):645-651.
87. Kronborg O, Fenger C, Snergaard O, et al. Initial mass screening for colorectal cancer with fecal occult blood test. *Scand J Gastroenterol* 1987;22(6):677-686.
88. Kronborg O, Fenger C, Olsen J, et al. Repeated screening for colorectal cancer with fecal occult blood test. A prospective randomized study at Funen, Denmark. *Scand J Gastroenterol* 1989;24(5):599-606.
89. Kronborg O, Fenger C, Olsen J, et al. Randomized study of screening for colorectal cancer with faecal-occult-blood test. *Lancet* 1996;348(9040):1467-1471.
90. Guidelines for the cancer-related chec kup: recommendations and rationale. *CA Cancer J Clin* 1980;30(4):194-240.

91. Morrison AS. *Screening in Chronic Disease*. New York: Oxford University Press; 1985.
92. Selby JV, Friedman GD, Collen MF. Sigmoidoscopy and mortality from colorectal cancer: the Kaiser Permanente Multiphasic Evaluation Study. *J Clin Epidemiol* 1988;41(5):427-434.
93. Herrinton LJ, Selby JV, Friedman GD, et al. Case-control study of digital-rectal screening in relation to mortality from cancer of the distal rectum. *Am J Epidemiol* 1995;142(9):961-964.
94. Gilbertsen VA. Proctosigmoidoscopy and polypectomy in reducing the incidence of rectal cancer. *Cancer* 1974; 34(3 suppl):936-939.
95. Gilbertsen VA, Nelms JM. The prevention of invasive cancer of the rectum. *Cancer* 1978;41(3):1137-1139.
96. Hertz RE. Value of periodic examinations in detecting cancer of the colon and rectum. *Postgrad Med* 1960;27:290-294.
97. Crespi M, Weissman GS, Gilbertsen VA, et al. The role of proctosigmoidoscopy in screening for colorectal neoplasia. *CA Cancer J Clin* 1984;34(3):158-166.
98. Winawer SJ, Miller C, Lightdale C, et al. Patient response to sigmoidoscopy. A randomized, controlled trial of rigid and flexible sigmoidoscopy. *Cancer* 1987;60(8):1905-1908.
99. Winawer SJ, Zauber AG, Ho MN, et al. Prevention of colorectal cancer by colonoscopic polypectomy. The National Polyp Study Workgroup. *New Eng J Med* 1993;329(27):1977-1981.
100. Chamberlain J, Day NE, Hakama M, et al. UICC workshop of the Project on Evaluation of Screening Programmes for Gastrointestinal Cancer. *Int J Cancer* 1986;37(3):329-334.
101. Neugut AI, Pita S. Role of sigmoidoscopy in screening for colorectal cancer: a critical review. *Gastroenterology* 1988;95(2):492-499.
102. Eddy DM, Nugent FW, Eddy JF, et al. Screening for colorectal cancer in a high-risk population. Results of a mathematical model. *Gastroenterology* 1987;92(3):682-692.
103. Eddy DM. Screening for colorectal cancer. *Ann Intern Med* 1990;113(5):373-384.
104. Newcomb PA, Norfleet RG, Storer BE, et al. Screening sigmoidoscopy and colorectal cancer mortality. *J Natl Cancer Inst* 1992;84(20):1572-1575.
105. Selby JV, Friedman GD, Quesenberry CP Jr, et al. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. *New Engl J Med* 1992;326(10):653-657.
106. Granberg S, Wikland M, Jansson I. Macroscopic characterization of ovarian tumors and the relation to the histological diagnosis: criteria to be used for ultrasound evaluation. *Gynecol Oncol* 1989;35(2):139-144.

107. Jacobs I, Bast RC Jr. The CA 125 tumour-associated antigen: a review of the literature. *Hum Reprod* 1989;4(1):1-12.
108. Einhorn N, Sjøvall K, Knapp RC, et al. Prospective evaluation of serum CA 125 levels for early detection of ovarian cancer. *Obstet Gynecol* 1992;80(1):14-18.
109. Helzlsouer KJ, Bush TL, Alberg AJ, et al. Prospective study of serum CA-125 levels as markers of ovarian cancer. *JAMA* 1993;269(9):1123-1126.
110. Zurawski VR Jr, Orjaseter H, Andersen A, et al. Elevated serum CA 125 levels prior to diagnosis of ovarian neoplasia: relevance for early detection of ovarian cancer. *Int J Cancer* 1988;42(5):677-680.
111. Higgins RV, van Nagell JR Jr, Woods CH, et al. Interobserver variation in ovarian measurements using transvaginal sonography. *Gynecol Oncol* 1990;39(1):69-71.
112. van Nagell JR Jr, Higgins RV, Donaldson ES, et al. Transvaginal sonography as a screening method for ovarian cancer. A Report of the first 1000 cases screened. *Cancer* 1990;65(3):573-577.
113. Andolf E, Jorgensen C, Astedt B. Ultrasound examination for detection of ovarian carcinoma in risk groups. *Obstet Gynecol* 1990;75(1):106-109.
114. Campbell S, Bhan V, Royston P, et al. Transabdominal ultrasound screening for early ovarian cancer. *BMJ* 1989;299(6712):1363-1367.
115. DePriest PD, van Nagell JR Jr, Gallion HH, et al. Ovarian cancer screening in asymptomatic postmenopausal women. *Gynecol Oncol* 1993; 51(2):205-209.
116. Bourne TH, Campbell S, Reynolds KM, et al. Screening for early familial ovarian cancer with transvaginal ultrasonography and colour blood flow imaging. *BMJ* 1993;306(6884):1025-1029.
117. Freedman LS, Green SB. Statistical designs for investigating several interventions in the same study: methods for cancer prevention trials. *J Natl Cancer Inst* 1990;82(11):910-914.
118. Etzioni RD, Connor RJ, Prorok PC, et al. Design and analysis of cancer screening trials. *Stat Methods Med Res* 1995;4(1):3-17.
119. Shapiro S, Venet W, Strax P, et al. *Periodic Screening for Breast Cancer. The Health Insurance Plan project and its sequelae, 1963-1986*. Baltimore: The Johns Hopkins University Press; 1988.
120. Tabar L, Fagerberg G, Duffy SW, et al. Update of the Swedish two-county program of mammographic screening for breast cancer. *Radiologic Clin North Am* 1992;30(1):187-210.
121. Simpson NK, Johnson CC, Ogden SL, et al. Recruitment strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: the first six years. *Control Clin Trials* \*\* THIS SUPPLEMENT \*\*

122. Hayes RB, Reding D, Kopp W, et al. Etiologic and early marker studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. *Control Clin Trials* \*\* THIS SUPPLEMENT \*\*
123. Weissfeld JL, Fagerstrom RM, O'Brien B. Quality control of cancer screening examination procedures in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. *Control Clin Trials* \*\* THIS SUPPLEMENT \*\*
124. Miller AB, Yurgalevitch S, Weissfeld JL. Death review process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. *Control Clin Trials* \*\* THIS SUPPLEMENT \*\*
125. Taylor WF, Fontana RS. Biometric design of the Mayo Lung Project for early detection and localization of bronchogenic carcinoma. *Cancer* 1972; 30(5):1344-1347.
126. Dunnett CW, Gent M. An alternative to the use of two-sided tests in clinical trials. *Stat Med* 1996; 15(16):1729-38.
127. 1987 Annual Cancer Statistics Review, Including Cancer Trends: 1950-1985. Bethesda, MD: National Cancer Institute, Division of Cancer Prevention and Control; NIH Publication No. 88-2789; 1988.
128. Potosky AL, Annett DQ, Coyle L. Guide to using CAN\*TROL, version 2.0. Bethesda, MD: National Cancer Institute, Division of Cancer Prevention and Control; 1995.
129. Brown ML, Potosky AL, Thompson GB, et al. The knowledge and use of screening tests for colorectal and prostate cancer: data from the 1987 National Health Interview survey. *Prev Med* 1990; 19(5):562-574.
130. Polednak AP. Knowledge of colorectal cancer and use of screening tests in persons 40-74 years of age. *Prev Med* 1990; 19(2):213-226.
131. Hasson MA, Fagerstrom RM, Kahane DC, et al. Design and evolution of the data management systems in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. *Control Clin Trials* \*\* THIS SUPPLEMENT \*\*
132. Day NE. Estimating the sensitivity of a screening test. *J Epidemiol Community Health* 1985; 39(4):364-366.
133. Day NE, Walter SD. Simplified models of screening for chronic disease: estimation procedures from mass screening programs. *Biometrics* 1984; 40(1):1-14.
134. Walter S, Day NE. Estimation of the duration of a pre-clinical state using screening data. *Am J Epidemiol* 1983; 118(6):865-886.
135. Kafadar K, Prorok PC. A data-analytic approach for estimating lead time and screening benefit based on survival curves in randomized cancer screening trials. *Stat Med* 1994; 13(5-7):569-586.
136. Kafadar K, Prorok PC. Estimating the difference in location parameters of two survival curves, with applications to cancer screening. *J Statist Planning Inference* 1997; 57: 165-179.

137. Day NE, Williams DRR, Khaw KT. Breast cancer screening programmes: the development of a monitoring and evaluation system. *Br J Cancer* 1989;59(6):954-958.
138. Lan KKG, DeMets DL. Group sequential procedures: calendar versus information time. *Stat Med* 1989;8(10):1191-1198.
139. Lin DY, Yao Q, Ying Z. A general theory on stochastic curtailment for censored survival data. *J Am Stat Assoc* 1999;94(446):510-521.

## **APPENDIX F**

### **Appendix F: PI-List**

**APPENDIX F: PRINCIPAL INVESTIGATORS FROM  
THE 10 SCREENING CENTERS**

## LIST OF PRINCIPLE INVESTIGATORS

### University of Colorado - 01

E. David Crawford, M.D.  
Anschutz Cancer Pavilion  
1665 North Ursula Street  
P.O. Box 6510 MS 710  
Aurora, CO 80010  
Phone: (720) 848-0183  
FAX: (720) 848-0203  
E-Mail: david.crawford@uchsc.edu

### Georgetown University - 02

Edward P. Gelmann, M.D.  
Professor of Medicine and Cell Biology  
Georgetown University Medical Center  
Lombardi Cancer Research Center  
3800 Reservoir Road, N.W.  
Podium Level - Corridor B  
Washington, DC 20007  
Phone: (202) 687-2207  
FAX: (202) 444-1229  
E-Mail: gelmanne@georgetown.edu

### Pacific Health Research Institute - 03

Lance Yokochi, M.D., M.P.H.  
Pacific Health Research Institute  
839 South Beretania Street  
Honolulu, HI 96813  
Phone: (808) 545-3006  
FAX: (808) 524-5559  
E-Mail: layokochi@phrihawaii.org

### Henry Ford Health System - 04

Paul A. Kvale, M.D.  
Henry Ford Health System  
Pulmonary and Critical Care Medicine  
Dept. K-17  
2799 West Grand Blvd.  
Detroit, MI 48202  
Phone: (313) 916-2539  
FAX: (313) 916-9102  
E-Mail: pkvale1@hfhs.org

### University of Minnesota School of Public Health/ Virginia L. Piper Cancer Institute - 05

Timothy Church, Ph.D.  
Associate Professor  
EOH Health Studies Section  
University of Minnesota  
350 McNamara Alumni Center  
200 Oak Street, SE  
Minneapolis, MN 55455-2008  
Phone: (612) 625-9091  
FAX: (612) 625-4363  
E-Mail: trc@cccs.umn.edu

### Washington University School of Medicine - 06

Gerald L. Andriole, M.D.  
Washington University  
Division of Urology  
4960 Children's Place  
St. Louis, MO 63110  
Phone: (314) 362-8213  
FAX: (314) 361-2203  
E-Mail: andrioleg@msnotes.wustl.edu

### University of Pittsburgh Cancer Institute - 08

Joel L. Weissfeld, M.D. M.P.H.  
PLCO  
UPMC Cancer Pavilion, 3<sup>rd</sup> Floor  
5150 Centre Avenue  
Pittsburgh, PA 15232  
Phone: (412) 623-3313  
FAX: (412) 623-3303  
E-Mail: weissfeldjl@msx.upmc.edu

### University of Utah School of Medicine - 09

Sandra Buys, M.D.  
Oncology Division  
University of Utah  
2000 Circle of Hope, Suite 2100  
Salt Lake City, UT 84112-5550  
Phone: (801) 585-0255  
FAX: (801) 585-0159  
E-Mail: saundra.buys@hsc.utah.edu

**Marshfield Medical Research**  
and Educational Foundation - 10  
Douglas Reding, M.D., M.P.H., F.A.C.P.  
Marshfield Medical Research  
and Education Foundation  
1000 North Oak Avenue  
Marshfield, WI 54449-5790  
Phone: (715) 387-5134  
FAX: (715) 389-3535  
E-Mail: reding.douglas@marshfieldclinic.org

**University of Alabama at Birmingham -  
11**  
Mona Fouad, M.D., M.P.H.  
The University of Alabama at Birmingham  
Division of Preventive Medicine  
MTB #618  
1530 Third Avenue South  
Birmingham, AL 35294-4410  
Phone: (205) 934-2125  
FAX: (205) 934-7959  
E-Mail: mfouad@dopm.uab.edu

## **APPENDIX G**

### **Appendix G: Abbreviations**

## **G-17-1**

### List of Common Abbreviations

## ABBREVIATIONS

The following is a list of commonly used abbreviations in the Manual of Operations and Procedures:

<b>Abbreviation</b>	<b>Form Name</b>
ACC	All Cancer Confirmation
BIO	Biorepository
BRS	Biorepository System
BSI II	Biorepository Report Generation System
BUC	Buccal Cell Sample
CC	Coordinating Center
CCODE	Cancer Code
CIT	Center for Information Technology
CTR	Certified Tumor Registrar
DCEG	Division of Cancer Etiology and Genetics (NCI)
DCRT	Division of Research and Technology
DEES	Data Entry and Editing System
DIF	Data Investigation Form
DRC	Death Review Committee
DRP	Death Review Process
ESC	Etiologic Studies Consent
FCM	Final Complete
FDISP	Final Disposition
FIC	Final Incomplete
FTD	Follow-up to DIF
HCFA	Health Care Financing Administration
ICD-9-CM	International Classification of Diseases, 9 <sup>th</sup> Edition, Clinical Modification
ICD-O-2	International Classification of Diseases, Oncology
ICM	Interim Complete
ID	Identification Number
IRB	Institutional Review Board
MAP	Monitoring and Advisory Panel
MBR	Medical Background Report
MRA	Medical Record Abstract
NAME	Participant Name Table

<b>Abbreviation</b>	<b>Form Name</b>
NCI	National Cancer Institute
NCS	National Computer Systems
NDI	National Death Index
NPL	National Processing Laboratory
OFR	Open Forms Report
OTH	Other
PCC	Protocol Changes Consent
PHY	Physician
PID	Participant Identification Number
PIF	Problem Investigation Form
PLCO	Prostate, Lung, Colorectal and Ovarian
POR	Participant Overview Report
PV	Protocol Violation
REL	Relative
SC	Screening Center
SCF	Screening Consent Form
SCRF	Software Change Request Form
SMS	Study Management System
STRR	Screening Test Results Report
SY	Study Year
VS	Vital Status
WOC	Westat Online Change

The following is a list of abbreviations for PLCO Screening Trial forms

NON-OPSCAN FORMS

<b>Abbreviation</b>	<b>Form Name</b>
ADR	Additional Documentation Request (Form)
ASU	Annual Study Update
ATF	Administrative Tracking Form
BLF	Baseline Locator Form
CAN	Record of Credentials, Medical Record Abstractor and Nosologist Registration Form
CCF	Comments Continuation Form
DCF	Death Certification Verification Form

<b>Abbreviation</b>	<b>Form Name</b>
DDS	Death Documentation Sheet
DPI	Death Review Principal Investigator (Form)
ECT	Record of Experience, Credentials and Training
ES	Eligibility Screener
EVF	Eligibility Verification Form
FLF	Follow-up Locator Form
HOM	History of Malignancy (Form)
HSM	Health Status Questionnaire – Male
HSQ	Health Status Questionnaire
HSW	Health Status Questionnaire - Female
MDF	Missing Data Form
NRF	Nonresponse Form
PCR	Participant Control Record
RAE	Report of Adverse Events for NIH-Sponsored Clinical Trials

OPSCAN FORMS

<b>Abbreviation</b>	<b>Form Name</b>
BCF(3)	Blood Collection Form
BCF(3) Vanguard	Blood Collection Form - Vanguard Participants
BFF(2)	T4/T5 Blood Collection Form
BQF (3)	Baseline Questionnaire - Female
BQM(3)	Baseline Questionnaire - Male
CDQ	Cause of Death Questionnaire
DEC(3)/DCQ(3)	Diagnostic Evaluation – Colon/ Diagnostic - Colon - QA
DEL(3)/DLQ(3)	Diagnostic Evaluation – Lung/ Diagnostic - Lung - QA
DEO(3)/DOQ(3)	Diagnostic Evaluation – Ovary/ Diagnostic - Ovary - QA
DEP(3)/DPQ(3)	Diagnostic Evaluation – Prostate/ Diagnostic - Prostate - QA
DHQ	Diet History Questionnaire
DOX	Dietary Questionnaire
DRE(2)	Digital Rectal Screening Examination of the Prostate Form
DRQ(2)	Digital Rectal Screening Examination of the Prostate for Quality Assurance Form
DSS(3)	Diagnostic/Staging Procedures Supplement
FSG(2)	Flexible Sigmoidoscopy Screening Examination Form

<b>Abbreviation</b>	<b>Form Name</b>
FSQ(2)	Flexible Sigmoidoscopy Screening Examination for Quality Assurance Form
OCF/OCQ	Other Cancer Confirmation Form/Other Cancer Confirmation Form QA
TIC(2)/TCQ(2)	Treatment Information – Colon/Treatment – Colon-QA
TIL(2)/TLQ(2)	Treatment Information - Lung/Treatment – Lung-QA
TIO(2)/TDQ(2)	Treatment Information – Ovary/Treatment – Ovary-QA
TIP(2)/TPQ(2)	Treatment Information - Prostate/Treatment – Prostate-QA
TVQ(2)	Transvaginal Ultrasound Screening Examination for Quality Assurance Form
TVU(2)	Transvaginal Ultrasound Screening Examination Form
XRQ(2)	Chest X-Ray Screening Examination for Quality Assurance Form
XRY(2)	Chest X-Ray Screening Examination Form

**DISCONTINUED FORMS**

<b>Abbreviation</b>	<b>Form Name</b>
AER	Adverse Experience Form
OVR(2)	Ovarian Palpation Screening Examination Form
OVQ(2)	Ovarian Palpation Screening Examination for Quality Assurance Form
PSH	Periodic Survey of Health
SCF	Screening Consent Form
TCQ	Treatment Colorectal - QA
TLQ	Treatment Lung - QA
TOQ	Treatment Ovary - QA
TPQ	Treatment Prostate - QA

**G-17-2**

Staff Positions

## STAFF POSITIONS - SCREENING EXAMINATIONS

<b>Position</b>	<b>Abbreviation</b>	<b>Definition</b>
BLD Phlebotomist	BLD Phl	Draws Blood
BLD Processor	BLD Pro	Processes Blood
BLD Trainer/Supervisor	BLD T	Trains/Supervises Phlebotomists and Processors
DRE Examiner	DRE E	Examiner - performs DRE exams
DRE Trainer/Supervisor	DRE T	Physician - trains/supervises DRE examiners
DRE QA Examiner	DRE QA	Examiner or Physician - performs DRE exams for QA purposes
FSG Examiner	FSG E	Examiner - performs FSG exams
FSG Trainer/Supervisor	FSG T	Physician - trains/supervises FSG examiners
FSG QA Examiner	FSG QA	Physician - performs FSG exams for QA purposes
OVR Examiner	OVR E	Examiner - performs OVR exams
OVR Trainer/Supervisor	OVR T	Physician - trains/supervises OVR examiners
OVR QA Examiner	OVR QA	Physician - performs OVR exams for QA purposes
TVU Examiner	TVU E	Sonographer or Physician - performs exam
TVU Interpreter	TVU I	Sonographer or Physician - interprets film
TVU Trainer/Supervisor	TVU T	Trainer/Supervisor for sonographers
TVU QA Examiner	TVU QA	Sonographer or Physician -performs/interprets exams for QA purposes
XRY Examiner	XRY E	Radiologic Technician - takes films
XRY Interpreter	XRY I	Radiologist - interprets films
XRY Trainer/Supervisor	XRY T	Supervisor for Radiologic Technicians
XRY QA Examiner	XRY QA	Radiologist - interprets films for QA purposes

## **APPENDIX H**

### **Appendix H: Answers to Participant Questions**

**APPENDIX H: ANSWERS TO PARTICIPANT'S  
QUESTIONS**

## ANSWERS TO PARTICIPANT QUESTIONS

### Participation:

#### 1. Why should I participate?

The trial is designed to determine whether screening tests are useful in detecting prostate, lung, colorectal and ovarian cancers at an early stage, and as a result, in reducing the number of deaths from these cancers. In order to answer these questions, the participation of many people in your community is important. By participating, you can help determine if these tests will reduce cancer deaths.

#### 2. Why should I participate if I don't get the screening tests?

By participating you will make an important contribution to this research. Lung and colorectal cancers account for 46% of cancer deaths in males and 34% of cancer deaths in females. The prostate is the third major site associated with cancer deaths in men accounting for 11% of cancer deaths; in females ovarian cancer has accounted for 5% of cancer deaths. All participants have an equal chance of being in either the screened group or the control group. To determine the effect of the screening tests, it is important to compare the participants who receive the screening tests according to the study protocol, with a very similar group of study participants who follow their normal health care routine.

#### 3. Why do I have to fill out so many forms/answer so many questions?

The trial is designed to determine whether screening tests are useful in detecting prostate, lung, colorectal and ovarian cancers at an early stage, and as a result, in reducing the number of deaths from these cancers. In order to answer these research questions, we need to have certain information about your health on a yearly basis from everyone who participates. If you need some help in answering the questions or filling out the form(s), please call [SC Coordinator or designee]. S/he will be happy to help you complete the form(s).

#### 4. What other hospitals are in the study?

The PLCO Cancer Screening Trial is being conducted at ten medical centers:

- University of Colorado Health Sciences Center
- Georgetown University Medical Center, Lombardi Cancer Research Center
- Pacific Health Research Institute
- Henry Ford Health System
- University of Minnesota School of Public Health/Virginia L. Piper Cancer Institute
- Washington University School of Medicine
- University of Pittsburgh Cancer Institute
- University of Utah School of Medicine
- Marshfield Medical Research and Education Foundation
- University of Alabama at Birmingham

#### 5. I had a bad experience with the hospital/the government lately, why should I help them?

I'm sorry that your experience was a bad one. However, this is a special research effort, a controlled trial sponsored by the National Cancer Institute. We are committed

to making your participation in the study a positive experience. By participating in the study you are helping us to learn more about the effectiveness of the screening tests in detecting certain cancers at an early stage and whether early detection will reduce the mortality from these cancers.

**6. How will I benefit from the study?**

If the study shows that these screening tests are effective, then screening for these cancers will become common practice in the future. If this study shows that these screening tests do not decrease the chances of dying of these cancers, doctors will know not to use them, saving you and others unnecessary inconvenience and expense.

**Eligibility:**

**1. Am I eligible to participate in this study even though I have \_\_\_\_\_ (another serious medical problem which is not an exclusion criteria)?**

If the medical problem would not interfere with your ability to fill out the required questionnaires, [if in screened group] participate in the screening tests and if it was acceptable to your physician and to [PI] here at [SC] who is directing the study, you would be eligible to participate.

**2. If I have \_\_\_\_\_ (symptom) am I still eligible for the study?**

[If a potential participant reports a symptom s/he should be advised to make an appointment with a physician so that they symptom can be evaluated. The potential participant should be asked to contact the SC after the medical evaluation so that eligibility can be determined. The SC Coordinator could consider keeping a list of such individuals and contacting them after several weeks have passed to inquire about the outcome of the physician visit and if appropriate, encourage them to participate.]

**3. If I recently had \_\_\_\_\_ (screening exam), am I still eligible for the study?**

[If the screening examination was a PSA blood test, a sigmoidoscopy, colonoscopy or barium enema, then explain to the potential participant that s/he is not eligible for the trial. If it was some other test, the Coordinator might ask what the result was, and if normal s/he is eligible. If result was abnormal and s/he is currently undergoing diagnostic work up, s/he should contact the SC when results of work up are known.]

**4. I'm (54 years old/75 years old) why can't I be in the trial?**

The burden of disease is much lower among people less than 55 years of age. The age range 55 to 74 years of age was selected to include high risk groups for PLCO cancers. Please contact us when you reach your 55th birthday.

**Screening:**

**1. Who will be conducting these tests? Are they qualified?**

The tests will be conducted by qualified hospital/clinic staff: doctors, nurses, x-ray technicians and sonographers.

**2. Is the blood draw/digital rectal exam/flexible sigmoidoscopy/transvaginal ultrasound painful?**

The \_\_\_\_\_ is usually well tolerated but may cause mild discomfort. The doctor/nurse/technician will tell you exactly what to expect during the examination/procedure.

**3. Will you screen my husband/relative/friend?**

If your husband/relative/friend is interested in participating in the trial, s/he should call the recruitment coordinator [appropriate person at SC] to determine if s/he is eligible. Remember, an eligible participant has an equal chance of being assigned to either the screened group or the control group. If assigned to the screened group, your husband/relative/friend would receive the screening tests; if assigned to the control group, your husband/relative/friend would not receive the screening tests.

#### **Results:**

**1. If my test results are abnormal, does that mean I have cancer?**

An abnormal screening test result usually means that further testing is needed. A screening test is not intended to diagnose a disease. Some abnormal test results will be harmless conditions or conditions other than cancer which may or may not require treatment. All participants with test results which are suspicious for cancer will be referred to their doctor for diagnostic evaluation.

**2. I don't have a doctor. Who will get my test results?**

All test results will be sent to you and to the physician of your choice. If you do not have a doctor and you have an abnormal test result, we will be happy to refer you to a doctor here at [SC associated hospital].

**3. Can I have the results of my test?**

[If in a screened group: During the four years of screening, your test results will be sent to you within three weeks.] This study has been planned to continue for approximately 16 years, so the final results of the entire study will not be known until after that time.

At various times during the study, a variety of reports will be published. It is possible that some of these findings will be reported by your local newspaper. As the study progresses, you may request an address to write to for a copy of any published reports.

**4. If something abnormal is found, do I have to go to a doctor here, or can I go to my own doctor?**

You may go to the doctor of your choice. All test results will be sent to your doctor. If you would like to be referred to a doctor here at [SC], we will be happy to give you a referral list of recommended doctors.

**5. Who will see the results of my tests?**

You and the physician of your choice will be notified as to whether the results of your tests are normal or abnormal. Results will be seen by certain study personnel. All study personnel must conform to the hospital and federal regulations regarding confidentiality and must keep confidential all information provided by study participants.

**6. If I have a cancer detected in this study, will I continue to actively participate in the screening examinations?**

If the cancer is of the prostate, lung, colorectum or ovary, you would not actively participate in the screening test for the affected organ. As long as it was acceptable to you and your physician, you could actively participate in the other screening tests.

#### **Follow-Up:**

**1. What if I detect/my physician detects a health problem between screening visits?**

Screening tests are not intended to be a substitute for your usual health care. If you detect a health problem, inform your physician and make an appointment to have the problem evaluated. If you do not have a physician and would like us to refer you to a physician, just call [appropriate person at SC] and we will be happy to give you the names of recommended physicians/follow the recommendation of your physician for evaluation of the problem.

**2. Will you recommend specific diagnostic examinations if abnormalities are detected on the screening exams?**

Although we will not recommend specific diagnostic examinations, we will be happy to assist you in any way possible to obtain the best medical care. The screening center will send a letter notifying you and your physician to the results of the examinations. When abnormalities are detected, the letter states that we recommend that you make an appointment to discuss these findings with your physician. Your physician may recommend specific diagnostic examinations or refer you to a specialist who can evaluate the abnormality found on the screening examination.

If you do not have a primary care physician and would like us [SC] to provide you with a list of recommended physicians, we will be happy to do so.

**3. If my screening exams detect abnormalities, will you recommend specific doctors, if I ask, to perform a diagnostic work up?**

If the screening exams detect abnormalities and you would like us [SC] to give you a list of recommended physicians, we will be happy to do so.

**4. Will the screening center recommend specific surgeons if I ask?**

If you would like us [SC] to give you a list of recommended surgeons, we will be happy to do so.

**General Questions About Cancer:**

**1. What can I do to lower my risk of \_\_\_\_\_ cancer?**

The [Health Education/Risk Reduction/\_\_\_\_\_ Clinic here at SC\Cancer Information Service of the National Cancer Institute at 1-800-4-CANCER] has/have information about what you can do to lower your risk of cancer. I'll be glad to tell you how to contact them.

**2. If I have already been diagnosed with \_\_\_\_\_ cancer, do I have an increased risk of developing other types of cancer?**

I'll be happy to make an appointment [give you the telephone number] so you can/to speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area, and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**3. Do you have additional information on \_\_\_\_\_ cancer?**

I'll be happy to [give you the telephone number so you can/to speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**4. My relative had \_\_\_\_\_ cancer. Does that mean I'll get it too?**

Factors that are associated with an increased likelihood of developing a disease or condition, such as heart disease, obesity or cancer are called risk factors. For some cancers, having a close relative with that cancer is considered a risk factor and is believed to increase the risk. However, having an increased risk for a cancer does not mean that the person will get that cancer.

If you'd like me to, I'll be happy to make an appointment [give you the telephone number] so you can/to speak with \_\_\_\_\_ here at SC [associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**5. There's a lot of cancer in my family, that worries me.**

For some cancers, having a close relative with one of those cancers is believed to increase the likelihood that other relatives will get that cancer. However, having an increased risk for a cancer does not mean that the person will get that cancer.

If you like, I'll be happy to make an appointment [give you the telephone number] so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**6. My relative was recently diagnosed with \_\_\_\_\_ cancer. I wonder if s/he's getting the right treatment?**

I'll be happy to make an appointment [give you the telephone number] so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**7. Do you have a support group for individuals who have \_\_\_\_\_ cancer?**

Yes, I'll be happy to give you the name and telephone number of the contact person/ I'm not sure, so I will give you the telephone number of \_\_\_\_\_ here at [SC associated medical center] who will know what support groups are available/give you the telephone number of Cancer Information Service of the National Cancer Institute, 1-800-4-CANCER. Either one can tell you what support groups are available.

**8. I think I am at high risk for cancer and I should be in the group that receives the screening tests.**

At this time, it is not known whether screening is beneficial or not beneficial for those at high risk.

All participants in the PLCO Trial consent to be assigned by a random statistical process to the screened group or the control group. An eligible participant has an equal chance to being assigned to either group.

## **Appendix I: Cancer Codes**

**I-1-1**

Cancer Code List

## CANCER CODE LIST

(To be used on the ASU, BQF, BQM, OCF, and MDF)

Code	Site
001	Abdomen
002	Adrenal gland
003	Bladder
004	Bone
005	Brain
006	Breast
007	Cervix
008	THIS CODE IS INACTIVE, for Colon use 080
009	Diaphragm and connective tissue of thorax
010	Digestive system, other and unspecified
011	Esophagus
012	Fallopian tubes
013	Female genital, other and unspecified
014	Hodgkin's disease
015	Intestine
016	Ill-defined sites such as head, face, jaw, neck, back, hip, arm, leg, hand, foot
017	Kidney and renal pelvis
018	Larynx
019	Leukemia
020	Liver
021	Lung <i>(For use on BQF/M and OCF only)<sup>a</sup></i>
022	Lymph nodes
023	Male genital, other and unspecified
024	Melanoma
025	Lip, oral cavity and pharynx
026	Non-Hodgkin's Lymphoma
027	THIS CODE IS INACTIVE, for Omentum use 030
028	Ovary <i>(For use on BQF/M and OCF only)*</i>

Code	Site
029	Pancreas
030	Peritoneum
031	Prostate <i>(For use on BQF/M and OCF only)*</i>
032	THIS CODE IS INACTIVE, for Rectum use 080
033	Skin
034	Stomach
035	Testis
036	THIS CODE IS INACTIVE, for Throat use 025
037	Thyroid
038	Uterus
039	Vagina
040	Anus and Anal Canal
041	Connective, subcutaneous and other soft tissues and peripheral nervous system
042	Endocrine glands
043	Endometrium
044	Eye
045	Gallbladder
046	Heart, mediastinum and pleura
047	Hematopoietic and reticuloendothelial systems
048	Kaposi's sarcoma
049	Meninges
050	Multiple myeloma
051	Nasopharynx, nasal cavity and middle ear, sinuses
052	Pelvis
053	Penis
054	Placenta
055	Respiratory system
056	Spinal cord and cranial nerves
057	Spleen
058	Thymus
059	Trachea

Code	Site
060	Ureter, urinary organs
080	Colorectum <i>(For use on BQF/M and OCF only)*</i>
880	Prostate and some other cancer <i>(For use on BQF/M only)*</i>
881	Lung and some other cancer <i>(For use on BQF/M only)*</i>
882	Colorectum and some other cancer <i>(For use on BQF/M only)*</i>
883	Ovary and some other cancer <i>(For use on BQF/M only)*</i>
884	More than one non-PLCO cancer <i>(For use on BQF/M only)*</i>
885	More than one PLCO cancer <i>(For use on BQF/M only)*</i>
886	Colon and some other cancer <i>(For use on BQF/M only)*</i>
887	Rectum and some other cancer <i>(For use on BQF/M only)*</i>
888	Other
998	Don't Know
999	Not Ascertained

- a. Refer to the BQFM and BQM specifications for instructions for coding multiple cancers and PLCO cancers in combination with other cancers.

**I-1-2**

Cancer Code List, Included Sites in Alphabetical  
Order

## SPECIFICATIONS FOR THE CANCER CODE LIST - INCLUDED SITES IN ALPHABETICAL ORDER

(For use on the ASU, BQF, BQM, OCF, and MDF)

Site	Code
Abdomen	001
Abdominal	001
Abdominal wall	001
Adrenal gland	002
Anal canal	040
Anorectum ( <i>BQF/M and OCF only</i> )*	080
Anus	040
Aortic body	042
Appendix	080
Arm	016
Back	016
Bile duct	010
Biliary tract	010
Bladder	003
Blood	047
Bone (regardless of the bone site- e.g., limbs, pelvis, etc.).	004
Bone marrow	047
Bowel	080
Brain	005
Breast (male or female)	006
Burkitt's cell leukemia	019
Buttock	052
Cardiac _____	046
Carotid body	042
Cerebellum	005
Cerebral meninges	049
Cerebrum	005
Cervix/cervical	007
Cholangiocarcinoma	010
Chronic lymphocytic leukemia/CLL	019
Clitoris	013

<b>Site</b>	<b>Code</b>
Cloacogenic zone ( <i>BQF/M and OCF only</i> )*	080
Colon ( <i>For use on BQF/M and OCF only</i> ) *	080
Colon and some other cancer ( <i>For use on BQF/M only</i> )*	886
Colorectum ( <i>BQF/M and OCF only</i> )*	080
Colorectum and some other cancer ( <i>For use on BQF/M only</i> )*	882
Connective, subcutaneous and other soft tissues, of all body sites, except thorax and pelvis.	041
Connective, subcutaneous or other soft tissues of the thorax	009
Cornea	044
Cranial nerves	056
Cul-de-sac of Douglas	030
Di Guglielmo's disease	019
Diaphragm	009
Digestive system	010
Duct of Santorini	029
Duct of Wirsung	029
Duodenum	015
Endocervix	007
Endocrine gland	042
Endometrium/Endometrial	043
Esophagus	011
Exocervix	007
Extrahepatic bile duct	010
Eye	044
Eyeball	044
Eye lid	033
Face	016
Fallopian tube(s)	012
Female organs, genital, and other vague responses	013
Foot	016
Foreskin	053
Frontal lobe	005
Gallbladder	045
Gartner's duct	039
Gastric	034

Site	Code
Gastrointestinal tract	015
Glottis	018
Gluteus maximus muscle	052
Groin	052
Gum	025
Hand	016
Head	016
Heart	046
Heilmeyer-Schoner disease	019
Hematopoetic systems	047
Hip	016
Hodgkin's Lymphoma	014
Hymen	039
Hypopharynx	025
Ileum	015
Iliac artery	052
Iliac vein	052
Inner ear	051
Intestine	015
Intrahepatic bile duct	020
Islets of Langerhans	029
Jaw	016
Jejunum	015
Joint	004
Kaposi's sarcoma (regardless of site)	048
Kidney	017
Labia	013
Larynx	018
Leg	016
Lentigo maligna	024
Lentigo maligna melanoma	024
Leukemia	019
Lip	025
Liver	020

<b>Site</b>	<b>Code</b>
Lung <i>(For use on BQF/M and OCF only) *</i>	021
Lung and some other cancer <i>(For use on BQF/M only)*</i>	881
Lymph node, regardless of the body site	022
Lymphoma (regardless of the body site - except Hodgkin's)	026
Macroglobulemia	047
Male organs, genital, and other vague responses	023
Mammary gland	006
Mediastinum	046
Melanoma, regardless of body site (skin, eye, etc.)	024
Meninges	049
Mesentery	030
Mesocolon	030
Mesothelioma	046
Middle ear	051
More than one non-PLCO cancer <i>(For use on BQF/M only)*</i>	884
More than one PLCO cancer <i>(For use on BQF/M only)*</i>	885
Mouth	025
Multiple myeloma	050
Mycosis fungoides	033
Myeloma	050
Nasal Cavity	051
Nasopharynx	051
Neck	016
Neurofibromatosis	888
Nipple	006
Non-Hodgkin's Lymphoma	026
Nose	051
Nostril	051
Omentum	030
Oral cavity	025
Oropharynx	025
Osteosarcoma	004
Other	888
Ovary <i>(For use on BQF/M and OCF only)*</i>	028

Site	Code
Ovary and some other cancer <i>(For use on BQF/M and OCF only)*</i>	883
Palate	025
Pancreas/pancreatic	029
Parathyroid gland	042
Parotid gland	025
Pelvis	052
Penis/penile	053
Peripheral nerves and autonomic nervous system, regardless of body site.	041
Peritoneum/peritoneal	030
Pharynx	025
Pineal gland	042
Pituitary gland	042
Placenta	054
Plasma cell leukemia	050
Pleura	046
Prostate <i>(For use on BQF/M and OCF only)*</i>	031
Prostate and some other cancer <i>(For use on BQF/M only)*</i>	880
Pyriiform sinus	051
Rectouterine pouch	030
Rectum <i>(For use on BQF/M and OCF only)*</i>	080
Rectum and some other cancer <i>(For use on BQF/M only)*</i>	887
Renal	017
Renal pelvis	017
Respiratory system	055
Respiratory tract	055
Reticuloendothelial systems	047
Retina	044
Retroperitoneum	030
Salivary glands (e.g., Sublingual gland, Submaxillary gland, Submandibular gland)	025
Scrotum	023
Seminal vesicles	023
Sinus	051
Sipple's syndrome	037
Skin	033

Site	Code
Skin of penis	053
Skin of scrotum	023
Skin of vulva, labia or clitoris	013
Small intestine	015
Spinal cord	056
Spinal meninges	049
Spleen	057
Stomach	034
Temporal lobe	005
Testes	035
Testicles/testicular	035
Testis	035
Throat	025
Thymus	058
Thyroid	037
Tongue	025
Tonsil	025
Trachea	059
Tube(s)	012
Umbilicus	001
Ureter	060
Urethra	060
Urinary organs	060
Uterine	038
Uterine tube(s)	012
Uterus	038
Vagina	039
Vaginal	039
Vas deferens	023
Vocal cord	018
Voice box	018
Vulva	013
Waldenstrom's macroglobulemia	047

\* Refer to the BQF and BQM specifications for instructions for coding multiple cancers and PLCO cancers in combination with other cancers.

**I-1-3**

Specifications for the Cancer Code List

## SPECIFICATIONS FOR CANCER CODE LIST

The Cancer Code List should be used to code responses to Items 21 and 30 on the Baseline Questionnaire (BQF/BQM), Item 2 on the Annual Study Update (ASU) (what type of cancer was diagnosed), Item A.12 on the Other Cancer Form (OCF) (Reported Metastases), and a Missing Data Form (MDF) completed for an OCF.

The following specifications for using the cancer code list are designed to assist a non-medical coder in coding participant responses into 3-digit codes. If there is a question regarding how to code the participant's response, the SC staff member should consult the SC Coordinator or an appropriate medical professional.

There are several notes regarding this list that may be useful to the staff member reviewing and coding cancers.

- Coding morphology (cancer cell type) vs. topography (cancer site):

In general, when the BQF, BQM, or ASU asks the participant what type of cancer was diagnosed, we are expecting the response to be a body site (e.g., "brain", "carcinoma in stomach", etc.). Therefore, most of the cancer types in the list are body sites. In some common situations, however, the participant may provide the type of cancer in terms of its morphology. Some morphologic types are also provided in the list: leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, Kaposi's sarcoma, melanoma, and multiple myeloma. If the participant indicates one of these morphologic types, code the cancer according to its morphology, regardless of the body site.

There are other situations, however, where the participant provides a morphologic type such as "carcinoma" or "adenocarcinoma" but does not provide the body site. In such cases, the SC may elect to perform data retrieval to determine the body site of the cancer, before the BQF, BQM, or ASU is coded and keyed into the SMS, however this data retrieval is not required.

Note that if the participant provides the morphologic type of "basal cell" for skin cancer, *this should not be coded, nor entered into the SMS*. (Refer to the specifications for the ASU, MOOP Appendix A-7-1.)

- The codes for PLCO cancers are to be used on the BQF, BQM, and OCF only. On the OCF they are to be used to code metastases in cases where the primary site is unknown.
- The specifications table includes the following columns:

**PLCO Cancer Code:** This is the PLCO 3-digit cancer code.

**Site:** This is the name of the code. This name will appear on reports that provide the type of cancer in a decoded (i.e., English) format. The codes are in alphabetical order in two parts. The codes 001 through 039 were available prior to the most recent revision and the codes 040 through 060 and 080 are more recent codes.

**Use this code for cancers reported as:** These are the body sites that are included in the definition for this code.

**Do not use this code for cancers reported as:** These are the body sites that are not included in the definition for this code. For each site, the appropriate 3-digit code is provided in parentheses.

**Notes:** These are notes that may be helpful to the coder in determining whether or not to use this code.

- Using the code 888 (Other – specify):

If the staff member is unable to classify the participant's response into one of the 3-digit codes, s/he should code the response as 888 and the participant's response should be keyed verbatim into the SMS.

PLCO Cancer Code	Site	Use this code for cancers reported as:	<u>Do not</u> use this code for cancers reported as: (Use the code in parentheses instead)	Notes
001	Abdomen	Abdomen Abdominal Abdominal wall Umbilicus	Skin of the abdomen (033) Skin of the abdominal wall (033) Stomach (034)	
002	Adrenal gland	Adrenal gland		
003	Bladder	Bladder	Other urinary organs not specified as the bladder (060)	
004	Bone	Bone (regardless of the bone site (e.g., limbs, pelvis, etc.). Osteosarcoma Joint	Bone marrow (047)	
005	Brain	Brain Cerebrum Frontal lobe Temporal lobe Cerebellum Other parts of the brain	Meninges (049)	
006	Breast	Breast (male or female) Nipple Mammary gland	Skin of the breast (033).	
007	Cervix	Cervix/cervical Endocervix Exocervix		Do not use this code if the cancer reported is not clearly cervical cancer. If there is any question, use Female genital, other and unspecified (013) or Other (888).
008	INACTIVE		Colon (080, BQF/M and OCF only) Colorectal (080, BQF/M and OCF only)	This code is no longer active. The code 080 should now be used to code colon and colorectal cancers.

<b>PLCO Cancer Code</b>	<b>Site</b>	<b>Use this code for cancers reported as:</b>	<b>Do not use this code for cancers reported as: (Use the code in parentheses instead)</b>	<b>Notes</b>
009	Diaphragm and connective tissue of thorax	Diaphragm Connective, subcutaneous or other soft tissues of the thorax.		Connective, subcutaneous and other soft tissues include: adipose tissue, aponeuroses, artery, blood vessel, bursa, connective tissue, fascia, fatty tissue, fibrous tissue, ligament, lymphatic, muscle, skeletal muscle, subcutaneous tissue, synovia, tendon, tendon sheath, vein, vessel.
010	Digestive system, other and unspecified	Digestive system Extrahepatic bile duct Bile duct Biliary tract Cholangiocarcinoma	Esophagus (011) Stomach (034) Gallbladder (045)	
011	Esophagus	Esophagus	Throat (025)	
012	Fallopian tubes	Fallopian tube(s) Uterine tube(s) "tube(s)"		If the response indicates part of the female genital tract but it is not clear that the participant is referring to the fallopian tubes, code the response as 013 (female genital, other and unspecified).
013	Female genital, other and unspecified	Vulva Labia Clitoris Skin of vulva, labia or clitoris "female organs", "genital" and other vague responses	Ovaries (028, BQF and OCF only) Fallopian tubes (012) Vagina (039) Uterus (038) Cervix (007) Endometrium (043) Primary Peritoneal (030)	Use this code for any response that refers to the female genitals or reproductive organs, but does not have a specific code assigned to it.

PLCO Cancer Code	Site	Use this code for cancers reported as:	<b>Do not use this code for cancers reported as: (Use the code in parentheses instead)</b>	Notes
014	Hodgkin's disease	"Hodgkin's _____"		Use this code for any cancer reported by the participant using the term "Hodgkin's" such as Hodgkin's disease, Hodgkin's lymphoma, Hodgkin's sarcoma, Hodgkin's granuloma, etc.
015	Intestine	Intestine Duodenum Jejunum Ileum Gastrointestinal tract Small intestine	Large intestine (code as 080, BQF/M and OCF only) Bowel (code as 080, BQF/M and OCF only)	
016	Ill-defined sites such as head, face, jaw, neck, back, hip, arm, leg, hand, foot	General sites such as head, face, jaw, neck, back, hip, arm, hand, leg, foot.		If the report is more specific – e.g., skin on face, pelvis, etc. code the more specific site.
017	Kidney and renal pelvis	Kidney Renal Renal pelvis	Other urinary organs (060) Ureter (060) Urethra (060)	
018	Larynx	Larynx Glottis "Vocal cord" "Voice box."	Throat (025)	
019	Leukemia	Leukemia Di Guglielmo's disease Heilmeyer-Schoner disease, Burkitt's cell leukemia Chronic lymphocytic leukemia/CLL	Plasma cell leukemia (050)	
020	Liver	Liver Intrahepatic bile duct	"bile duct" (010)	
021	Lung	Lung	Lung and a non-PLCO cancer (881) Lung and a PLCO cancer (885) Trachea (059)	For use on the BQF/M and OCF only

PLCO Cancer Code	Site	Use this code for cancers reported as:	<b>Do not use this code for cancers reported as: (Use the code in parentheses instead)</b>	Notes
022	Lymph nodes	Lymph node, regardless of the body site.	Lymphoma (014 – Hodgkin’s or 026 – Non-Hodgkin’s)	
023	Male genital, other and unspecified	Scrotum Vas deferens Seminal vesicles Skin of scrotum “Male organs”, “genital”, and other vague responses.	Penis (053) Testicles/Testes (035) Prostate (031, BQM and OCF only)	Use this code for any response that refers to the male genitals or reproductive organs, but does not have a specific code assigned to it.
024	Melanoma	Melanoma, regardless of body site (skin, eye, etc.). Lentigo maligna melanoma Lentigo maligna		Note: if the participant reports skin cancer and does not indicate that it is melanoma, the SC does not have to do data retrieval. It can be coded as skin cancer.
025	Lip, oral cavity and pharynx	Mouth Lip Tongue Gum Palate Parotid gland Salivary glands (e.g., Sublingual gland, Submaxillary gland, Submandibular gland) Tonsil Throat Oropharynx Hypopharynx	Larynx (018)	The code 036 (Throat) was deleted from the cancer code list and all cancers previously recorded as 036 have been recoded to 025.
026	Non-Hodgkin’s Lymphoma	Lymphoma (regardless of the body site - except Hodgkin’s)	Hodgkin’s disease (014) Lymph node (022)	Use this code if the participant reports cancer using the term “lymphoma” unless it is Hodgkin’s.
027	INACTIVE		Omentum (030)	This code is no longer active. The code 030 should now be used to code omentum.

PLCO Cancer Code	Site	Use this code for cancers reported as:	<b><u>Do not use this code</u> for cancers reported as: (Use the code in parentheses instead)</b>	Notes
028	Ovary	Ovary	Ovary and a non-PLCO cancer (883) Ovary and a PLCO cancer (885)	For use on the BQF/M and OCF only
029	Pancreas	Pancreas/pancreatic Islets of Langerhans Duct of Santorini Duct of Wirsung		
030	Peritoneum	Peritoneum/peritoneal Retroperitoneum Cul-de-sac of Douglas Omentum Rectouterine pouch Mesentery Mesocolon Primary Peritoneal		[Changes from the last version: The code 027 (Omentum) was deleted from the cancer code list and all cancers previously recorded as 027 have been recoded to 030]
031	Prostate	Prostate	Prostate and a non-PLCO cancer (880) Prostate and a PLCO cancer (885)	For use on the BQF/M and OCF only
032	INACTIVE		Rectum (080)	This code is no longer active. The code 080 should now be used to code rectum.
033	Skin	Skin Eye lid	Skin of the vulva, labia or clitoris (013) Skin of penis (053) Skin of scrotum (023) Melanoma of skin (024) Lentigo maligna melanoma (024) Lentigo maligna (024) Mycosis fungoides (026)	
034	Stomach	Stomach Gastric	Abdomen (001) Gastrointestinal (015)	
035	Testis	Testicles/testicular Testis Testes	Scrotum (023)	

PLCO Cancer Code	Site	Use this code for cancers reported as:	<b>Do not use this code for cancers reported as: (Use the code in parentheses instead)</b>	Notes
036	INACTIVE		Throat (025)	This code is no longer active. The code 025 should now be used to code throat.
037	Thyroid	Thyroid Sipple's syndrome	Parathyroid (042)	
038	Uterus	Uterus Uterine	Endometrium (043) Cervix (007)	
039	Vagina	Vagina Vaginal Hymen Gartner's duct		Do not use this code for any other part of the female genital tract if not specified as vagina.
040	Anus and Anal Canal	Anus Anal canal	Skin of anus (033) Perianal skin (033) Anorectum (080, BQF/M and OCF only) Rectum (080, BQF/M and OCF only) Cloacogenic zone (080, BQF/M and OCF only)	
041	Connective, subcutaneous and other soft tissues and peripheral nervous system	Connective, subcutaneous and other soft tissues, of all body sites, except thorax and pelvis.  Peripheral nerves and autonomic nervous system, regardless of body site.	Diaphragm (009) Pelvis (052)	Connective, subcutaneous and other soft tissues include: adipose tissue, aponeuroses, artery, blood vessel, bursa, connective tissue, fascia, fatty tissue, fibrous tissue, ligament, lymphatic, muscle, skeletal muscle, subcutaneous tissue, synovia, tendon, tendon sheath, vein, vessel.
042	Endocrine glands	Endocrine gland Parathyroid gland Pituitary gland Pineal gland Carotid body Aortic body	Thyroid (037) Adrenal Gland (002) Thymus (058)	

PLCO Cancer Code	Site	Use this code for cancers reported as:	<u>Do not use this code</u> for cancers reported as: (Use the code in parentheses instead)	Notes
043	Endometrium	Endometrium/ Endometrial	Uterus (038)	
044	Eye	Eye "Eyeball" Cornea Retina	Eye lid (033)	
045	Gallbladder	Gallbladder		
046	Heart, mediastinum and pleura	Heart "_____cardium" "Cardiac _____" Mediastinum Pleura Mesothelioma	Aortic body (042)	Use this code for any cancers reported by the participant using the terms "cardium" or "cardiac."
047	Hematopoetic and reticuloendothelial systems	Blood Bone marrow Waldenstrom's macroglobulemia Macroglobulemia	Spleen (057) Leukemia (019) Lymphoma (026)	
048	Kaposi's sarcoma	Kaposi's sarcoma (regardless of site)		
049	Meninges	Meninges Spinal meninges Cerebral meninges	Brain (005)	
050	Multiple myeloma	Myeloma Multiple myeloma Plasma cell leukemia		
051	Nasopharynx, nasal cavity and middle ear, sinuses	Pyriform sinus Nasopharynx Nasal Cavity Nostril Middle ear Inner ear "Nose" "_____ sinus"		Use this code for any cancers reported by the participant using the term "sinus."
052	Pelvis	Pelvis Buttock Groin Gluteus maximus muscle Iliac artery Iliac vein	Peritoneum (030) Skin of buttock or groin (033)	If the participant reports "pelvis" you may do data retrieval to determine soft tissues of pelvis vs. bones of pelvis. If data retrieval is not performed, code "pelvis" as 052.

<b>PLCO Cancer Code</b>	<b>Site</b>	<b>Use this code for cancers reported as:</b>	<b><u>Do not use this code</u> for cancers reported as: (Use the code in parentheses instead)</b>	<b>Notes</b>
053	Penis	Penis/penile Foreskin Skin of penis		
054	Placenta	Placenta	Uterus (038)	
055	Respiratory system	Respiratory system Respiratory tract	Lungs (021, BQF/M and OCF only) Trachea (059)	
056	Spinal cord and cranial nerves	Spinal cord Cranial nerves		If the participant reports "spine", you may perform data retrieval to determine spinal cord vs. bones of spine. If data retrieval is not performed, code "spine" as 888 (Other-specify).
057	Spleen	Spleen		
058	Thymus	Thymus		
059	Trachea	Trachea		
060	Ureter, urinary organs	Ureter Urinary organs Urethra	Bladder (003) Kidney (017)	
080	Colorectum	Colorectum Colon Rectum Appendix Anorectum Bowel Cloacogenic zone Large intestine	Intestine (015) Mesocolon (030) Colorectum and a non-PLCO cancer (882) Colorectum and a PLCO cancer (885) Colon and a non-PLCO cancer (886) Colon and a PLCO cancer (885) Rectum and a non-PLCO cancer (887) Rectum and a PLCO cancer (885)	For use on the BQF/M and OCF only
880	Prostate + other	Prostate cancer + any other non-PLCO cancer		For use on the BQF/M only
881	Lung + other	Lung cancer + any other non-PLCO cancer		For use on the BQF/M only

<b>PLCO Cancer Code</b>	<b>Site</b>	<b>Use this code for cancers reported as:</b>	<b><u>Do not use this code</u> for cancers reported as: (Use the code in parentheses instead)</b>	<b>Notes</b>
882	Colorectum + other	Colorectal cancer + any other non-PLCO cancer		For use on the BQF/M only
883	Ovary + other	Ovarian cancer + any other non-PLCO cancer		For use on the BQF/M only
884	>1 non-PLCO	More than one non-PLCO cancer		For use on the BQF/M only
885	>1 PLCO	More than one PLCO cancer		For use on the BQF/M only
886	Colon + other	Colon cancer + any other non-PLCO cancer		For use on the BQF/M only
887	Rectum + other	Rectal cancer + any other non-PLCO cancer		For use on the BQF/M only
888	Other	Neurofibromatosis		Use this code for cancers reported in a site that is not listed in these specifications, or the SC staff cannot determine the correct site to code.
998	Don't Know			Use this code if the participant indicated that s/he was diagnosed with cancer but does not know the type.
999	Not Ascertained			Use this code if the participant indicated that s/he was diagnosed with cancer and either specified the site as "unknown primary," or did not specify the site and the SC was unable to contact the participant to determine the site.

**I-1-4**

Location Code List

## LOCATION CODES

FOR USE ON BASELINE LOCATOR FORMS ONLY

State Name	Letter Code	Numeric Code
ALABAMA	AL	01
ALASKA	AK	02
ARIZONA	AZ	04
ARKANSAS	AR	05
CALIFORNIA	CA	06
COLORADO	CO	08
CONNECTICUT	CT	09
DELAWARE	DE	10
DISTRICT OF COLUMBIA	DC	11
FLORIDA	FL	12
GEORGIA	GA	13
HAWAII	HI	15
IDAHO	ID	16
ILLINOIS	IL	17
INDIANA	IN	18
IOWA	IA	19
KANSAS	KS	20
KENTUCKY	KY	21
LOUISIANA	LA	22
MAINE	ME	23
MARYLAND	MD	24
MASSACHUSETTS	MA	25
MICHIGAN	MI	26
MINNESOTA	MN	27
MISSISSIPPI	MS	28
MISSOURI	MO	29
MONTANA	MT	30
NEBRASKA	NE	31

<b>State Name</b>	<b>Letter Code</b>	<b>Numeric Code</b>
NEVADA	NV	32
NEW HAMPSHIRE	NH	33
NEW JERSEY	NJ	34
NEW MEXICO	NM	35
NEW YORK	NY	36
NORTH CAROLINA	NC	37
NORTH DAKOTA	ND	38
OHIO	OH	39
OKLAHOMA	OK	40
OREGON	OR	41
PENNSYLVANIA	PA	42
RHODE ISLAND	RI	44
SOUTH CAROLINA	SC	45
SOUTH DAKOTA	SD	46
TENNESSEE	TN	47
TEXAS	TX	48
UTAH	UT	49
VERMONT	VT	50
VIRGINIA	VA	51
WASHINGTON	WA	53
WEST VIRGINIA	WV	54
WISCONSIN	WI	55
WYOMING	WY	56
<b>U.S. TERRITORIES</b>		
PUERTO RICO	PR	57
AMERICAN SAMOA	AS	58
GUAM	GU	59
FEDERATED STATES OF MICRONE- SIA	FM	60
MARSHALL ISLANDS	MH	61
PALAU	PW	62

State Name	Letter Code	Numeric Code
VIRGIN ISLANDS	VI	63
<b>FOREIGN COUNTRY</b>		
		00

FOR USE ON BASELINE *AND* FOLLOW-UP LOCATOR FORMS ONLY

State Name	Letter Code	Numeric Code
ALABAMA	AL	01
ALASKA	AK	02
ARIZONA	AZ	04
ARKANSAS	AR	05
CALIFORNIA	CA	06
COLORADO	CO	08
CONNECTICUT	CT	09
DELAWARE	DE	10
DISTRICT OF COLUMBIA	DC	11
FLORIDA	FL	12
GEORGIA	GA	13
HAWAII	HI	15
IDAHO	ID	16
ILLINOIS	IL	17
INDIANA	IN	18
IOWA	IA	19
KANSAS	KS	20
KENTUCKY	KY	21
LOUISIANA	LA	22
MAINE	ME	23
MARYLAND	MD	24
MASSACHUSETTS	MA	25
MICHIGAN	MI	26
MINNESOTA	MN	27

<b>State Name</b>	<b>Letter Code</b>	<b>Numeric Code</b>
MISSISSIPPI	MS	28
MISSOURI	MO	29
MONTANA	MT	30
NEBRASKA	NE	31
NEVADA	NV	32
NEW HAMPSHIRE	NH	33
NEW JERSEY	NJ	34
NEW MEXICO	NM	35
NEW YORK	NY	36
NORTH CAROLINA	NC	37
NORTH DAKOTA	ND	38
OHIO	OH	39
OKLAHOMA	OK	40
OREGON	OR	41
PENNSYLVANIA	PA	42
RHODE ISLAND	RI	44
SOUTH CAROLINA	SC	45
SOUTH DAKOTA	SD	46
TENNESSEE	TN	47
TEXAS	TX	48
UTAH	UT	49
VERMONT	VT	50
VIRGINIA	VA	51
WASHINGTON	WA	53
WEST VIRGINIA	WV	54
WISCONSIN	WI	55
WYOMING	WY	56
<b>U.S. TERRITORIES</b>		
PUERTO RICO	PR	57
AMERICAN SAMOA	AS	58
GUAM	GU	59

<b>State Name</b>	<b>Letter Code</b>	<b>Numeric Code</b>
FEDERATED STATES OF MICRONE-SIA	FM	60
MARSHALL ISLANDS	MH	61
PALAU	PW	62
VIRGIN ISLANDS	VI	63
<b>CANADA</b>		
ALBERTA	AB	64
BRITISH COLUMBIA	BC	65
MANITOBA	MB	66
NEW BRUNSWICK	NB	67
NEWFOUNDLAND	NF	68
NORTHWEST TERRITORY	NT	69
NOVA SCOTIA	NS	70
ONTARIO	ON	71
PRINCE EDWARD ISLAND	PE	72
QUEBEC	PQ	73
SASKATCHEWAN	SK	74
YUKON	YT	75
<b>FOREIGN COUNTRY</b>		
		00

**I-1-5**

Relationship Code List

## RELATIONSHIP CODES

### FOR USE ON BASELINE QUESTIONNAIRE ONLY

01=MOTHER  
02=FATHER  
03=PARENT (SEX UNSPECIFIED)  
04=SISTER  
05=BROTHER  
06=SIBLING (SEX UNSPECIFIED)  
07=DAUGHTER  
08=SON  
09=CHILD (SEX UNSPECIFIED)  
23=RELATIVE (UNSPECIFIED)  
24=HALF-SISTER  
25=HALF-BROTHER  
88=OTHER (SPECIFY)  
98=DON'T KNOW  
99=NOT ASCERTAINED

### FOR USE ON BASELINE AND FOLLOW-UP LOCATOR FORMS ONLY

01=MOTHER  
02=FATHER  
03=PARENT (SEX UNSPECIFIED)  
04=SISTER  
05=BROTHER  
06=SIBLING (SEX UNSPECIFIED)  
07=DAUGHTER  
08=SON  
09=CHILD (SEX UNSPECIFIED)  
10=AUNT  
11=UNCLE  
12=NIECE  
13=NEPHEW  
14=COUSIN (UNSPECIFIED)  
15=GRANDDAUGHTER

16=GRANDSON  
17=GRANDCHILD (SEX UNSPECIFIED)  
18=FRIEND  
19=HUSBAND  
20=WIFE  
21=SPOUSE  
22=PARTNER  
23=RELATIVE (UNSPECIFIED)  
24=HALF-SISTER  
25=HALF-BROTHER  
26=SISTER-IN-LAW  
27=BROTHER-IN-LAW  
28=MOTHER-IN-LAW  
29=FATHER-IN-LAW  
30=IN-LAW (UNSPECIFIED)  
31=STEP SON  
32=STEP DAUGHTER  
33=STEP CHILD (SEX UNSPECIFIED)  
34=STEP MOTHER  
35=STEP FATHER  
36=NEIGHBOR  
37=EMPLOYER/BOSS  
38=FIANCE  
39=FIANCEE  
40=GIRLFRIEND  
41=BOYFRIEND  
42=DAUGHTER-IN-LAW  
43=SON-IN-LAW  
88=OTHER (SPECIFY)  
98=DON'T KNOW  
99=NOT ASCERTAINED

## **I-1-6**

Translation of ICD-O-2 and ICD-9-CM into 3-Digit  
PLCO Cancer Codes

**TRANSLATION OF ICD-O-2 AND ICD-9-CM INTO 3-DIGIT PLCO CANCER CODES**

ICD-O		Code	Site	M/F Only	ICD-9-CM							
Topography	Morphology				"Primary"			"In situ"				
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5				
C762				001	Abdomen			195	2	X		
C74x	0,1,9			002	Adrenal gland			194	0	X		
C67x	0,1,2,3,4,5,6,7,8,9			003	Bladder			188	0,1,2,3,4,5,6,7,8,9	X	2337	X
C40x	0,1,2,3,8,9			004	Bone			170	0,1,2,3,4,5,6,7,8,9	X		
C41x	0,1,2,3,4,8,9			005	Brain			238	0	X		
C71x	0,1,2,3,4,5,6,7,8,9			005	Brain			191	0,1,2,3,4,5,6,7,8,9	X		
C50x	0,1,2,3,4,5,6,8,9			006	Breast			237	5	X		
				006	Breast			174	0,1,2,3,4,5,6,8,9	X	2330	X
								175	0,9	X		
								238	3	X		
C53x	0,1,8,9			007	Cervix			180	0,1,8,9	X	2331	X

ICD-O			Code	Site	M/F Only	ICD-9-CM				
Topography	Morphology					"Primary"			"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5		
<b>CODE 008 IS NOT ACTIVE</b>				Use 080 (Colorectal) instead						
C493				171	4	X				
C24x	0,1,8,9			156	1,2,8,9	X	2309	X		
C268				159	8,9	X				
C269				235	5	X				
C15x	0,1,2,3,4,5,8,9			150	0,1,2,3,4,5,8,9	X	2301	X		
C570				183	2	X				
C51x	0,1,2,8,9			183	3,4,5,8,9	X	2333	X		
C57x	1,2,3,4,7,8,9			184	1,2,3,4,8,9	X				
				236	3	X				
		965	0,2,3,4,5,7,8,9	201	0,1,2,4,5,6,7,9	0,1,2,3,4,5,6,7,8				
		966	0,1,2,3,4,5,6,7							
C260				152	0,1,2,3,8,9	X	2307	X		

ICD-O		Code	Site	M/F Only	ICD-9-CM				
Topography	Morphology				"Primary"			"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5	
C17x	0,1,2,3,8,9			159	0	X			
C76x	0,1,4,5,7,8		Ill defined sites such as head, face, neck, back, hip, arm, leg, hand, foot	195	0,1,4,5,8	X			
C649			Kidney and Renal	189	0,1	X			
C659			Pelvis	236	9	1			
C32x	0,1,2,3,8,9		Larynx	161	0,1,2,3,8,9	X	2310	X	
			Leukemia	235	6	X			
		019		204	0,1,2,8,9	0,1			
		980		205	0,1,2,3,8,9	0,1			
		982		206	0,1,2,8,9	0,1			
		983		207	0,1,2,8	0,1			
		984		208	0,1,2,8,9	0,1			
		985							
		986							
		987							
		988							

ICD-O		Code	Site	M/F Only	ICD-9-CM					
Topography	Morphology				digits 1-3	digit 4	digit 5	digits 1-4	"In situ" digit 5	
digits 1-4	4th digit, x=									
C22x	0,1	020	Liver			155	0,1,2	X	2308	X
						235	3	X		
C34x	0,1,2,3,8,9	021	Lung			162	2,3,4,5,8,9	X	2312	X
						235	7	X		
C77x	0,1,2,3,4,5,8,9	022	Lymph nodes							
C63x	0,1,2,7,8,9	023	Male genital, other and unspecified			187	5,6,7,8,9	X	2336	X
				M		236	6	X		
		024	Melanoma			172	0,1,2,3,4,5,6,8,9	X		
		872								
		873								
		874								
		875								
		876								

ICD-O		Code	Site	M/F Only	ICD-9-CM				
Topography	Morphology				"Primary"			"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5	
C00x	0,1,2,3,4,5,6,8,9	877	0,1,2,3,4	140	0,1,3,4,5,6,8,9	X	2300	X	
C019		878	0	141	0,1,2,3,4,5,6,8,9	X			
C02x	0,1,2,3,4,8,9	879	0	142	0,1,2,8,9	X			
C03x	0,1,9			143	0,1,8,9	X			
C04x	0,1,8,9			144	0,1,8,9	X			
C05x	0,1,2,8,9			145	0,1,2,3,4,5,6,8,9	X			
C06x	0,1,2,8,9			146	0,1,2,3,4,5,6,7,8,9	X			
C079				148	0,2,3,8,9	X			
C08x	0,1,8,9			149	0,1,8,9	X			
C09x	0,1,8,9			235	0,1	X			
C10x	0,1,2,3,4,8,9								
C13x	0,1,2,8,9								
C14x	0,2,8								





ICD-O			Code	Site	M/F Only	ICD-9-CM				
Topography	Morphology					"Primary"			"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5		
C16x	0,1,2,3,4,5,6,8,9			151	0,1,2,3,4,5,6,8,9	X	2329	X		
C62x	0,1,9		034	186	0,9	X	2302	X		
			035	236	4	X				
<b>CODE 036 IS NOT ACTIVE</b>			<b>036</b>	<b>Use 025 Instead</b>						
C739			037	193		X				
C54x	0,2,3,8,9		038	179	X	X	2332	X		
C559				182	1,8	X				
C529			039	184	0	X				
C21x	0,1		040	154	2,3	X	2305	X		
C47x	0,1,2,3,4,5,6,8,9		041	171	0,1,2,3,5,6,7,8,9	X				
C49x	0,1,2,4,6			238	1	X				
							2306	X		

ICD-O			Code	Site	M/F Only	ICD-9-CM				
Topography		Morphology				"Primary"			"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5		
C75x	0,1,2,3,4,5,8,9			194	1,3,4,5,6,8,9	X	2348	X		
C541				182	0	X				
C69x	0,1,2,3,4,5,6,8,9			190	0,1,2,3,4,5,6,7,8,9	X	2340	X		
C239				156	0	X				
C38x	0,1,2,3,4,8			164	1,2,3,8,9	X				
				163	0,1,8,9	X				
				235	8	X				
C42x	0,1,3,4			238	4,5,6,7	X				
		914	0	176	0,1,2,3,4,5,8,9	X				
C70x	0,1,9			192	1,3	X				
				237	6	X				
		973	2	203	0,1,8	0,1				
C30x	0,1			147	0,1,2,3,8,9	X				
C31x	0,1,2,3,8,9			148	1	X				
C11x	0,1,2,3,8,9			160	0,1,2,3,4,5,8,9	X				

ICD-O			Code	Site	M/F Only	ICD-9-CM				
Topography	Morphology					"Primary"			"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8	digits 1-3	digit 4	digit 5	digits 1-4	digit 5		
C129										
C495			052	Pelvis		195	3	X		
C763										
C60x	0,1,2,8,9		053	Penis	M	187	1,2,3,4	X		
C589			054	Placenta	F	181	X	X		
						236	1	X		
C39x	0,8,9		055	Respiratory system		165	0,8,9	X		
						235	9	X		
C72x	0,1,2,3,4,5,8,9		056	Spinal cord and cranial nerves		192	0,2,8,9	X		
						237	6,9	X		
C422			057	Spleen		159	1	X		
C379			058	Thymus		164	0	X		
C339			059	Trachea		162	0	X		
C669			060	Ureter, urinary organs		189	2,3,4,8,9	X		
C68x	0,1,8,9					236	9	0,9		
C18x	0,1,2,3,4,5,6,7,8,9		080	Colorectal		153	0,1,2,3,4,5,6,7,8,9	X		
C199						154	0,1,8	X		
C209						235	2	X		
C212										
C218										

ICD-O			Code	Site	M/F Only	ICD-9-CM							
Topography		Morphology		Code	Site	M/F Only	"Primary"					"In situ"	
digits 1-4	4th digit, x=	digits 5-7	digit 8				digits 1-3	digit 4	digit 5	digits 1-4	digit 5		
				888	Other		237	7	0,1,2				
				998	Don't Know		238	8	X				
C809				999	Not Ascertained		199	1	X	2349	X		X
							238	9	X				

## **APPENDIX J**

### **Appendix J: Screening Examination Protocols**

**J-11-1**

J-11-1: Protocol for Chest X-Ray Examination

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**  
**PROTOCOL FOR CHEST X-RAY EXAMINATION**

**1. Standardization of the Chest X-Ray**

**A. Participant Preparation**

1. The participant will be told that the examination is a screening examination for lung cancer, not a routine examination, and that s/he should consult his/her own physician for evaluation of any symptoms and for routine medical care.
2. The participant will be told that s/he will receive written documentation of the results of all screening examinations within approximately three weeks. If the Screening Center plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.
3. The participant will be instructed to inhale deeply and to hold his/her breath while the x-ray is being taken.

**B. Examination Steps**

1. The participant will wear a hospital gown.
2. The technologist will explain the procedure and position the participant.
3. The participant will be instructed to inhale deeply and to hold his/her breath while the x-ray is being taken.
4. A postero-anterior X-ray will be taken.

**C. Requirements for Standardization of the Examination**

1. The examination will be documented on the data collection form. (See Appendix A-11-1 - Chest X-Ray Screening Examination Form).
2. The equipment: The chest X-ray will be taken using dedicated high-kV equipment (approximately 110-140 kV) at a tube-to-film distance of 6 to 10 feet. The Screening Center will use a wide latitude film with a 12 to 1 standard grid or higher.

**D. Minimum Quality Standards for the Examination**

1. The quality of the X-ray will be such that lung vessels are clearly visible and the mediastinal structures are sufficiently penetrated to allow for adequate visualization.

**E. Minimum Qualifications of Examiners**

1. Technologists will be an American Registry of Radiologic Technologists certified (ARRT) radiologic technician.
2. The radiologist and QA examiner who interpret chest X-rays will be American Board of Radiology (ABR) board certified or board eligible radiologists.
3. The Screening Center will report the qualifications and licensure of each technologist and radiologist to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of relevant diplomas, certificates, and/or licenses. Any exception to the above minimum qualifications should be approved by NCI on a case by case basis as stated in Appendix A, section A.2 of the PLCO Quality Assurance Plan (MOOP Appendix L).

## **F. Examiner Training, Certification and Quality Assurance**

### Training

1. The Screening Center Coordinator will train the technologist and the interpreting radiologist on the use of study forms and Screening Center administrative procedures.
2. The Screening Center will submit a training plan to the NCI for review and approval.

### Certification

1. No additional certification will be necessary for technologists or radiologists for the PLCO trial. Documentation of qualifications will suffice as documentation of certification.

Quality Assurance of Examiners, see Appendix A section C of the PLCO Quality Assurance Plan (MOOP Appendix L)

### Technologists:

1. For each technologist, the Screening Center will monitor the number of and reason for inadequate examinations.
2. The Screening Center will submit a plan for quality assurance of technologists to the NCI for approval.
3. The Screening Center will report the results of quality assurance of technologists to the NCI on a semi-annual basis, including the number of X-rays repeated due to poor film quality.

### Radiologists:

1. In each quarter, a selected sample of all screening x-rays will be re-interpreted by a second designated qualified radiologist. To the extent possible, participants with abnormal findings should be included in the sample of examinations that are re-interpreted. NCI will determine the number of subjects and method for their selection. Note: If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.
2. The Screening Center will submit a plan for quality assurance of radiologists to the NCI for approval.
3. The Screening Center will report the results of quality assurance of radiologists to the NCI on a semi-annual basis, including the number of positive (Abnormal Suspicious) examinations, the number of X-rays re-interpreted and the level of agreement between the two radiologists.

## **G. Documentation of the Examination**

1. See Appendix A-11-1 - Chest X-ray Screening Examination Form.
2. See Appendix A-11-2 - Chest X-ray Screening Examination Quality Assurance Form.
3. 3.The X-ray film will be labeled with the participant's name and ID number.

## **H. Equipment Specifications**

1. Equipment used will be high kV (approximately 110-140 kV), dedicated equipment.
2. Quality control of the equipment will be assured by individual institutions, all of which will be state licensed.
3. Quality control of processors should be performed at least three times a week, and should include sensitometric testing.
4. Quality control will also include yearly documentation of kV calibration within 5 percent, radiation output assessed by use of an anatomic phantom, documentation of film-screen contact, demonstration that the X-ray spectrum is free of low energy contaminants through use of half-value layer, collimation, dose exposure, and function of automatic exposure control.
5. The Screening Center will send the NCI documentation of the equipment used for the chest x-ray including the film type used (e.g. symmetric or asymmetric film screen combinations, etc.), and a record of maintenance and quality checks as demanded by state licensing requirements.

## **I. Photo Documentation**

1. The PA chest film will be the photo documentation.

## **2. Interpretation of Results of the Chest X-Ray:**

### **A. Criteria for Determination of a Negative or an Inadequate X-ray**

1. Negative Screen - No Abnormalities:

Chest x-ray evaluation reveals midline structure and heart to be of normal size and not displaced or enlarged. Pulmonary parenchyma reveals no suspicious abnormality for cancer.

2. Inadequate:

An X-ray will be judged to be inadequate if the entire lung and mediastinal structures are not included on the film. Possible reasons are: excessive rotation, inadequate inspiration, motion or processing artifact, and over or under penetration.

The technologist taking the X-ray will make the initial judgment about quality of the film before the participant has left the Screening Center. If it is felt to be inadequate, the X-ray will be repeated. The Screening Centers will do their best to ensure that when a repeat X-ray is necessary, it will be performed during the first visit. If the interpreting radiologist finds the X-ray to be inadequate, the participant will be asked to return for a repeat examination. Note: A QA exam with an inadequate result should not be repeated as a PLCO screening exam or as a PLCO QA exam.

### **B. Classification and Definition of Abnormal Examination Results**

1. Positive Screen (Referral Required):

Evaluation reveals any of the following pulmonary abnormalities:

- nodule (a circular opacity < to 3.0 cm in diameter);
- mass (any discrete opacity > 3.0 cm in diameter without regard to contour, homogeneity or border characteristics);
- hilar or mediastinal lymph node enlargement (exclude calcified nodes);

- major atelectasis/lobar collapse;
- infiltrate/consolidation/alveolar opacity;
- pleural mass.

2. Negative Screen - Other Abnormalities (Referral Optional):

Evaluation reveals any of the following abnormalities:

- pneumonia (particularly TB)
- marked cardiac enlargement
- pulmonary edema
- congestive heart failure (CHF)
- pericardial effusion
- pleural effusion
- valvular heart disease
- shunt vascularity
- thoracic aortic aneurysm, dissection
- pneumothorax
- pneumomediastinum
- unexplained foreign body (catheter fragment in heart, etc.)
- granuloma
- rib/spine/shoulder girdle metastases
- plasmacytomas
- acute fractures
- hepatomegaly
- splenomegaly
- old rib fractures
- compression fractures of the spine
- shoulder fractures
- scoliosis
- pleural calcification, pleural thickening, plaques
- previous mastectomies, breast implants
- COPD, emphysema, bullae
- old granulomatous disease, parenchymal calcification, calcified nodes
- pneumoconiosis
- mild to moderate cardiac enlargement
- pulmonary vascular congestion
- interstitial fibrosis, honeycombing, small scars
- pulmonary fibrosis with hilar retraction,

- radiation fibrosis
- previous lung surgery
- biopsy sites
- changes related to old trauma, retained shrapnel, etc.
- previous cardiac surgery (CABG, valve replacements)
- vascular anomalies (right aortic arch, etc.)
- vascular calcification
- bronchiectasis
- hiatal hernia, gallstones
- linear or plate atelectasis
- enlarging tracheal nodule

### **C. Reporting of Results to Participants and Physicians**

1. The Screening Center will report results in writing to the participant and to the participant's physician of choice within three weeks of the screening visit.
2. The Study Management System will produce a brief report of results which will be sent to participants and physicians with a cover letter. Additional findings may be sent at the discretion of the SC. However, any additional material must be approved by NCI.
3. The Screening Center may also give the participant a preliminary summary of results, either verbal or written, during the screening visit.
4. Participants with a result of "Positive Screen" will be referred to their physician of choice for diagnostic evaluation and possible treatment. Participants with a result of "Negative Screen - Other Abnormalities" will be referred according to standard practice at the Screening Center. The Screening Center will continue to monitor and follow-up all participants who have a positive screening result that is suspicious for cancer.
5. The examiner will assign the result of the examination exclusively according to the findings of the examination, without taking into consideration the results or findings of any previous examinations. If, after the result has been assigned, the SC wishes to compare the result or findings of the examination to those of prior examinations (prior PLCO radiographs, or radiographs taken prior to the participant's enrollment in the trial), it may do so as an "internal referral." The participant will be notified of the results of the internal referral. If the SC deems it necessary, or the participant requests it, the SC may then refer the participant "externally" for further evaluation to the participant's physician of choice. All internal and external referrals for a positive screen will be considered part of the diagnostic evaluation of the positive screen.
6. If a quality assurance examination does not have the same findings as the initial screening examination, referral will be made on the "worst case" abnormal findings, regardless of whether the original examiner or QA examiner found the abnormal result. When the Screening Test Results Report (STRR) is generated, the following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the x-ray negative with a referral code

of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

**D. Diagnostic Follow-up Recommendations**

1. No formal recommendations for diagnostic follow-up of positive screens will be given. The Screening Center should refer inquiries to providers they deem to be expert in the field, and provide the 1-800-4-CANCER hotline number as an additional source of information. It is expected that diagnostic follow-up will be state-of-the-art when handled by Screening Center referral providers.

**E. Cancer Confirmation**

1. The final diagnosis of lung cancer will be based on histopathologic criteria. The cancer will be coded according to ICD-O codes by a trained medical coder at the Screening Center. Pathology slides and reports that support the cancer diagnosis will be obtained for review by a central study pathologist for all participants diagnosed with lung cancer. One stained slide will be required by the NCI for permanent retention. Additional slides may also be required by the NCI. A final diagnosis based on clinical examination only may also be accepted in certain circumstances where no pathological examination was done.

**F. Treatment Recommendations for Individuals Diagnosed with Cancer**

1. No treatment recommendations will be given.

**J-12-1**

Protocol for Digital Rectal Examination of the Prostate

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**  
**PROTOCOL FOR DIGITAL RECTAL EXAMINATION OF THE PROSTATE**

**1. Standardization of the Prostate Examination**

**A. Participant Preparation**

1. Written information about the procedure will be provided to the participant.
2. The participant will be asked if he has ever had a prostate examination.
3. The preferred positioning will be described.
4. A description of the complete procedure including the discomfort associated with it will be given by the examiner and questions will be answered.
5. The participant will be told that a second examiner may repeat the examination for quality control purposes.
6. The participant will be told that the examination is a screening examination for prostate cancer, not a routine examination, and that he should consult his own physician for evaluation of any symptoms and for routine medical care.
7. The participant will be told that he will receive written results for all examinations in approximately three weeks. If the Screening Center plans to report preliminary results to the participant, the participant should also be told this in advance of the examination.

**B. Examination Steps**

1. After the participant has entered the examining room, he will remove his clothes from the waist down.
2. The examiner will explain the procedure to the participant.
3. The examiner will position the participant. The participant may be bent at the waist over the end of the exam table, in the kneeling knees to chest position, or in the lateral decubitus position with knees pulled up to chest.
4. The examiner will visualize the anal area.
5. The examiner may request the participant to bear down or perform a valsalva maneuver.
6. The examiner will apply a lubricated gloved index finger at the 6 o'clock position to relax the sphincter, and will then introduce it into the anal area to palpate the prostate.
7. The examiner will examine the anterior portion of the rectal vault, i.e., the base, apex and lateral lobes of the prostate, and the seminal vesicles.
8. The examiner will then remove the gloved examining finger.

**C. Requirements for Standardization of the Examination**

1. The examination will be documented on the data collection form. (See Appendix A-12-1 - Digital Rectal Screening Examination of the Prostate Form).
2. The examination will be performed after the blood draw for the PSA test.
3. The position of the participant may vary depending on examiner's preference and the participant's capabilities. Positions include: 1) lateral decubitus position with knees pulled up to chest; 2) bent at the waist over end of examina-

tion table; and 3) kneeling, knees to chest position. The position will be documented on the data collection form.

4. The whole prostate will be palpated, including the base, apex, and lateral lobe of the prostate, as well as the seminal vesicles.

#### **D. Minimum Quality Standards for the Examination**

1. The examiner must document palpation of the prostate on the data collection form.
2. The examiner must estimate prostate size to the nearest half-centimeter.
3. The examiner must note texture of each portion of the prostate and document the overall consistency of the gland (e.g. normal, boggy, induration).
4. The examiner must document the number of areas of induration on the data collection form.
5. The examiner must document the location, type, grade, extent, and approximate size of the three largest areas of induration (if present) on the data collection form.

#### **E. Minimum Qualifications for Examiners**

1. The examiner will be a R.N., Certified Physician's Assistant, Nurse Practitioner, Physician, or equivalent. Equivalency is to be determined by the SC Principal Investigator and documented in a letter to be submitted with a completed ECT to NCI.
2. The Screening Center will report the qualifications and licensure of each examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of relevant diplomas, certificates and/or licenses.

#### **F. Minimum Qualifications for QA Examiners**

1. The QA examiner will be any licensed physician who is adequately trained and experienced in the digital rectal examination or a certified PLCO DRE examiner.
2. The Screening Center will report the qualifications and board certification of each QA examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates.

#### **G. Minimum Qualifications for Trainers**

1. The trainer will be a board certified urologist.
2. The Screening Center will report the qualifications and board certification of each trainer to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates.

#### **H. Examiner Training, Certification and Quality Assurance**

##### Training

1. Examiners will be trained locally at each Screening Center.
2. A non-physician examiner will be taught the correct examination procedure by the trainer.
3. Imitation models may be used to demonstrate normal and abnormal prostate texture.

4. The non-physician examiner and trainer will both perform at least 30 digital rectal examinations on the same individuals, including 10 examinations on individuals with abnormal findings. Initially the trainer will demonstrate; the examiner will follow. As the examiner begins to demonstrate competence, the trainer will observe the examiner, then confirm examiner findings.
5. The Screening Center Coordinator will train all examiners on the use of study forms and Screening Center administrative procedures.
6. The Screening Center will submit a training plan to the NCI for review and approval.

#### Certification

1. Certification will be conducted at the Screening Center.
2. Of the training examinations, at least 15 examinations (including 10 examinations on individuals with abnormal findings), will be performed successfully for certification. A successful examination will be one in which the examiner demonstrates to the trainer the ability to examine the prostate, give the size estimate, and document any abnormality on the examining sheet prospectively, such that, in the judgment of the trainer, there is general agreement in each of the following categories:
  - 1) result of exam (negative or positive);
  - 2) size of prostate;
  - 3) extent of prostate abnormality; and
  - 4) location of prostate abnormality.
3. The Screening Center will report the results of examiner certification to the NCI on the Record of Experience, Credentials and Training (ECT).

#### Quality Assurance of Examiners see Appendix B section C of the PLCO QA Plan (MOOP Appendix L)

1. In each quarter, a selected sample of all screening tests performed will be repeated by the trainer or a similarly qualified professional (QA examiner). To the extent possible, participants with abnormal findings should be included in the sample receiving repeat examinations. NCI will determine the number of subjects and method for their selection. Note: If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.
2. The Screening Center will submit a plan for quality assurance of examiners to the NCI for approval.
3. The Screening Center will report the results of quality assurance of examiners to the NCI on a semi-annual basis, including the number of examinations performed and the level of agreement between the examiner and the QA examiner.
4. The Screening Center will report the prevalence of positive (Abnormal Suspicious) exams by examiner. The prevalence of inadequate exams will also be reported by examiner and reason for inadequacy.

## **I. Documentation of the Examination**

1. See Appendix A-12-1 - Digital Rectal Screening Examination of the Prostate Form.
2. See Appendix A-12-2 - Digital Rectal Screening Examination of the Prostate Quality Assurance Form.

## **2. Interpretation of Results of the Digital Rectal Examination**

### **A. Criteria for Determination of a Negative or an Inadequate Examination**

1. Negative Screen - No Abnormalities:
  - Symmetric, soft, non-nodular prostate.
2. Inadequate:
  - Participant unwilling to allow completion of examination;
  - Participant unable to tolerate discomfort of examination;
  - Examiner unable to palpate prostate due to participant obesity.
  - Examiner unable to palpate the apex, base and lateral lobes of the prostate, and seminal vesicles, and no abnormality suspicious for cancer is found in the area palpated;
  - Prostate has been previously removed and no abnormalities are identified.

When appropriate, the SC should make every attempt to reschedule inadequate examinations. However, a duplicate or repeat exam performed for QA purposes with an inadequate result should not be repeated as a PLCO screening exam or as a PLCO QA exam.

### **B. Classification and Definition of Abnormal Examination Results**

1. Positive Screen (Referral Required):
  - Nodularity or induration of prostate gland;
  - Examiner judges the prostate to be suspicious for cancer, in the absence of nodularity or induration.

**Note:** In the event that the examiner judges the prostate to be suspicious for cancer (i.e., a positive screen) but there is no nodularity or induration, the examiner is required to describe the basis of this judgement in the comments section.
2. Negative Screen - Other Abnormalities (Referral Optional):
  - Enlargement;
  - Tenderness;
  - Bogginess (with no other abnormal findings);
  - Asymmetry in a prostate of normal consistency and of normal size or slightly enlarged;
  - Prostate has been previously removed and abnormalities not indicative of a positive screen are identified.

### **C. Reporting of Results to Participants and Physicians**

1. The Screening Center will report results in writing to the participant and to the participant's physician of choice within three weeks of the screening visit.
2. The Study Management System will produce a brief report of results which will be sent to participants and physicians accompanied by a cover letter. Additional findings may be sent at the discretion of the SC. However, any additional material must be approved by NCI.
3. The Screening Center may also give the participant a preliminary summary of results, either verbal or written, during the screening visit.
4. Participants with a screening result of "Positive Screen" will be referred to their physician of choice for diagnostic evaluation and possible treatment. Participants with a screening result of "Negative Screen-Other Abnormalities" will be referred according to standard practice at the Screening Center. The Screening Center will continue to monitor and follow-up all participants who have a positive screening result that is suspicious for cancer.
5. The examiner will assign the result of the examination exclusively according to the findings of the examination, without taking into consideration the results or findings of any previous examinations. If, after the result has been assigned, the SC wishes to compare the result or findings of the examination to those of prior examinations, it may do so as an "internal referral." If the SC deems it necessary, or the participant requests it, the SC may then refer the participant "externally" for further evaluation to the participant's physician of choice.
6. If a quality assurance examination does not have the same findings as the initial screening examination, referral will be made on the "worst case" abnormal findings, regardless of whether the original examiner or QA examiner found the abnormal result. When the Screening Test Results Report (STRR) is generated, the following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the exam negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

### **D. Diagnostic Follow-up Recommendations**

1. No formal recommendations for diagnostic follow-up of positive screens will be given. The Screening Center should refer inquiries to providers they deem to be expert in the field, and provide the 1-800-4-CANCER hotline number as an additional source of information. It is expected that diagnostic follow-up will be state-of-the-art when handled by Screening Center referral providers.

### **E. Cancer Confirmation**

1. The final diagnosis of prostate cancer will be based on histopathologic criteria. The cancer will be coded according to ICD-O codes by a trained medical coder at the Screening Center. Pathology slides and reports that support the cancer diagnosis will be obtained for review by a central study pathologist for all participants diagnosed with prostate cancer. One stained slide will be required by the NCI for permanent retention. Additional slides may also be required by the NCI. A final diagnosis based on clinical examination only may also be accepted in certain circumstances when no pathological examination was done.

**F. Treatment Recommendations for Individuals Diagnosed with Cancer**

1. No treatment recommendations will be given.

## **J-13-1**

J-13-1: Protocol for Flexible Sigmoidoscopy Examination

**Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial**  
**PROTOCOL FOR FLEXIBLE SIGMOIDOSCOPY EXAMINATION**

**1. Standardization of the Flexible Sigmoidoscopy Examination**

**A. Participant Preparation**

1. Written information about the procedure will be provided to the participant.
2. The participant will be instructed that if s/he is constipated, s/he should take a laxative the night before the examination.
3. The participant will be informed of the risks and complications of sigmoidoscopy and that a physician, physician's assistant or trained nurse will be performing the examination, as appropriate.
4. The participant will be told that the examination is a screening examination for colorectal cancer, not a routine examination, and that s/he should consult his/her own physician for evaluation of any symptoms and for routine medical care.
5. If the Screening Center's plan for quality assurance includes direct observation by a gastroenterologist, the participant will be told that such an observation may take place.
6. The participant will be told that s/he will receive written documentation of the results of all his/her screening examinations within approximately three weeks. If the Screening Center plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.
7. Physical Preparation: the bowel preparation will include a Fleet enema, repeated once or twice if necessary on the morning of the exam (at the participant's home or in the examination room), and may also include an oral preparation such as Colyte or Golytely.

**B. Examination Steps**

1. Standard medical practice requires that a brief medical history be obtained prior to sigmoidoscopy. In addition, vital signs will be measured before and after sigmoidoscopy. The SC will determine the content of the medical history. It is recommended that in the presence of certain medical conditions, clearance be obtained from a study physician before the sigmoidoscopy examination can be allowed to proceed. Significant conditions include:
  - the presence of heart rhythm irregularity;
  - pulse rate below 60/minute or above 100/minute;
  - systolic blood pressure below 100 mm Hg or above 180 mm Hg;
  - diastolic blood pressure below 60 mm Hg or above 95 mm Hg;
  - myocardial infarction or cerebrovascular accident within six months;
  - recent fainting spells;
  - chest pain within 24 hours; or
  - increased shortness of breath.

2. If the participant has not administered enemas at home prior to coming to the Screening Center, s/he will be prepped with a disposable enema kit until it appears the rectum has had all stool evacuated.
3. The examiner will explain the procedure to the participant. The participant will then lie on his/her left side with the anal/rectal area exposed.
4. Upon agreement of the participant, the examiner will do a digital rectal examination to exclude any low rectal lesion and to determine the path of the rectum.
5. The examiner will introduce a lubricated flexible scope with capability to 60 centimeters of examination. The examiner will visualize the rectum and the colon as the scope is advanced. Air for inflation or exposure will be used at the discretion of the examiner.
6. Once the scope is advanced to the full length or to a distance maximally tolerated by the participant, the examiner will withdraw the scope and visualize the colon and the rectum as the scope is withdrawn. Once the examination is completed, the participant will be asked to sit briefly.

#### **C. Requirements for Standardization of the Examination**

1. The examination will be documented on the data collection form (See Appendix A-13-1 - Flexible Sigmoidoscopy Screening Examination Form).
2. The bowel preparation: Fleet enema, repeated once or twice if necessary on morning of exam (at the participant's home or in the examination room).
3. The instrumentation: flexible endoscope and light source.
4. The goal of full insertion of the 60 centimeter scope unless one or more of the following occur:
  - Undue participant discomfort;
  - Inadequate preparation with unclear lumen;
  - Vasovagal response;
  - Palpitations with tachycardia;
  - Severe diverticulosis with unclear lumen; or
  - Severe ulcerative colitis.
5. For female participants, the flexible sigmoidoscopy will be performed after the transvaginal ultrasound.
6. Instrument cleaning and disinfection procedures will be performed according to standard medical practice and pertinent federal and local regulations.
7. Instrument testing: leak testing will be performed daily.

#### **D. Minimum Quality Standards for the Examination**

1. An adequate preparation, that is, greater than 90 percent of the mucosa visible per examiner estimation.
2. An insertion of at least 50 cm unless a specific lesion or other abnormality suspicious for cancer is found (for example an obstructing carcinoma). If the examiner cannot insert the scope to at least 50 cm, the on-call gastroenterologist should be notified and, if possible, s/he will come and perform the procedure on that individual participant.

3. If minimal standards are not met for reasons of inadequate preparation, one additional Fleet enema should be administered and the procedure repeated during the participant's visit.

**Note Regarding Biopsies:**

The PLCO study is designed as a screening trial, and the study protocol refers to screening examinations only. If circumstances require, a biopsy may be performed during the screening sigmoidoscopy. This is acceptable only if the examiner is a physician and if a separate informed consent is obtained for the biopsy. The separate informed consent will specify that biopsy is not part of the PLCO trial and that the costs of the biopsy will be charged to the participant.

In Screening Centers where physicians may be performing a biopsy during the flexible sigmoidoscopy procedure, the participant should be instructed about what to do if s/he is taking aspirin, warfarin, non-steroidal anti-inflammatory drugs or if s/he has conditions that require prophylactic antibiotic therapy.

**E. Minimum Qualifications for Examiners**

1. The examiner will be a R.N., Certified Physician's Assistant, Nurse Practitioner, Physician, or equivalent. Equivalency is to be determined by the SC Principal Investigator and documented in a letter to be submitted with a completed ECT to NCI.
2. The Screening Center will report the qualifications and licensure of each examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of relevant diplomas, certificates and/or licenses.

**F. Minimum Qualifications for QA Examiners**

1. The QA examiner will be either a PLCO FSG trainer or a PLCO FSG examiner who has performed at least 240 PLCO FSG examinations in the prior 12 months (average 20 per month) and achieved 50+cm insertion depth in at least 85 percent of cases with adequate bowel preparation.
2. The Screening Center will report the qualifications and board certification of each QA examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates. FSG QA examiner status must be renewed at annual intervals.

**G. Minimum Qualifications for Trainers**

1. The trainer will be a board-certified gastroenterologist.
2. The Screening Center will report the qualifications and board certification of each trainer to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates.

**H. Examiner Training, Certification and Quality Assurance**

Training

1. Examiners will be trained locally at each Screening Center.
2. All examiners except board certified gastroenterologists and physicians with hospital privileges to perform flexible sigmoidoscopies or colonoscopies, will be trained to perform flexible sigmoidoscopies for the PLCO trial.

3. Training will include watching the ASGE's tape on flexible sigmoidoscopy and may include practicing at least two hours on a model where the examiner manipulates the instrument in the model to gain familiarity with the controls and hand coordination.
4. The examiner will observe 10 procedures (flexible sigmoidoscopies or colonoscopies) performed by the trainer who will talk through the procedure. The examiner will then perform 10 procedures where he/she withdraws the scope, operates the manual controls, and learns the feel of a sigmoidoscopy examination. At this point, the trainer will decide whether the examiner may then begin attempting sigmoidoscopies. The examiner will do enough sigmoidoscopies to demonstrate competence as judged by the trainer.
5. The Screening Center Coordinator will train the examiner on the use of study forms and Screening Center administrative procedures.
6. The Screening Center will submit a training plan to the NCI for review and approval.

#### Certification

1. Certification will be conducted at the Screening Center.
2. For certification of all examiners except board certified gastroenterologists, a minimum of 25 of the training examinations performed by the examiner, must be judged successful by the trainer.
3. The Screening Center will report the results of examiner certification to the NCI on the Record of Experience, Credentials and Training (ECT).

#### Quality Assurance of Examiners see Appendix A, section C of the PLCO QA Plan (MOOP Appendix L)

1. On a quarterly basis, in Screening Centers with the appropriate video equipment, a selected sample of all sigmoidoscopies will be randomly videotaped and reviewed by the trainer or a similarly qualified professional (QA examiner). In those Screening Centers that do not have the appropriate video equipment, an alternative quality assurance method will be proposed to the NCI. Although they may be ideal, repeat FSG exams are not practical within the context of the study. Review of videotape and real-time observation have potential biases, but either method will be an acceptable option for QA.

To the extent possible, participants with abnormal findings should be included in the sample of examinations that are reviewed. NCI will determine the number of samples and the method for their selection. Note: If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

2. The Screening Center will submit a plan for quality assurance of examiners to the NCI for approval.
3. The Screening Center will report the results of quality assurance of examiners to the NCI on a semi-annual basis, including the number of examinations performed and the level of agreement between the examiner and the QA examiner.

4. The Screening Center will report the prevalence of positive (Abnormal Suspicious) exams by examiner. The prevalence of inadequate exams will also be reported by examiner and reason for inadequacy.

#### **I. Documentation of the Examination**

1. See Appendix A-13-1 - Flexible Sigmoidoscopy Screening Examination Form.
2. See Appendix A-13-2 - Flexible Sigmoidoscopy Screening Examination Quality Assurance Form.

#### **J. Equipment Specifications**

1. Flexible endoscope with capability to 60 cm.;
2. Light source.
3. The Screening Center will send the NCI documentation of the equipment used for flexible sigmoidoscopy.

### **2. Interpretation of Results of the Flexible Sigmoidoscopy Examination**

#### **A. Criteria for Determination of a Negative or an Inadequate Examination**

1. Negative Screen - No Abnormalities:

An examination in which the examiner is able to advance the scope to the full or desired length and give a description of negative findings (i.e., no abnormalities are detected).

2. Inadequate:

An examination in which less than 90 percent of mucosa are visible or the flexible sigmoidoscope is inserted to less than 50 cm. with no obstructing lesion and no abnormalities suspicious for cancer in the region visualized. Possible reasons for an inadequate examination:

- Participant discomfort;
- Participant refusal;
- Equipment malfunction;
- Inadequate preparation with unclear lumen;
- Vasovagal response;
- Palpitations with tachycardia;
- Severe diverticulosis with unclear lumen; and
- Severe ulcerative colitis.

When appropriate, the SC should make every attempt to reschedule inadequate examinations. However, a duplicate or repeat exam performed for QA purposes with an inadequate result should not be repeated as a PLCO screening exam or as a PLCO QA exam.

#### **B. Classification and Definition of Abnormal Examination Results**

1. Positive Screen (Referral Required):

Visible or palpable evidence of a mucosal abnormality:

- rectal nodule(s);
- rectal and colon mass(es) and;

- rectal and colon polyp(s).
2. Negative Screen - Other Abnormalities (Referral Optional):
    - External hemorrhoids;
    - Rectal tenderness;
    - Blood;
    - Stricture;
    - Fistulas;
    - Fissures;
    - Diverticulosis;
    - Diverticulitis;
    - Colitis;
    - Vascular lesions;
    - Ulcers;
    - Melanosis coli;
    - Internal hemorrhoids; and
    - Anal warts.

### **C. Reporting of Results to Participants and Physicians**

1. The Screening Center will report results in writing to the participant and to the participant's physician of choice within three weeks of the screening visit.
2. The Study Management System will produce a brief report of results which will be sent to participants and physicians accompanied by a cover letter. Additional findings may be sent at the discretion of the SC. However, any additional material must be approved by NCI.
3. The Screening Center may also give the participant a preliminary summary of results, either verbal or written, during the screening visit.
4. Participants with a screening result of "Positive Screen" will be referred to their physician of choice for diagnostic follow-up and possible treatment. Participants with a screening result of "Negative Screen-Other Abnormalities" will be referred according to standard practice at the Screening Center. The Screening Center will continue to monitor and follow-up all participants who have a positive screening result that is suspicious for cancer.
5. The examiner will assign the result of the examination exclusively according to the findings of the examination, without taking into consideration the results or findings of any previous examinations. If, after the result has been assigned, the SC wishes to compare the result or findings of the examination to those of prior examinations, it may do so as an "internal referral." This internal referral is considered follow-up and is not part of the screening process. If the SC deems it necessary, or the participant requests it, the SC may then refer the participant "externally" for further evaluation to the participant's physician of choice.
6. If a quality assurance examination does not have the same findings as the initial screening examination, referral will be made on the "worst case" abnormal findings, regardless of whether the original examiner or QA examiner found

the abnormal result. When the Screening Test Results Report (STRR) is generated, the following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the exam negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

#### **D. Diagnostic Follow-up Recommendations**

1. No formal recommendations for diagnostic follow-up of positive screens will be given. The Screening Center should refer inquiries to providers they deem to be expert in the field, and provide the 1-800-4-CANCER hotline number as an additional source of information. It is expected that diagnostic follow-up will be state-of-the-art when handled by Screening Center referral providers.

#### Note Regarding Biopsies:

In Screening Centers in which polyps are biopsied during the screening procedure, the biopsy may be considered follow-up. The information obtained from the pathological examination of the biopsied specimen should be recorded on the Medical Record Abstract Diagnostic Evaluation Form - Colorectum.

#### **E. Cancer Confirmation**

1. The final diagnosis of colorectal cancer will be based on histopathologic criteria. The cancer will be coded according to ICD-O codes by a trained medical coder at the Screening Center. Pathology slides and reports that support the cancer diagnosis will be obtained for review by a central study pathologist for all participants diagnosed with colorectal cancer. One stained slide will be required by the NCI for permanent retention. Additional slides may also be required by the NCI. A final diagnosis is based on clinical examination only may also be accepted in certain circumstances where no pathological examination was done.

#### **F. Treatment Recommendations for Individuals Diagnosed with Cancer**

1. No treatment recommendations will be given.

**J-14-1**

Protocol for Ovarian Palpation Examination

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**  
**PROTOCOL FOR OVARIAN PALPATION EXAMINATION**

**1. Standardization of the Ovarian Palpation Examination:**

**A. Participant Preparation**

1. The participant will be told that the examination is a screening examination for ovarian cancer, not a routine examination, and that she should consult her own physician for evaluation of any symptoms and for routine medical care.
2. The participant will be informed that the ovarian palpation examination is not a complete gynecologic examination and will not include a Pap smear. If the Screening Center offers a Pap smear, the participant will be advised that it is not part of the PLCO trial and that there will be a charge for it. The Screening Center will obtain a separate written informed consent for the Pap smear.
3. If a second examiner plans to repeat the examination for quality control purposes, the participant must be told this before the primary examination.
4. The participant will be told that she will receive written results for all screening examinations within approximately three weeks. If the Screening Center plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.
5. Physical Preparation: The participant will empty her bladder within 30 minutes prior to the examination.

**B. Examination Steps**

1. The participant will be in the dorsal recumbent position, in stirrups and draped.
2. The examiner will explain the procedure to the participant step-by-step as it is being performed.
3. The examiner will note right and left ovaries separately. The cervix will not be visualized. The examiner will note if there is gross blood on glove after the examination.
4. The examiner will perform a rectovaginal examination.

**C. Requirements for Standardization of the Examination**

1. The examination will be documented on the data collection form (See Attachment A - Ovarian Palpation Screening Examination Form).
2. The participant preparation: an empty bladder.
3. The examiner will be blind to the results of the transvaginal ultrasound and the sonographer will be blind to the results of the ovarian palpation examination. In order to maintain the blinding of examiners, no information will be given to the participant regarding the ovarian palpation examination nor the transvaginal ultrasound examination until both examinations are completed.

**D. Minimum Quality Standards for the Examination**

1. The examiner must document the palpation of the right and left ovaries.
2. The examiner must document the symmetry of the right and left ovaries.
3. The examiner must note the number of palpable adnexal masses. The location, size, shape, nodularity, consistency, tenderness and mobility for each palpable

adnexal mass must also be noted. Cul-de-sac nodularity observed during the rectovaginal examination will also be noted.

#### **E. Minimum Qualifications for Examiners**

1. The examiner will be a Clinical Nurse Specialist, R.N., a Certified Physician's Assistant, or equivalent. Equivalency is to be determined by the SC Principal Investigator and documented in a letter to be submitted with a completed ECT to NCI.
2. The Screening Center will report the qualifications and licensure of each examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of relevant diplomas, certificates and/or licenses.

#### **F. Minimum Qualifications for QA Examiners**

1. The QA examiner will be any licensed physician with adequate training and experience in ovarian palpation or a certified PLCO OVR examiner.
2. The Screening Center will report the qualifications and board certification of each QA examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates.

#### **G. Minimum Qualifications for Trainers**

1. The trainer will be a board-certified gynecologist or gynecologic oncologist.
2. The Screening Center will report the qualifications and board certification of trainers to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates.

#### **H. Examiner Training, Certification and Quality Assurance**

##### Training

1. Examiners will be trained locally at each Screening Center.
2. Non-physician examiners will spend at least two full days working with a trainer.
3. Non-physician examiners will successfully perform a minimum of 40 ovarian palpation examinations on post-menopausal women, including 10 examinations with abnormal findings. Initially the trainer will demonstrate and the examiner will follow. As the examiner begins to demonstrate competence, the trainer will observe the examiner, then confirm examiner findings.
4. The Screening Center may employ professional models, although this will not be covered under the screening trial budget.
5. The Screening Center Coordinator will train all examiners on the use of the study forms and Screening Center administrative procedures.
6. The Screening Center will submit a training plan to the NCI for review and approval.

##### Certification

1. Certification will be conducted at the Screening Center.
2. The examiner will display competence during training by successfully performing the ovarian palpation examinations under the supervision of the trainer. The trainer will document that the examiner successfully performed the examinations.

3. The Screening Center will report the results of examiner certification to the NCI on the Record of Experience, Credentials and Training (ECT).

Quality Assurance of Examiners see Appendix D, Section C of the PLCO QA Plan (Appendix L)

1. In each quarter, a selected sample of all screening tests will be repeated by the trainer or a similarly qualified professional (QA examiner). To the extent possible, participants with abnormal findings should be included in the sample receiving repeat examinations. NCI will determine the number of samples and the method of their selection.
2. The Screening Center will submit a plan for quality assurance of examiners to the NCI for approval.
3. The Screening Center will report the results of quality assurance of examiners to the NCI on a semi-annual basis, including the number of examinations performed and the level of agreement between the examiner and the QA examiner.
4. The Screening Center will report correspondence measures on comparisons between OVR and TVU results.
5. The Screening Center will report the prevalence of positive (Abnormal Suspicious) or inadequate exams by examiner and reason for inadequacy.

#### **I. Documentation of the Examination**

1. See Attachment A - Ovarian Palpation Screening Examination Form.
2. See Attachment B - Ovarian Palpation Screening Examination Quality Assurance Form.

#### **2. Interpretation of Results of the Ovarian Palpation Examination:**

##### **A. Criteria for Determination of a Negative or an Inadequate Examination**

1. Negative Screen - No Abnormalities:
  - Adequate examination fully completed and no adnexal masses or other abnormalities detected.
  - For non-obese participants with non-palpable ovaries, the examination will be considered negative.
2. Inadequate:
  - The examination was not completed, (including the rectovaginal exam) (due to participant discomfort, participant refusal, or some other reason), and no abnormalities indicative of a positive screen are identified;
  - Both ovaries are reported by the participant as removed and no abnormalities indicative of a positive screen are identified.
  - Participant so obese that the examiner is unable to adequately examine the ovaries.

##### **B. Classification and Definition of Abnormal Examination Results**

1. Positive Screen (Referral Required):
  - Palpable adnexal mass; or
  - Cul-de-sac nodularity.

2. Negative Screen - Other Abnormalities (Referral Optional): An adequate exam, fully completed and one or more of the following abnormalities detected:
  - Abdominal pain or tenderness on examination;
  - Vaginal bleeding;
  - Other significant clinical findings noted incidentally while doing the examination. (For example: lesions on external genitalia, enlarged uterus, or other non-ovarian pelvic masses).

### **C. Reporting of Results to Participants and Physicians**

1. The Screening Center will report results in writing to the participant and to the participant's physician of choice within three weeks of the screening visit.
2. The Study Management System will produce a brief report of results which will be sent to participants and physicians accompanied by a cover letter. Additional findings may be sent at discretion of the SC. However, any additional material must be approved by NCI.
3. The Screening Center may also give the participant a preliminary summary of results, either verbal or written, during the screening visit.
4. Participants with a result of "Positive Screen" will be referred to their physician of choice for diagnostic evaluation and possible treatment. Participants with a result of Negative Screen - Other Abnormalities" will be referred according to standard practice at the Screening Center. The Screening Center will continue to monitor and follow-up all participants who have a positive screening result that is suspicious for cancer.
5. The examiner will assign the result of the examination exclusively according to the findings of the examination, without taking into consideration the results or findings of any previous examinations. If, after the result has been assigned, the SC wishes to compare the result or findings of the examination to those of prior examinations, it may do so as an "internal referral." The participant will be notified of the results of the internal referral. If the SC deems it necessary, or the participant requests it, the SC may then refer the participant "externally" for further evaluation to the participant's physician of choice. All internal and external referrals for a positive screen will be considered part of the diagnostic evaluation of the positive screen.
6. If a quality assurance examination does not have the same findings as the initial screening examination, referral will be made on the "worst case" abnormal findings, regardless of whether the original examiner or QA examiner found the abnormal result.

### **D. Diagnostic Follow-up Recommendations**

1. No formal recommendations for diagnostic follow-up of positive screens will be given. The Screening Center should refer inquiries to providers they deem to be expert in the field, and provide the 1-800-4-CANCER hotline number as an additional source of information. It is expected that diagnostic follow-up will be state-of-the-art when handled by Screening Center referral providers.

### **E. Cancer Confirmation**

1. The final diagnosis of ovarian cancer will be based on histopathologic criteria. The cancer will be coded according to ICD-O codes by a trained medical coder at the Screening Center. Pathology slides and reports that support the diagnosis of cancer will be obtained for review by a central study pathologist for all

participants diagnosed with ovarian cancer. One stained slide will be required by the NCI for permanent retention. Additional slides may also be required by the NCI. A final diagnosis based on clinical examination only may also be accepted in certain circumstances where no pathological examination was done.

**F. Treatment Recommendations for Individuals Diagnosed with Cancer**

1. No treatment recommendations will be given.

## **J-15-1**

J-15-1: Protocol for Transvaginal Ultrasound Examination

**Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial**  
**PROTOCOL FOR TRANSVAGINAL ULTRASOUND EXAMINATION**

**1. Standardization of Transvaginal Ultrasound Examination**

**A. Participant Preparation**

1. The participant will be told that the examination is a screening examination for ovarian cancer, not a routine examination, and that she should consult her own physician for evaluation of any symptoms and for routine medical care.
2. If a repeat examination is planned for quality control purposes, the participant will be told this in advance of the examination.
3. The participant will be told that she will receive written results for all screening examinations within approximately three weeks. If the Screening Center plans to report preliminary results to the participant, the participant will also be told this in advance of the examination.
4. Prior to beginning the examination, the sonographer will briefly explain the procedure. A sample script follows:

*"Your bladder should be empty. The exam involves the insertion of a small probe, which is covered with a protective sheath, into the vagina. The probe lets me see your pelvic organs. The sensations from the probe and the speculum used for the pap smear test are very similar. Sometimes, participants experience some discomfort during this part of the test. (To make sure that the test results are correct, a second sonographer or doctor may ask your permission to repeat the exam.) Your test results will be sent to your home within three weeks."*

5. Physical Preparation: The participant will empty her bladder prior to the examination.

**B. Examination Steps**

1. The sonographer will image both the left and right ovary in two planes and will record the transverse, longitudinal, and anteroposterior diameters for both the left and right ovary.
2. Using calipers, the sonographer will take measurements on the image along the major and minor axes in both transverse and longitudinal planes.

**C. Requirements for Standardization of the Examination**

1. The examination will be documented on the data collection form. (See Appendix A-15-1 - Transvaginal Ultrasound Screening Examination Form).
2. The examiner will search no less than five minutes per ovary for each ovary, to ensure an adequate search for the ovaries; however, if the iliac vessels are visualized and no ovaries are visualized, the examiner may conclude the search for the ovaries.
3. The equipment: 5-7.5 MHz transvaginal probe.
4. The participant preparation: an empty bladder.
5. The transvaginal ultrasound will be performed prior to the flexible sigmoidoscopy.

#### **D. Minimum Quality Standards for the Examination**

1. Every reasonable attempt will be made to image and photograph both ovaries in two perpendicular planes (four images total).
2. Complete documentation of the ovarian dimensions will be required for each examination.
3. In those participants who have had an ovary removed, a complete examination would indicate visualization of the remaining structures.
4. If one or both ovaries are not visualized appropriately in an adequate examination, the examination should be considered negative.

#### **E. Minimum Qualifications for Examiners**

1. The examiner will be a sonographer who is registered by the American Registry of Diagnostic Medical Sonographers (ARDMS), has passed the OB/Gyn section of the ARDMS certification examination, and has performed 50-100 prior transvaginal ultrasound examinations. The examiner may also be a physician who is adequately trained in transvaginal ultrasonography as determined by the Principal Investigator.
2. The Screening Center will report the qualifications and licensure of each examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of relevant diplomas, certificates and/or licenses.

#### **F. Minimum Qualifications for QA Examiners**

1. The QA examiner will be either a PLCO TVU trainer or a PLCO TVU examiner who has performed at least 240 TVU examinations in the prior 12 months (average 20 per month) and detected one or both ovaries in at least 60 percent of those exams deemed adequate.
2. The Screening Center will report the qualifications and board certification of each QA examiner to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of board certificates. The TVU QA examiner status should be renewed at annual intervals.

#### **G. Minimum Qualifications for Trainers**

1. The trainer will be a certified radiologist with specific training in ultrasonography.
2. The Screening Center will report the qualifications and licensure of each trainer to the NCI by submitting a completed Record of Experience, Credentials and Training (ECT) with copies of relevant diplomas, certificates and/or licenses.

#### **H. Examiner Training, Certification and Quality Assurance**

##### Training

1. Sonographers will be trained locally on performing the transvaginal ultrasound examination and ovarian measurements. Prior to acting as a PLCO sonographer, the individual must have performed 50-100 transvaginal ultrasound examinations. These may be done as training exams or prior to PLCO involvement.
2. The sonographer will demonstrate competence by successfully performing accurate examinations.

3. The Screening Center Coordinator will train the sonographer and the trainer on the use of study forms and Screening Center administrative procedures.
4. The Screening Center will submit a training plan to the NCI for review and approval.

#### Certification

1. The sonographer will display competence by successfully performing examinations accurately during training.
2. The Screening Center will report the results of examiner certification to the NCI on the Record of Experience, Credentials and Training (ECT).

#### Quality Assurance of Examiners see Appendix E, Section C of the PLCO QA Plan (MOOP Appendix L)

1. On a quarterly basis, a selected sample of all screening tests performed will be randomly selected to be repeated by the trainer or a similarly qualified professional (QA examiner). Where available, in lieu of repeat examinations, a review of films may be performed by the QA examiner. To the extent possible, participants with abnormal findings should be included in the sample of examinations that are repeated or reviewed. NCI will determine the number of samples and method for their selection. Note: If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.
2. The Screening Center will submit a plan for quality assurance of examiners to the NCI for approval.
3. The Screening Center will report the results of quality assurance of examiners to the NCI on a semi-annual basis including the number of examinations performed and the level of agreement between the examiner and the QA examiner.
4. The Screening Center will report correspondence measures on comparisons between the OVR and TVU results.
5. The Screening Center will report the prevalence of positive (Abnormal Suspicious) or inadequate exams by examiner and reason for inadequacy.

#### **I. Documentation of the Examination**

1. See Appendix A-15-1 - Transvaginal Ultrasound Screening Examination Form.
2. See Appendix A-15-2 - Transvaginal Ultrasound Screening Examination Quality Assurance Form.
3. The following items will be documented on the data collection form:
  - a. Presence or absence of a sonographically detectable left and right ovary;
  - b. Left and right ovary size (volume calculated using the prolate ellipsoid formula: width x height x thickness x 0.523);
  - c. Presence or absence of morphologic abnormality in each adnexal area;
  - d. Description of every identified discrete adnexal abnormality; and
  - e. Description of discrete abnormalities in terms of:
    - location (right or left adnexal area);

- maximum diameter;
- volume (calculated using (maximum diameter)<sup>3</sup> x 0.523);
- solid areas;
- septal structure;
- cyst outline;
- cyst wall thickness; and
- echogenicity.

#### **J. Equipment Specifications**

1. 5-7.5 MHz transvaginal probe.
2. Equipment must meet FDA guidelines and institution and state licensure regulations.
3. The Screening Center will send the NCI documentation of the equipment used for transvaginal ultrasound.

#### **K. Photo Documentation**

1. A photograph, computerized image, or thermal printout will be obtained for documentation of all adequate examinations, regardless of whether or not the ovaries were visualized, and will be retained as part of the permanent record. It is acceptable to store transvaginal ultrasound images on thermal paper, radiographic film, or digitally. If digital storage is chosen a back-up copy should also be maintained. The storage method should meet requirements of 20-year storage with no decrease in the quality of the image and with the capability to retrieve a film or paper image at any time during the 20-year storage period.

### **2. Interpretation of Results of the Transvaginal Ultrasound**

#### **A. Criteria for Determination of a Negative or an Inadequate Examination**

1. Negative Screen - No Abnormalities:

An adequate examination in which no abnormalities or any kind are found (regardless of whether or not the ovaries are visualized).

2. Inadequate:

- Participant discomfort or pain which prevents completion of the examination;
- Participant refusal to complete examination;
- Inability to insert the probe;
- Equipment malfunction;
- Bowel interference; or
- Some other condition.

When appropriate, the SC should make every attempt to reschedule inadequate examinations. However, a duplicate or repeat exam performed for QA purposes with an inadequate result should not be repeated as a PLCO screening exam or as a PLCO QA exam.

## **B. Classification and Definition of Abnormal Examination Results**

### 1. Positive Screen (Referral Required):

The Screening Center will use the prolate ellipsoid formula (width x height x thickness x 0.523) to calculate the volume of each ovary or cyst. For cysts, the maximum diameter of the cyst will be used in volume calculations [(maximum diameter)<sup>3</sup> x 0.523]. An abnormal (positive) transvaginal ultrasound will consist of an examination with one or more of the following features:

- Any ovary or cyst greater than 10 cubic cm in volume;
- Any solid area or papillary projection extending into the cavity of a cystic ovarian tumor of any size;
- Any mixed (solid/cystic) component within a cystic ovarian tumor.

### 2. Negative Screen - Other Abnormalities (Referral Optional):

An adequate examination that reveals one or more abnormalities that do not satisfy the criteria for a positive screening examination.

Note: If the examiner notes a nabothian cyst, defined as a cyst of the nabothian gland (located on the cervix), the examiner can make the decision whether to code the result as either Negative Screen - No Abnormalities or Negative Screen - Other Abnormalities.

## **C. Reporting of Results to Participants and Physicians**

1. The Screening Center will report results in writing to the participant and to the participant's physician of choice within three weeks of the screening visit.
2. The Study Management System will produce a brief report of results which will be sent to participants and physicians accompanied by a cover letter. Additional findings may be sent at the discretion of the SC. However, any additional material must be approved by NCI.
3. The Screening Center may also give the participant a preliminary summary of results, either verbal or written, during the screening visit.
4. Participants with a result of "Positive Screen" will be referred to their physician of choice for diagnostic evaluation and possible treatment. Participants with a result of "Negative Screen - Other Abnormalities" will be referred according to standard practice at the Screening Center. The Screening Center will continue to monitor and follow-up all participants who have a positive screening result that is suspicious for cancer.
5. The examiner will assign the result of the examination exclusively according to the findings of the examination, without taking into consideration the results or findings of any previous examinations. If, after the result has been assigned, the SC wishes to compare the result or findings of the examination to those of prior examinations, it may do so as an "internal referral." The participant will be notified of the results of the internal referral. If the SC deems it necessary, or the participant requests it, the SC may then refer the participant "externally" for further evaluation to the participant's physician of choice. All internal and external referrals for a positive screen will be considered part of the diagnostic evaluation of the positive screen.
6. If a quality assurance examination does not have the same findings as the initial screening examination, referral will be made on the "worst case" abnormal findings, regardless of whether the original examiner or QA examiner found

the abnormal result. When the Screening Test Results Report (STRR) is generated, the following hierarchy exists for reporting worst case results: First, the referral level is taken into account (1-4, with a 1 being the highest level of referral.) Second, the diagnosis hierarchy is defined as AS, AN, NG, IN, and RP. For example, if one examiner finds the exam negative with a referral code of 4 (NG-4) and the other finds it abnormal, not suspicious with a referral code of 3 (AN-3), the result will be reported based on the highest referral level and the highest diagnosis code (AN-3).

#### **D. Diagnostic Follow-up Recommendations**

1. No formal recommendations for diagnostic follow-up of positive screens will be given. The Screening Center should refer inquiries to providers they deem to be expert in the field, and provide the 1-800-4-CANCER hotline number as an additional source of information. It is expected that diagnostic follow-up will be state-of-the-art when handled by Screening Center referral providers.

#### **E. Cancer Confirmation**

1. The final diagnosis of ovarian cancer will be based on histopathologic criteria. The cancer will be coded according to ICD-O codes by a trained medical coder at the Screening Center. Pathology slides and reports that support the cancer diagnosis will be obtained for review by a central study pathologist for all participants diagnosed with ovarian cancer. One stained slide will be required by the NCI for permanent retention. Additional slides may also be required by the NCI. A final diagnosis based on clinical examination only may also be accepted in certain circumstances where no pathological examination was done.

#### **F. Treatment Recommendations for Individuals Diagnosed with Cancer**

1. No treatment recommendations will be given.

## **APPENDIX K**

**Appendix K: General Interviewing/Abstracting Techniques**

**K-17-1**

General Interviewing Techniques

**PLCO Cancer Screening Trial**  
**GENERAL INTERVIEWING TECHNIQUES**

**1. Types of Questions**

In using the Baseline Questionnaire, you will encounter different types of questions. These are precoded, open-ended, and dependent questions.

- A. **PRECODED QUESTIONS.** A precoded or closed-ended question is one in which the choice of answers is provided with the question. The simplest form of a precoded question requires a "yes/no" answer:

<p>Have you ever smoked cigarettes regularly for six months or longer?</p> <p style="margin-left: 100px;"><input type="radio"/> No</p> <p style="margin-left: 100px;"><input type="radio"/> Yes</p>
---

Other precoded questions are written so they include all possible answers:

<p>What is your marital status?</p> <p style="margin-left: 40px;"><input type="radio"/> MARRIED</p> <p style="margin-left: 40px;"><input type="radio"/> SEPARATED/DIVORCED</p> <p style="margin-left: 40px;"><input type="radio"/> WIDOWED</p> <p style="margin-left: 40px;"><input type="radio"/> NEVER MARRIED</p>
--

Although precoded questions are written so that the suggested answers are both exhaustive and mutually exclusive, there may sometimes be an overlap between given categories. In such cases, respondents must choose the one that is closest to what they think or do.

- B. **OPEN-ENDED QUESTIONS.** Open-ended questions, which are also called "free answer" questions, are those which are followed by a blank space, and which do not list possible answers.

<p>What has been your usual adult occupation?</p> <hr style="width: 80%; margin: 10px auto;"/> <hr style="width: 80%; margin: 10px auto;"/>
---

The typical open-ended question requires at least a sentence or two to answer, and often more. However, there is a special type of short open-ended question that may best be described as a cross between a precoded and open-ended question that need to be considered briefly. This is a question that simply asks the respondent to name an amount, or perhaps a date ("How long?" "How much?")

"When?") Sometimes, these short questions are followed by code boxes to fill in the answer.

- C. **DEPENDENT QUESTIONS.** Dependent questions are those which are asked only of some respondents. The determination of who is to be asked the question is "dependent" upon the answer to a previous question. You will be instructed in the questionnaire by what we call "skip" instructions, when this kind of question is to be omitted based on a previous response. Questions can be either precoded or open-ended. An example of a dependent question is:

10. Have you ever smoked cigarettes regularly for six months or longer?

No (GO TO QUESTION 16)

Yes

11. At what age did you start smoking cigarettes regularly?

|\_|\_| In years

In this case, the instructions after Question 10 direct you to ask Question 11 only of those respondents who said yes to smoking regularly for six months or longer. Therefore, Question 11 is dependent upon the answer to Question 10.

It is surprisingly easy to begin to ask a dependent question before you suddenly realize that it should not have been asked. To avoid this, you should mentally review the instructions before starting the interview. If it should happen that you ask a dependent question when you should not, simply excuse your error and go onto the next possible questions.

## 2. Asking the Questions

Here are some principles and techniques that you must follow while administering the questionnaire.

- A. **REVIEW THE QUESTIONNAIRE BEFORE STARTING.** Before you start, you must feel at ease with the questions. If you do not feel comfortable, you may transmit uncertainty to the respondent. It is important to remember that the questions are there for specific reasons.
- B. **ALWAYS REMAIN NEUTRAL.** You must maintain a neutral attitude with your respondents. You must be careful that nothing in words or vocal tone implies criticism, surprise, approval or disapproval of either the questions asked or of the respondent's answers and comments.

Through your relaxed, professional attitude, you can put the respondent at ease and gain his/her confidence. You must not influence the respondent's answers in any way, directly or indirectly. Another interviewer should be able to obtain the same answers from the same respondent.

Practice asking all questions in an interested yet "matter of fact" way. By doing so, you will find in most cases neither you nor your respondent will feel sensitive about any questions asked.

- C. **ASK ALL QUESTIONS IN THE ORDER PRESENTED IN THE QUESTIONNAIRE.** Never change the order of the questions in the questionnaire. The questions follow one another in a carefully designed sequence; to change that sequence would subvert

the intent of the questionnaire and the research objectives of the study. Some questions may be asked after certain other questions so as not to affect the answers to the earlier questions.

If your respondent is talking freely, s/he may answer some questions before you get to them. If this happens: DO NOT SKIP OVER ANY OF THE QUESTIONS (UNLESS YOU ARE INSTRUCTED TO DO SO), EVEN THOUGH YOU THINK THERE MAY BE SOME REPETITION. If a respondent should get a little annoyed and say, "I just told you that," you can always say something pleasant like:

- "I have to make sure that I had your full answer to that," or
- "I didn't know whether you would have others things to say on the subject," or
- "You may have already told me this, but let me make sure I have your answer correctly."

- D. ASK ALL QUESTIONS EXACTLY AS WORDED. Do not change even one little word in the question that is printed out for you. Many times, the smallest change can affect the whole meaning of the question. Simply repeat the question if the need arises. If you do repeat the question, read all the words in the question.

EVEN THOUGH YOU FEEL THAT THE QUESTION COULD BE WORDED MUCH MORE SIMPLY, DO NOT IMPROVISE ON THE METHOD OF ASKING THE QUESTION. EVERY WORD IS THERE FOR A PURPOSE. Emphasize only those words which are underlined, and pause only at commas or after each answer category when they are included in the question itself. Read everything in a natural, even-toned manner.

In order for all the interviewers' work to be combined, there must be no doubt that each respondent heard exactly the same question before answering.

Sometimes respondents will ask you to define words in a question or explain some part of a question. Unless a definition or explanation is provided, do not provide one. Simply let respondents know that they should answer using their own definition. Say, "Whatever it means to you—just answer that way."

- E. DISCOURAGE UNRELATED CONVERSATION WHILE ASKING QUESTIONS. Occasionally a particular question may cause the respondent to reminisce or relate a lengthy story illustrating the point just made, especially among older, lonely, or more talkative respondents.

You'll do both yourself and the respondent a favor if you keep the interview businesslike in tone. If you hit upon a rambling respondent, or one who launches into irrelevant conversation, don't hesitate to interrupt and politely bring him/her back to the point of the question by repeating what you want to know. At the same time, of course, you must be careful not to antagonize the respondent, though you may find that talkative persons are the ones who least mind being interrupted. You can always say something like: "That's very interesting..." and repeat the question.

### 3. Instructions in the Questionnaire

In addition to the questions you must ask, the questionnaire will also contain instructions. They are there to help you use the questionnaire correctly and must be followed closely. The following are some of the more common rules relating to instructions in the questionnaire.

- A. "SKIP INSTRUCTIONS." Many answer categories are followed by skip instruction, either in parentheses or in a box. These tell you what questions to ask next. In most instances, you will be referred to a specific question.

Skip instructions in parentheses are used primarily in situations where you skip to different places, depending upon how the respondent answers the question you have just asked. In instances where the answer is not followed by a skip instruction, you simply proceed to the next question after you have recorded the answer.

- B. WORDS IN PARENTHESES FOLLOWING THE QUESTION. Occasionally you will find a word or phrase in parentheses following the question. These are additional instructions to help the participant correctly answer the question.
- C. INSTRUCTIONS ON HOW TO RECORD ANSWERS. Where appropriate, questions are followed by an instruction about how to record the answer, e.g., OTHER (SPECIFY).

#### **4. Probing**

Probing is the technique used by the interviewer to obtain more information when a respondent's answer is not clear or is incomplete, or does not adequately answer the question. On the Baseline Questionnaire there are critical data items that require data retrieval when an answer is incomplete, unclear or not answered. These questions will usually require probing during data retrieval.

##### **4.1. Probing Precoded and Open-Ended Questions**

- A. PROBING PRECODED QUESTIONS. Although open-ended questions more often require probing, you may also need to probe on a precoded question. Sometimes the best probe for a precoded question is repeating the original question or giving the non-directive probe, "Well, which comes closest?"

Another situation may occur in precoded questions when the respondent gives additional information or explains his/her choice. In this case write down (in the blank space) relevant comments the respondent volunteers while answering a precoded question. However, do not probe for clarification of these comments.

- B. PROBING OPEN-ENDED QUESTIONS. In the case of the longer open-ended questions, the techniques of probing must be used to the fullest, for frequently the initial answers given by the respondent will fall far short of the being specific, clear, and complete.

##### **4.2. Probing Methods Should be Neutral**

It is very important to always use neutral probes. By this we mean you should not imply to the respondent that you expect a specific answer or that you are dissatisfied with an answer.

Remember the reason for probing is to motivate the respondent to answer more fully or to focus the answer, without introducing bias. The potential for bias is great in the use of probes. Under the pressure of the interviewing situation, the interviewer may quite unintentionally imply that some answers are more acceptable than others or may hint that a respondent might want to consider this or include that in giving responses.

##### **4.3. Kinds of Probes**

There are several different neutral probes, which appear as part of a normal conversation that can be used to stimulate a fuller, clearer response.

- A. AN EXPRESSION OF INTEREST AND UNDERSTANDING. By saying such things as "uh-huh" or "I see" or "yes," the interviewer indicates that the response has been

heard, that it is interesting and that more is expected. Be very careful how you say these; avoid sounding approving or disapproving.

- B. REPEAT THE QUESTION. When the respondent does not seem to understand the question, misinterprets it, seems unable to decide, or strays from the subject, it is often useful to repeat the question. Many respondents, when hearing the question for the second time, realize what kind of answer is needed. You can preface the question by saying, "Let me repeat the question."
- C. REPEATING THE RESPONDENT'S REPLY. Simply repeating what the respondent has said is often an excellent probe. Hearing the response just given often stimulates the respondent to further thought. You can say something like: "Let me make sure I have this correctly. You said, (REPEAT RESPONSE)." Make sure your approach to this does not sound incredulous. Think of it as a verification.
- D. A NEUTRAL QUESTION OR COMMENT. Neutral questions or comments are often used to obtain clearer and fuller responses. The following are some suggestions for probing questions that may help you explore may types of insufficient answers.

PROBES USED TO OBTAIN CLEARER RESPONSES

"What do you mean exactly?"

"What do you mean by...?"

"Could you please explain that a little? I don't think I quite understand."

PROBES USED TO OBTAIN SPECIFIC RESPONSES

"Could you be more specific about that?"

"Tell me about that."

PROBES USED TO OBTAIN MORE RELEVANT RESPONSES

"I see. Well, let me ask you again...(REPEAT EXACT QUESTION)."

"Would you tell me how you mean that?"

PROBES USED TO OBTAIN COMPLETE RESPONSES

"What else?"

"What else can you think of?"

#### **4.4. The Don't Know (DK) Response**

The "I don't know" answer can mean a number of things. For instance:

- The respondent doesn't understand the question and says "don't know" to avoid saying s/he doesn't understand;
- The respondent is thinking the question over, and says "don't know" to fill the silence and give himself/herself time to think;
- The respondent may be trying to evade the issue because s/he feels uninformed, or is afraid of giving a wrong answer, or because the question seems too personal; or

- The respondent may really not know or really may have no opinion on the question.

Try to decide which of the above may be the case. Don't be in too big a rush to settle for a "don't know" reply. If you wait expectantly your respondent will usually think of something further to say. Pausing and waiting are frequent probes for a "don't know." You'll also find that other useful probes are: "Well, what do you think?" or "I just want your own ideas on that."

If you feel the respondent has answered "don't know" out of fear of admitting ignorance, you may act reassuring by saying "There's really no right answer to this question -- we're just interested in your opinion."

You must always try at least once to obtain a reply to a "don't know" response, before accepting it as the final answer. But be careful not to antagonize the respondents or force an answer if they say again that they don't know.

#### **4.5. When to Stop Probing**

When you have obtained as much information from the respondent as possible and when you have encouraged the respondent to clarify the meaning of his or her own words to that you know exactly what s/he had in mind—only then do you have a complete answer and only then should you stop probing. However, if at any time the respondent becomes irritated or annoyed, discontinue probing. We do not want the respondent to refuse the rest of the interview.

### **5. Recording Answers**

The following are some general rules for recording answers.

- A. PLEASE ERASE IF IT IS NECESSARY TO CHANGE A CODE. However, the only time you should change a code is if you discover an error while interviewing or editing from the same source. Do not erase during data retrieval attempts.
- B. RIGHT JUSTIFY ALL NUMBERS. The term "right justify" means that numerical information should be entered in the rightmost coding boxes available for a given item and any coding boxes to the left of the number should be filled with zeros. That is, whenever there are more coding boxes available than numerals to fill them, put the number(s) in the rightmost boxes and put zeros in the unused boxes on the left. For example:

Month of July—two coding boxes -- July = |\_\_|\_\_|

MM

- C. FRACTIONS MUST BE ROUNDED. When figures are represented in fractions, the following rules apply:
  - If fraction is equal to .5 (1/2) or more, round up. E.g., 2.5 = 3
  - If fraction is less than .5 (1/2), round down. E.g., 2.3 = 2
- D. RECORDING VERBATIM. The key word in recording open-ended questions is "verbatim." This means writing down everything relevant the respondent says in his/her own words. Here are a few important rules, which will help you.
  - BE READY TO WRITE. Have your pencil poised when you ask your question. Start writing immediately; otherwise you'll be far behind from the beginning.

- USE ABBREVIATIONS. However, look over the abbreviations you have used after you hang up. If any abbreviations would be confusing to the people who have to read the responses, spell out the term completely while going over your work.
- ASK THE RESPONDENT TO SLOW DOWN.
- VERBATIM RECORDING, OF COURSE, MEANS THAT YOU SHOULD USE THE RESPONDENT'S OWN LANGUAGE WORD FOR WORD -- Don't correct or summarize what respondents say; let them speak for themselves!

**K-17-2**

General Abstracting Techniques

**PLCO Cancer Screening Trial**  
**GENERAL ABSTRACTING TECHNIQUES**

These are general guidelines that should be followed when abstracting medical records.

The abstractor's goal is to collect accurate information by using the abstract form according to sound data collection practices. To fulfill this goal, the abstractor needs to understand the format of the abstract form and the principles for using it.

Always review the entire medical record thoroughly before completing the abstract. Some items may require interpretation and other items can be abstracted *exactly* as it is given in the record. If interpretation is required, it should be based on sound reasoning with avoidance of guessing. When recording, bear in mind that regardless of how carefully you have researched a medical record for needed data, all your efforts will have been wasted if you fail to record the answer properly or legibly. Record all numbers carefully and print letters.

### **1. Types of Items**

You will find the following types of items on the Medical Record Abstract Forms.

- A. **PRECODED ITEMS.** A precoded or closed-ended question is one in which the answer choices are contained in the question. The simplest form of a precoded question requires a "no"/"yes"/"unknown" answer, while other precoded questions may offer several possible answers.

Some of the precoded questions are written so that the suggested answers are both exhaustive and mutually exclusive—that is, they provide for all possible answers and do not duplicate each other. Only one answer is allowed. Other precoded questions may list all possible answers and ask for "all that apply." More than one answer is allowed.

- B. **OPEN-ENDED ITEMS.** Open-ended items do not list possible answers, but are followed by a line or box in which to record the answer. There are two kinds of open-ended items in this abstract form.

Some open-ended items are a hybrid of precoded and open-ended items for which the range of possible answers can be anticipated. This type of question is called a short open-ended question and usually asks for a number, an amount, or a date. The correct number of boxes is given on the form and you can enter the appropriate numbers.

The other type of open-ended item requires you to record information on a designated line. It is important to write clearly and contain your entry within the space allotted. Examples of open-ended items are the "verbatim descriptions" and "specify" items.

### **2. Instructions in the Medical Records Abstract Forms**

Instructions may appear in the abstract forms in several ways, e.g., in a parentheses or in a box. The instructions are there to remind you how to use the abstract form correctly. The following are some of the common rules relating to instructions in the questionnaire.

- A. **WORDS IN PARENTHESES.** Instructions in parentheses may follow an item name or a response category.
- B. **"SKIP INSTRUCTIONS."** Many of the items have skip instructions, either in parentheses or in a box. These tell you which item to go to next. For example, many of the items direct you to complete a table if the item was answered "yes."

- C. INSTRUCTIONS ON HOW TO RECORD ANSWERS. Many of the items include instructions on how to record an answer. For example, an item may direct you to a list of codes from which to choose the appropriate response(s).

### 3. General Rules for Recording Answers

The following are some general rules for recording answers.

- A. CAREFULLY ENTER ONLY ONE CODE NUMBER IN EACH BOX.
- B. ERASE IF IT IS NECESSARY TO CHANGE A CODE AND ENTER THE CORRECT CODE IN ITS PLACE.
- C. RIGHT JUSTIFY ALL NUMBERS. The term "right justify" means that numerical information should be entered in the rightmost coding boxes available for a given item and any coding boxes to the left of the number should be filled with zeros. That is, whenever there are more coding boxes available than numbers to fill them, put the number(s) in the rightmost boxes and zeros in the unused boxes on the left. For example:

Month of July--two coding boxes -- July = |\_\_|\_\_|  
MM

- D. FRACTIONS MUST BE ROUNDED. When figures are represented in fractions, the following rules apply:
- If the fraction is equal to .5 (1/2) or more, round up. For example, 2.57 = 2.6, 3.5 = 4
  - If the fraction is less than .5 (1/2), round down. For example, 1.23 = 1.2, 2.3 = 2.
- E. RECORDING VERBATIM. Recording "verbatim" means writing down everything exactly as it appears in the medical record. Here are a few important rules to follow:
- USE ABBREVIATIONS AS THEY APPEAR IN THE MEDICAL RECORD. However, look over the abbreviations you have used after you have finished. If any abbreviations would be confusing to the people who have to read the responses, spell-out the term completely while going over your work.
  - VERBATIM RECORDING, OF COURSE, MEANS THAT YOU RECORD DATA FROM THE MEDICAL RECORD *WORD FOR WORD*. Don't correct or summarize what is written in the medical record. The *exact words and phrases should be used*.
- F. COMMENTS SECTION: Use this section to record any overflow information. Place an asterisk (\*) beside the item number which is being referenced. In the Comments Section, reference the item on which you are commenting. Initial and date your comments. If more space is needed, use the back of the abstract form or additional paper. If you reference the medical record, do not correct or summarize what is written in the medical record. Record the *exact words and phrases used*.
- Discrepant information should no longer be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Lead Abstractor, SC Coordinator and/or the Principal Investigator should review the discrepant information for the appropriate coding decision prior to calling the MRA Coordinator.

#### 4. Editing the Abstract Form

*As soon as possible* after abstracting a medical record, review the completed abstract form while it is still fresh in your mind. Make sure the form is filled out accurately and completely. This procedure is known as EDITING and, though it doesn't take long, it is an *important* part of an abstractor's job. Some of the purposes of editing are:

- A. TO CATCH AND CORRECT ERRORS AND OMISSIONS IN RECORDING. Common errors that can be caught in editing are: omitted codes and errors in entering codes. Check to make sure that no information is missing.
- B. TO LEARN FROM MISTAKES SO THEY ARE NOT REPEATED.
- C. TO CLARIFY HANDWRITING AND WRITE OUT ABBREVIATIONS MORE FULLY. Go over all illegible handwriting, and fill in all but the most common abbreviations.

#### 5. Photocopying

Whenever portions of medical records are photocopied, it is necessary to identify properly all photocopies. Identify pages to be photocopied by clipping the page(s) with paper clips. Be sure to follow these rules:

- A. Label each page with the Participant ID, and number each page, e.g., 1 of 3, 2 of 3, etc.
- B. Reference the specific item number for which the photocopy was made, e.g., the pathology report for an ovarian cancer is identified in Item 14 of the Medical Record Abstract Form--Diagnostic Evaluation for Ovary.
- C. *ALWAYS* attach the photocopied pages to the abstract form with a clip, or insert in the Medical Record Abstract Form Booklet.

#### 6. Definitions and Synonyms for Diagnostic/Staging Procedures

Following is a list of many of the diagnostic and staging procedures that are named as Procedure Codes on the DEP, DEL, DEC, and DEO forms. The list of procedures is in alphabetical order and is not arranged by cancer type. A definition/explanation is provided for each of the procedures. Also, if a particular procedure is commonly referred to by a different term or terms, the other term(s) is/are provided.

**Abdominal flat plate (plain film):** Radiographic examination requiring a frontal projection of the abdomen with the patient in a supine position. Also known as a KUB film.

**Abdominal/Vaginal Hysterectomy:** This is the surgical removal of the uterus. The approach is either through the vagina or the abdomen.

**Abdominal Ultrasound:** The use of sound waves (ultrasound) on the abdomen to differentiate composition differences in organs, cysts, or tissues.

**Barium enema/Barium enema radiograph:** The administration of barium, a radio-paque medium, for x-ray study of the lower intestinal tract. A hypaque enema radiograph would not be included here.

**Biopsy:** The procedure of removing tissue for gross and microscopic examination and diagnosis. Biopsies can be described by the location or approach to the tissue obtained. When possible, try using an existing code rather than specifying as "other" for the type of biopsy.

The following describe various techniques to obtain a biopsy of the lung or adjacent structures. Generally the type of biopsy will be indicated either in a procedure note, operation note, or pathology note. The following refer specifically to biopsies of the lung, lung tissue, or of pulmonary fluid:

- **Biopsy, endobronchial:** Biopsy obtained from within bronchial tubes via bronchoscopy.
- **Biopsy, needle aspiration (SPECIFY):** Removal of cells, fluid, and tissue fragments from tissue with a needle for cytologic analysis to check for cancer. This is a general term, so could be used if endobronchial, transbronchial, TNA, TBNA (biopsy) would not apply.
- **Biopsy, surgical, open:** Tissue obtained during surgery, typically through a thoracotomy incision.
- **Biopsy, transbronchial:** A needle biopsy into the lung tissue or lymph nodes during a bronchoscopy. The tissue being biopsied is accessible during the bronchoscopic procedure and implies a central lesion.
- **Biopsy, transbronchial needle aspiration (TBNA):** During a bronchoscopy, a needle is used to sample nodal or tissue areas immediately adjacent to the central airways to obtain fluid, tissue fragments, and cells for cytologic analysis. TBNA is also known as Wang Needle Aspiration. Note that a fine needle aspiration (FNA) is a type of TBNA.
- **Biopsy, transthoracic needle aspiration (TNA):** A needle is inserted through the skin (percutaneous) into the chest. Cells and tissue fragments are aspirated through the needle for cytologic analysis. Note that a fine needle aspiration (FNA) is a type of TNA. Also known as percutaneous transthoracic needle aspiration.

The following describe biopsies of specific organs:

- **Biopsy, liver:** This is the percutaneous sampling of the liver with a needle/trochar inserted through the skin;
- **Biopsy, lymph node - other (SPECIFY):** Use this if only one lymph node is removed. Specify the type of lymph node such as cervical, mediastinal, iliac, etc. Do not use if multiple lymph nodes are obtained, instead for multiple lymph node biopsies use lymphadenectomy or lymph node sampling.
- **Biopsy, other (SPECIFY); and**
- **Biopsy, scalene (supraclavicular) lymph node:** Biopsy of the supraclavicular lymph nodes above the clavicle or collar bone.
- **Bone radiograph:** X-ray of a bone. Use this for one bone; use radiograph-other if a film of multiple bones taken and specify, such as rib series or L-S spine.

**Bronchoscopy:** Examination of the bronchi through a flexible fiberoptic bronchoscope or a rigid bronchoscope.

**Chest radiograph:** X-ray of the chest cavity for the evaluation of the lungs and thoracic bones. This may also be referred to as CXR, PA, PA and LAT CXR. Record only those chest x-rays that are screening/diagnostic for cancer, and not those to check for complications post procedures.

**Clinical Evaluation:** A clinical evaluation is defined as a visit to a health care provider for medical care and should include a history and physical exam related to the

organ of interest. If a history includes information about the PLCO Screen only, this is to be considered a clinical evaluation. It does not include a telephone conversation to a health care provider. A clinical evaluation that only serves to repeat or confirm a previous finding should not be recorded. On the DEP3 and DEC3 forms, if a clinical evaluation includes a DRE, only the DRE gets recorded on the DEP3 and DEC3 forms and not the clinical evaluation.

**Color Doppler:** This procedure provides color flow maps for characterizing flow disturbances. Useful in identifying characteristics of pelvic masses. This procedure is also known as color flow Doppler, color flow mapping, or color flow imaging.

**CT scan - (abdominal, brain, chest, liver, pelvic, other, etc.):** Computed Tomography or Computed Transaxial Tomography. Procedure wherein a computerized tomography scanner is used to scan and produce an axial image of an organ or area of the body.

- An **abdominal CT** scan may include the liver, spleen, kidneys, pancreas, aorta, retroperitoneum, gastrointestinal tract, and pelvis for the purpose of diagnosis and/or evaluation of cysts, tumors, masses, aneurysm, metastases, abscesses, and trauma.
- An **abdominal and pelvis CT combined** is one CT scan of the abdomen which is extended to include the pelvic region as one procedure, rather than viewing the abdomen and pelvis as two separate CT scans. See definitions for both pelvic and abdominal CT scans.
- A **brain CT** scan may be used to evaluate known or suspected primary or secondary neoplasm, cystic lesions, seizure disorder, etc.
- A **chest CT** scan may extend from the lung apices to the posterior costophrenic sulci for the purpose of evaluating abnormalities of the lungs, mediastinum, pleura, and chest wall.
- A **chest and upper abdominal CT scan, combined** may extend from the lung apices to the mid-abdominal area as one procedure. It evaluates not only the chest contents but also the upper part of the abdomen, particularly lymph node abnormalities as well as the liver and spleen.
- A **liver CT** scan can provide detailed information as to the presence, extent, and vascularity of a lesion.
- A **pelvic CT** scan may include the bladder, prostate, ovaries, uterus, lower retroperitoneum, and iliac lymph node chains for the purpose of evaluating cysts, tumors, masses, metastasis, inflammatory processes, and lymphadenopathy.
- A **spiral CT of the chest** is a technique used to visualize small abnormalities, particularly in screening for cancer of the lung. "Spiral" refers to the technique in how the CT is taken. A reference to a helical technique also means that the CT done was a spiral CT.

**Culdocentesis:** Obtaining material from the posterior vaginal cul-de-sac by aspiration or surgical incision through the vaginal wall.

**Cystogram:** Examination in which contrast material goes into the bladder, and then a x-ray is taken. This is another way of looking for tumor involvement of the bladder, either directly in the wall, or by a mass pressing against the surface.

**Cystoscopy:** Examination inside the bladder using a scope with a lighted end piece (a cystoscope).

**Cystourethroscopy/cystopanendoscopy:** Examination of the lining of the urethra and all the contents to the superior part of the bladder by inserting an instrument with a lighted end piece.

**Cytology (sputum, bronchial washing/brushing):** The study of the anatomy, physiology, pathology, and chemistry of cells obtained from sputum, bronchial washing, or bronchial brushing.

- **Sputum** is material, especially mucus or mucopurulent material, that is expelled by coughing and then spitting out what came up with the cough. Sputum cytology is also known as pulmonary cytology series.
- **Bronchial washings** cytology, also known as bronchial wash cytology and bronchial aspirate cytology, involves the collection of washings or aspirates during endoscopic examination. The procedure routinely involves the evaluation of smears and cell block, and may include cytocentrifuge or filter preparations.
- **Bronchial brushing** cytology involves the brushing of suspected lesions via a flexible fiberoptic bronchoscope or other endoscopic device. Prepared smears or cytocentrifuge preparations are then examined.

**DRE (Digital Rectal Examination):** Palpation of the prostate and/or examination of the anterior portion of the rectal vault with the examiner's finger. On the DEP3 and DEC3 forms, if a clinical evaluation includes a DRE, only the DRE gets recorded on the DEP3 and DEC3 forms.

**Fluoroscopy:** Radiographic examination to view the thoracic contents with a fluoroscope. This is another way to look at the chest contents besides CT, MRI, and plain films (such as the standard chest x-ray.)

**Gallium Scan:** Nuclear medicine procedure in which a radioactive isotope (gallium) is injected into the blood to find an area of inflammation, infection or a tumor. A film shows where the gallium is concentrated.

**Hemicolectomy:** The surgical removal of half of the colon (which is also called the large bowel or large intestine.) For the removal of approximately half of the colon, as in right or left hemicolectomy. Do not use for local excision, APR, or polypectomy.

**Hysteroscopy:** The visualization of the uterine lining with an endoscope.

**Internal Referral:** An internal referral is performed when a SC radiologist compares the current PLCO screening chest x-ray to a previous PLCO screening chest x-ray and detects a new finding so that additional follow-up outside the PLCO screening trial is recommended.

**Intra-abdominal washings (peritoneal or pelvic):** A large volume of a balanced salt solution is used to wash the region of interest and is then collected for cytologic analysis.

**Intravenous pyelography (IVP)/excretory urography:** Radiography of the kidneys, ureters, and bladder following injection of contrast medium into a peripheral vein. IVP is also known as intravenous urography.

**Laparoscopic Lymph node biopsy:** Removal of a lymph node specimen for gross and microscopic examination and diagnosis with the use of a laparoscope. A laparoscope is an endoscope for examining the peritoneal cavity.

**Laparoscopy:** Insertion of a scope with a lighted end piece into a body cavity or hollow organ to directly visualize organs, tissue surfaces, or lining. The laparoscope is

inserted through the skin through a small incision into abdominal or peritoneal cavity/ space.

**Laparotomy:** Incision through any part of the abdominal wall.

**Lymphadenectomy/Lymph Node Sampling:** Excision of lymph nodes.

**Lymphangiogram:** Radiographic visualization of the lymphatic vessels and lymph nodes following the injection of contrast medium for the purpose of evaluating the lymph nodes for possible involvement with primary or metastatic cancer. Also known as bipedal lymphangiography.

**Mediastinoscopy/mediastinotomy:** Mediastinoscopy is the endoscopic examination of the mediastinum. Mediastinotomy is a surgical incision of the mediastinum. The mediastinum is the median partition of the thoracic cavity, covered by the mediastinal pleura and containing all the thoracic viscera and structures except the lungs. These procedures are used for the staging of lung cancer.

**MRI scan** (abdominal, brain, chest, liver, pelvic, other): Magnetic Resonance Imaging. Procedure in which the patient is placed in a strong magnetic field and radiofrequency pulses are transmitted into the patient in an extremely controlled and defined manner. An MRI provides 3-D images of the body's interior, delineating muscle, bone, blood vessel, nerve, organ, and tumor tissue.

**Needle aspiration:** Withdrawal of fluid from a cavity using a hollow needle. This is considered a biopsy if performed for diagnostic reason. If this is done for therapeutic reasons only, such as a withdrawal of fluid in someone with a malignant pleural effusion, do not record. Do not record as a diagnostic procedure unless the fluid is sent for cytology review.

**Omentectomy, complete/NOS:** The surgical removal of the entire omentum, which is a fold of peritoneum hanging like an apron in front of the intestines or bowels. Synonym: Total omentectomy. Omentectomy, NOS is included in this category.

**Omentectomy, partial:** The surgical removal of part of the omentum, which is the fold of peritoneum hanging like an apron in front of the intestines or bowels. Synonym: Infracolic omentectomy.

**Oophorectomy/Salpingo-oophorectomy:** The surgical removal of one or both ovaries, with or without the fallopian tubes. Also known as an ovariectomy, salpingo-ovariectomy.

**Other (SPECIFY):** A diagnostic or staging procedure other than those listed in the procedure codes. Use the SPECIFY line to record the type of procedure. When possible, use an existing code rather than using free text to describe.

**Other biopsy (SPECIFY):** Removal of tissue from an organ for microscopic examination. The SPECIFY line should be used to record the site of the biopsy, not the method of the biopsy. Before using this, review the existing list of biopsy types to determine if one could be used.

**Other endoscopy (SPECIFY):** This procedure is performed using a long tube with a lighted viewer on the end piece to observe the surface of a hollow organ or canal. Record the type of endoscopy on the SPECIFY line.

**Other radiograph (SPECIFY):** This term includes any type of x-ray film study. Record the type of x-ray on the SPECIFY line. Use this when one of the existing radiographic procedures does not apply, such as for "rib series", L-S spine series, etc.

**Paracentesis:** Procedure by which a needle is introduced into the peritoneal space of a patient with free ascites, and the fluid is sampled for diagnostic and/or therapeutic

purposes. This procedure is also known as abdominal paracentesis and ascites fluid tap.

**PET scan (Position Emission Topography):** This is an imaging study usually performed during cancer staging to look for metastasis.

**Preoperative carcinoembryonic antigen (CEA):** CEA is an oncofetal protein that may be detected in the serum of patients with colon cancer. It may also be identified in the cells of the colon and other carcinomas. Preoperative CEA levels, in general, reflect the tumor burden in patients with colon cancer, and so, serve as a prognostic indicator. CEA lab tests done after the surgical treatments of cancer are performed for surveillance of colon cancer progression or recurrence and would therefore not be recorded on DEC3 form.

**Preoperative prostatic acid phosphatase (PAP):** PAP is an enzyme that serves as a biochemical marker for prostate cancer. Preoperative PAP is used for the diagnosis, staging, and monitoring of a patient with prostate cancer.

**Proctosigmoidoscopy:** Visual examination of the rectum and sigmoid colon by use of a sigmoidoscope.

**Prostatectomy:** Surgical removal of a part or the entire prostate.

**Pulmonary function tests/ Spirometry:** The record indicates that the participant had spirometry, which is also known as a pulmonary function test (PFT). What follows is a listing of the components of a PFT for completeness. Do not record the separate components as individual procedures. The FVC and FEV1 provide much of the information about the pulmonary parenchyma and airways.

- **TLC:** Total lung capacity is the volume of air in the lungs after maximal inspiration.
- **VC:** Vital capacity is the maximum volume of air exhaled from the point of maximum inspiration.
- **FVC:** Forced vital capacity is the vital capacity measured during a maximally forced expiratory effort.
- **FRC:** Functional residual capacity is the volume of air remaining in the lungs at the end-expiratory position.
- **RV:** Residual volume is that volume of air remaining in the lungs after maximal exhalation.
- **IC, ERV:** Dividing the vital capacity into portions above and below the functional residual capacity defines the inspiratory capacity and expiratory reserve volume.
- **VT:** Tidal volume is the volume exhaled during normal breathing, and may increase, during exercise, to a large fraction of vital capacity.
- **FEV1:** Forced expiratory volume in 1 second is the volume of air exhaled in the first second of the forced vital capacity.
- **FEV1/FVC%:** The FEV1-to-FVC ratio, expressed as a percentage.
- **FEF75:** Instantaneous forced expiratory flow after 75% of the FVC has been exhaled.
- **MVV:** Maximal voluntary ventilation. The volume of air expired in a specified period during repetitive maximal respiratory effort, expressed as L/min.

- **PO2, PCO2:** Partial pressure of the indicated gas in air, blood, or other liquid, expressed in the same units as barometric pressure (mm Hg or kP).
- **FIO2:** Fractional inspired oxygen concentration, e.g., the FIO2 of air is 0.21.

**Radiograph, other (SPECIFY):** This term includes any type of x-ray film study other than those listed in the procedure codes. Record the type of x-ray on the SPECIFY line.

**Radioisotope bone scan:** The use of radiopharmaceutical agents to visualize bones. This procedure is useful in delineating metastases to the bone. For the DEP3, this is also known as a radionuclide scan of the bone.

**Radionuclide scan (bone, brain, liver):** The use of radiopharmaceutical agents to visualize the bones, brain, or liver.

- **Radionuclide scan of the bone** is also known as bone scan, bone scintigraphy, and whole body bone scan.
- **Radionuclide scan of the brain** is also known as brain scintigraphy, Ceretec brain scan, and Spectamine brain scan.
- **Radionuclide scan of the liver** is also known as liver scintigraphy, liver and spleen scan, liver-spleen scan, radioisotope hepatic scan, and spleen scan.

**Record Review:** A record review involves the review of a record by a health care provider for the purpose of determining if the conclusions and diagnoses are appropriate and/or if anything else should be considered. A record review may include a review of other doctors' notes, diagnostic procedures performed, or another review of the pathology slides.

**Resection:** Removal of part or all of a bone, organ, or other tissue.

**Sentinel Lymph Node Biopsy:** The selective removal of one or several lymph nodes from mapping out the lymphatic distribution of a cancer primary done in conjunction with nuclear medicine to reduce the need for extensive lymph node sampling.

**Sigmoidoscopy/Colonoscopy:** An endoscopic examination of the interior/lining of the sigmoid colon and rectum (sigmoidoscopy) or the large intestine or colon from the rectum to the cecum (colonoscopy).

**Spirometry:** See Pulmonary Function Tests.

**Stool occult blood:** The presence of blood in the feces in amounts too small to be seen. Occult blood is usually detected only by chemical tests or by microscopic or spectroscopic examination. Specimens of stool with no visible blood may be tested for the presence of hemoglobin (occult blood), using guaiac-impregnated paper. When treated with a developing solution guaiac turns blue if hemoglobin is present. The test for occult blood is also known as Colo-Rect<sup>®</sup>; Colo-Screen<sup>®</sup>; Fecal Occult Blood Test; Hema-Chek<sup>®</sup>; HemeSelect<sup>®</sup>; Hemocult<sup>®</sup> II Sensa; Hemocult<sup>®</sup> II, Stool; HemoQuant<sup>®</sup>; Quick-Cult<sup>®</sup>. Synonyms: Stool Guaiacs, FOBT

**Surgical open biopsy:** Biopsy of tissue obtained during a surgical procedure.

**Thoracentesis:** The insertion of a hollow trocar or needle with a cannula into the pleural cavity/lung space to remove fluid from the lung. Also known as pleuracentesis.

**Thoracoscopy:** Examination of the pleural cavity with an endoscope. The pleural cavity is the space between the parietal and visceral layers of the pleura. The pleura is the serous membrane enveloping the lungs and lining the walls of the thoracic cavity.

**Thoracotomy:** Surgical incision of the chest wall.

**Transabdominal/pelvic ultrasound or sonogram:** The imaging of tissue or organs in the transabdominal or pelvic region, including the uterus, fallopian tubes, ovaries, bilateral adnexa, and appendix, by means of soundwaves or ultrasonic echoes. This procedure is also known as a **lower abdomen ultrasound**.

**Transabdominal/pelvic and transvaginal ultrasound combined:** The imaging of tissue or organs in the abdominal or pelvic region by means of sound waves applied both from the exterior abdomen and from within the vagina.

**Transvaginal ultrasound:** The imaging of tissue or organs in the transvaginal region, including the uterus, ovaries, and adnexa, by means of soundwaves.

**TURP:** Transurethral Resection of the Prostate. Partial excision of the prostate.

**Ultrasound (SPECIFY):** This is the use of sound waves to distinguish different types of tissue within a section of the body. For example, the reflection or transmission of sound waves by different types of tissues is the method that determines whether a mass is a solid tumor or a fluid filled cyst. Record the type of ultrasound on the SPECIFY line.

**Upper GI evaluation--endoscopic/radiographic:** Examination of the upper part of the gastrointestinal tract. This can be performed either directly or indirectly. A direct approach uses an endoscope to view the esophagus, stomach, and first part of the small intestine to look at the surface. An indirect approach is a radiographic technique that has the participant swallow barium, with a film taken to note abnormalities. This radiographic technique is also known as a barium swallow or an upper GI series.

**Ureterogram:** Visualization of the ureter by injecting contrast material and taking a film to observe the flow of urine from the kidneys to the bladder.

**Ventilation perfusion lung scan/scintigraphy:** This is a nuclear medicine/radiology study whereby a radioactive isotope is given by vein and films are taken to check for pulmonary/ventilation mismatch. This is used to determine the likelihood for a pulmonary embolus.

## **7. Definitions and Synonyms for Medical Complications of Diagnostic Evaluation and Staging**

**Acute/chronic respiratory failure:** The record indicates that the participant had an acute or chronic respiratory failure as a result of a diagnostic or staging procedure. This is a decline in lung function so that breathing must be assisted.

**Adhesions:** The record indicates that the participant developed adhesions as a result of a diagnostic or staging procedure. Adhesions are the development of scar tissue binding two structures together. Record this as a medical complication only if intervention is required.

**Allergic reaction:** The record indicates that the participant experienced an allergic reaction, including swelling, itching, or rash (with or without local redness and warmth) that required treatment as a result of a diagnostic or staging procedure.

**Anaphylaxis:** The record indicates that the participant experienced anaphylaxis as a result of a diagnostic or staging procedure. Anaphylaxis is a **severe** allergic reaction with a dramatic drop in blood pressure, severe wheezing, or dramatic swelling and requiring immediate treatment with supplemental oxygen, possible intubation, and intravenous fluids.

**Atelectasis:** The record indicates that the participant experienced atelectasis, a collapsed or airless condition of a part or all of the lung(s). Record this as a medical complication only if intervention is required.

**Bladder neck contracture:** The record indicates that the participant had a bladder neck contracture as a result of a diagnostic or staging procedure. In a bladder neck contracture significant scarring of the bladder outlet occurs, affecting the bladder capacity and function.

**Blood in stool:** The record indicates the participant had blood in the stool as a result of a diagnostic or staging procedure. Any amount of blood warrants inclusion as a medical complication if intervention is required.

**Blood loss requiring transfusion:** The record indicates the participant had blood loss related to a diagnostic or staging procedure, requiring blood transfusion.

**Bowel injury:** The record indicates that the participant had a bowel injury as a result of a diagnostic or staging procedure. If it is noted in the record, it is significant enough to warrant recording as a medical complication.

**Bronchopulmonary fistula:** The record indicates that the participant had a bronchopulmonary fistula as a result of a diagnostic or staging procedure. A bronchopulmonary fistula is a connection or communication between the lung tissue (pleural) and the bronchus, usually from an infection or pus collection.

**Bronchospasm:** The record indicates that the participant had bronchospasm, a spasmodic contraction of smooth muscle of the bronchi, as a result of a diagnostic or staging procedure. Record as a medical complication only if medical intervention was required.

**Cardiac arrest:** The record indicates that the participant's heart stopped beating as a result of diagnostic or staging procedure.

**Cardiac arrhythmia:** The record indicates that the participant had an abnormal heart rhythm as the result of a diagnostic or staging procedure.

**Cerebral Vascular Accident (CVA)/ Stroke:** The record indicates that as a result of a diagnostic or staging procedure the participant had a cerebral vascular accident (CVA) or stroke, which is inadequate flow of blood to part of the brain.

**Congestive heart failure (CHF):** The record indicates that the participant had congestive heart failure or a heart-pumping malfunction, which caused fluid to back up, as a result of a diagnostic or staging procedure.

**Deep venous thrombosis (DVT):** The record indicates that the participant developed a blood clot in a vein, usually in the leg, as a result of a diagnostic or staging procedure.

**Diarrhea:** The record indicates that the participant developed diarrhea or loose, frequent, and/or watery stools as a result of a diagnostic or staging procedure.

**Diminished potency:** The record indicates that the participant had diminished potency, which is a reduced or inadequate ability to perform sexually as a result of a diagnostic or staging procedure.

**Extraperitoneal leakage from the bladder:** The record indicates that the participant had extraperitoneal leakage from the bladder as a result of a diagnostic or staging procedure. This is leakage of urine through a hole or tear in the bladder wall.

**Fever requiring antibiotics:** The record indicates that the participant had a fever (or temperature elevation) as a result of a diagnostic or staging procedure that required treatment with antibiotics.

**Hemoptysis:** The record indicates that the participant had a hemoptysis, spitting up of blood from the lungs or bronchial tubes, as a result of a diagnostic or staging procedure.

**Hemorrhage:** The record indicates that hemorrhage occurred as a result of a diagnostic or staging procedure. This is a significant blood loss and may necessitate a blood transfusion.

**Hemothorax:** The record indicates that the participant had a hemothorax, an accumulation of blood in the pleural cavity, as a result of a diagnostic or staging procedure. Record as a medical complication only if medical intervention was required.

**Hospitalization:** The record indicates that the participant needed to be admitted to the hospital as a result of a diagnostic or staging procedure. Use only if the reason for the hospitalization is not another selected condition.

**Hypotension:** The record indicates that the participant had hypotension or low blood pressure as a result of a diagnostic or staging procedure.

**Hypokalemia:** The record indicates that the participant had hypokalemia or a low blood level of potassium as a result of a diagnostic or staging procedure.

**Ileus:** The record indicates that the participant had an ileus as a result of a diagnostic or staging procedure. An ileus is a temporarily inactive bowel/intestine segment.

**Impotence:** The record indicates that the participant had impotence or significant sexual dysfunction as a result of a diagnostic or staging procedure.

**Incontinence—partial/stress:** The record indicates that the participant had incontinence—partial/stress or some loss of control over bladder function as a result of a diagnostic or staging procedure.

**Incontinence—total:** The record indicates that the participant had incontinence—total or a loss of bladder control as a result of a diagnostic or staging procedure.

**Infection (SPECIFY):** The record indicates that the participant developed an infection as a result of a diagnostic or staging procedure. Indicate the site of the infection on the SPECIFY line. A fever or a high white blood cell count does not always accompany an infection. Excludes urinary tract infection and wound infection on the DEO3.

**Myocardial infarction:** The record indicates that the participant had a myocardial infarction or heart attack as a result of a diagnostic or staging procedure. This is different than a cardiac arrest, in which the heart stops beating.

**Pain requiring referral to a pain specialist/anesthesiologist:** The record indicates that the participant had pain that required a consultation with a pain specialist or anesthesiologist, as a result of a diagnostic or staging procedure.

**Perforation:** The record indicates that the participant had a perforation as a result of a diagnostic or staging procedure. A hole develops through the wall of an organ that allows either contents or free air (in the case of the bowel) to escape. This can be spontaneous or result from surgery.

**Peritonitis:** The record indicates that the participant developed peritonitis as a result of a diagnostic or staging procedure. This is an infection or inflammation of the peritoneum.

**Pneumonia:** The record indicates that the participant developed pneumonia as a result of a diagnostic or staging procedure.

**Pneumothorax:** The record indicates that the participant had a pneumothorax, an accumulation of air or gas in the pleural cavity, as a result of a diagnostic or staging procedure. A pneumothorax may be considered a medical complication that required intervention when the medical record indicates one or more of the following conditions: (1) chest tubes are inserted into the thorax *following* a diagnosis of pneumothorax, (2) the patient remained in the hospital additional days for observation because of the pneumothorax, and/or (3) special diagnostic procedures (non-standardized radiographic views or serial chest x-rays for several days) were required before the patient was discharged from the hospital.

**Pulmonary embolus/emboli:** The record indicates that the participant had a pulmonary embolus (blood clot to the lung) as a result of a diagnostic or staging procedure.

**Rectal damage:** The record indicates that the participant had rectal damage as a result of a diagnostic or staging procedure. Record as a complication only if this required some medical intervention or further follow-up.

**Respiratory arrest:** The record indicates that the participant had a respiratory arrest or stopped breathing as a result of a diagnostic or staging procedure.

**Rib fracture(s):** The record indicates that the participant had one or more rib fractures as a result of a diagnostic or staging procedure.

**Small Bowel obstruction, partial or complete:** The record indicates that the participant had a partial or complete small bowel obstruction as a result of a diagnostic or staging procedure. In the small intestine, a blockage either impairs (in partial) or stops (in complete) the passage of intestinal contents.

**Urethral stricture:** The record indicates that the participant had an urethral stricture as a result of a diagnostic or staging procedure. A urethral stricture is a narrowing that impedes urine flow.

**Urinary tract infection (UTI):** The record indicates that the participant had a urinary tract infection as a result of a diagnostic or staging procedure. This is also called a bladder infection.

**Vocal cord immobility/paralysis:** The record indicates that the participant had vocal cord immobility or paralysis as a result of a diagnostic or staging procedure.

**Wound dehiscence:** The record indicates that the participant had a wound dehiscence as a result of diagnostic or staging procedure. This is a breakdown (separation, gaping, or opening) of a skin incision site.

**Wound infection:** The record indicates that the participant developed a wound infection as a result of a diagnostic or staging procedure.

## 8. Definitions and Synonyms for Surgical Procedures in the Treatment of Cancer

**Abdominal/vaginal hysterectomy:** The record indicates that the participant had a hysterectomy, or removal of the uterus with an approach through the abdomen or the vagina.

**Adhesiolysis:** The record indicates that the participant had a lysis (or cutting) of adhesions.

**Anatomic (bilateral nerve sparing) prostatectomy, retropubic:** The record indicates that the participant had a retropubic approach to a prostatectomy with bilateral

nerve sparing. This is done to preserve uro-genital function when removing the prostate.

**Anatomic (unilateral nerve sparing) prostatectomy, retropubic:** The record indicates that the participant had a retropubic approach to a prostatectomy, sparing only one of the nerves to maintain normal uro-genital function.

**Appendectomy:** The record indicates that the participant had an appendectomy performed as a treatment of cancer.

**Bilateral salpingo-oophorectomy:** The record indicates that the participant had both ovaries and fallopian tubes removed.

**Bilobectomy:** The record indicates that the participant had two lobes of a lung removed as a cancer treatment procedure.

**Bowel resection:** The record indicates that the participant had a resection (removal) of the bowel.

**Bypass surgery or palliative resection:** The record indicates that the participant had bypass surgery or palliative resection as a cancer treatment procedure. Part of the bowel is cut and reattached beyond the tumor, or part of the tumor is excised to improve the patient's symptoms. The intent of the procedure is to improve the quality of life when curative surgery is not possible.

**Chest wall resection:** The record indicates that the participant had some of the chest wall removed as part of a cancer treatment procedure.

**Cryosurgery:** The record indicates that the participant had cryosurgery as a cancer treatment procedure. Cryosurgery uses freezing to resect or destroy tissue in the treatment of cancer.

**Exploratory thoracotomy without resection:** The record indicates that the participant had a thoracotomy done as part of a cancer treatment procedure, but nothing from the chest was removed.

**Laser ablation:** The record indicates that the participant had laser ablation as a cancer treatment procedure. This is the use of laser to destroy tissue/tumor.

**Laser prostatectomy:** The record indicates that the participant had a laser prostatectomy as a cancer treatment procedure. See **laser ablation**, above.

**Lobectomy:** The record indicates that the participant had a removal of a lobe of the lung as a cancer treatment procedure.

**Local excision (including local transanal excision):** The record indicates that the participant had a local excision as a cancer treatment procedure. This is the resection or surgical removal of a small or limited amount of tissue.

**Lymphadenectomy/Lymph node sampling:** The record indicates that the participant had either lymph node sampling or lymphadenectomy as a cancer treatment procedure. This is the removal of lymph nodes. This is usually a diagnostic procedure, looking for the spread of the cancer, but could be considered treatment if the purpose is to remove cancer that has spread to the lymph nodes. For PLCO, lymphadenectomy/lymph node sampling is considered a treatment as well as a diagnostic/staging procedure.

**Median sternotomy:** The record indicates that the participant had a median sternotomy as a cancer treatment procedure. This is the approach to the chest by cutting through the midline of the sternum (breastbone).

**Omentectomy, complete/NOS:** The record indicates that the participant had a resection of the complete omentum (or that the amount resected is not otherwise specified). The omentum is a fold of peritoneum hanging like an apron in front of the intestines. Synonym: Total omentectomy. Omentectomy, NOS is also included in this category.

**Omentectomy, partial:** The record indicates that the participant had a partial resection of the omentum. The omentum is a fold of peritoneum hanging like an apron in front of the intestines. Synonym: Infracolic omentectomy.

**Other (SPECIFY):** The record indicates that the participant had a surgical treatment of cancer procedure not listed among the procedure codes. Record the procedure on the SPECIFY line.

**Partial pleurectomy:** The record indicates that the participant had removal of part of the pleura, which is the membrane that lines the chest cavity over the lungs, as a cancer treatment procedure.

**Pelvic exenteration, partial or total:** The record indicates that the participant had removal of all or part of the pelvic organs such as the uterus, ovaries, fallopian tubes, urinary bladder, and rectum.

**Pelvic node dissection (lymphadenectomy), laparoscopic:** The record indicates that the participant had laparoscopy to remove pelvic lymph nodes as a cancer treatment procedure.

**Pelvic node dissection (lymphadenectomy), surgical:** The record indicates that the participant had a surgical approach to pelvic node dissection, which is removal of the lymph nodes (lymphadenectomy), as a cancer treatment procedure.

**Pneumonectomy:** The record indicates that the participant had a lung removed as a cancer treatment procedure.

**Prostatectomy, NOS:** The record indicates that the participant had a prostatectomy, or removal of the prostate, as a cancer treatment procedure, but the procedure is not otherwise specified (NOS).

**Radical prostatectomy, perineal:** The record indicates that the participant had a perineal approach to a radical prostatectomy, or complete removal of the prostate, as a cancer treatment procedure.

**Radical prostatectomy, retropubic:** The record indicates that the participant had a retropubic surgical approach to a radical prostatectomy, or the complete removal of the prostate, as a cancer treatment procedure.

**Resection (SPECIFY):** The record indicates that the participant had resection or removal of all or part of a bone, organ, or other tissue. Use the SPECIFY line to record what was resected.

**Segmental resection:** The record indicates that the participant had a removal of a segment of a lobe of the lung as a cancer treatment procedure.

**Subtotal/simple prostatectomy with lymph node dissection:** The record indicates that the participant had a subtotal or simple prostatectomy with lymph node dissection as a cancer treatment procedure.

**Subtotal/simple prostatectomy without lymph node dissection:** The record indicates that the participant had a subtotal or simple prostatectomy without lymph node dissection (removal) as a cancer treatment procedure.

**Surgical resection with reanastomosis:** The record indicates that the participant had surgical resection with reanastomosis as a cancer treatment procedure. This is the surgical removal of section of bowel with reattachment of the remaining sections to make a functioning bowel.

**Surgical resection with colostomy:** The record indicates that the participant had a surgical resection with colostomy as a cancer treatment procedure. This is the surgical removal of part of the large bowel, with a diversion of the remaining bowel to the outside of the abdominal wall (the colostomy), rather than reattachment to the remainder of the colon or rectum.

**Thoracentesis:** The record indicates that the participant had a thoracentesis as a cancer treatment procedure. This is the insertion of a hollow trocar or needle with a cannula into the pleural cavity/lung space to remove fluid from the lung. Also known as pleuracentesis.

**Transurethral resection:** The record indicates that the participant had a transurethral resection of the prostate (TURP) as a cancer treatment procedure. Usually this procedure is performed to treat benign prostatic hypertrophy (BPH), whereby a blade in a cannula/trocar is inserted up the urethra into the prostate.

**Tumor debulking (Cytoreductive surgery):** The record indicates that the participant had a tumor debulking, which is the removal of as much macroscopic tumor as possible from the abdomen and pelvis. Synonyms: Cytoreductive surgery, tumor reduction surgery, debulking.

**Unilateral salpingo-oophorectomy:** The record indicates that the participant had a unilateral salpingo-oophorectomy, which is the removal of one fallopian tube and ovary.

**Wedge resection:** The record indicates that the participant had a removal of a wedge shaped section of the lung as a cancer treatment procedure.

## 9. Definition of Nodal vs. Extra-Nodal Lymphomas

Although lymphoma is considered a systemic (generalized) disease in contrast to solid tumors, such as breast or stomach cancer, the majority of lymphomas arise in lymph nodes (ICD-O-2 Topography – C77.\_) or lymphatic tissue, such as tonsils, spleen, Waldeyer's ring or thymus. These are all called "nodal" lymphomas. The rest of the NHL (25%) is extranodal, arising from lymphatic cells in organs such as stomach, intestine or breast. Extranodal Hodgkin's disease is uncommon.

Review the medical record carefully to determine the primary site of the lymphoma. Look for references to the primary site of origin, or the site from which the lymphoma arises.

For lymphomas, any mention of lymph nodes is indicative of involvement. Any reference to lymph nodes as enlarged, palpable, rubbery, "shotty," "matted," "fixed," or with visible swelling, enlargement, or lymphadenopathy, should be considered involvement by lymphoma. If one of the involved lymph node sites is designated as the primary site, code to this site in C77.\_\_. If the lymphoma is arising in more than one of the involved sites, code to C77.8, lymph nodes of multiple regions. Note: A reference to "rock hard" lymph nodes may mean involvement by carcinoma instead of lymphoma.

When a lymphoma arises in an extranodal site, with or without regional lymph node involvement, the primary site is the extranodal site. For example, a lymphoma arising in the stomach is considered to be primary of that site and coded to the appropriate subsite in C16.\_\_.

Common extranodal primary sites are stomach, small intestine, large intestine, skin, uterus, breast, bone and brain. Sites that probably are not extranodal primaries, but more likely involved with metastases or spread of disease, are bone, lung, pleura, liver and bone marrow. For bone lesions, determine whether there is a single lesion (possibly primary in bone) or multiple lesions (probably metastasis from another site).

The following sites are lymphatic tissue and are not extranodal primary sites: Spleen, tonsil, Waldeyer's ring, thymus, Peyer's patches.

When referring to nodal vs. extranodal lymphomas it is the *primary* site of the tumor that is considered and *not* the place of biopsy or the site of spread or metastasis. If only lymph nodes are involved, determine which lymph node chain is the origin of the lymphoma. The lymph node chain that is biopsied is not necessarily the one where the lymphoma originated. For example, cervical lymph nodes are easier to biopsy than mediastinal or retroperitoneal nodes. The primary site is where the lymphoma originated.

Sources: ICD-O-2, 1990, p. xxxv, *SEER Program Code Manual*, 3<sup>rd</sup> Edition, January 1998, p. 91, *The Registrar's Key to Abstracting*.

## **APPENDIX L**

### **Appendix L: Quality Assurance Plan**

**L-1**

## Quality Assurance Plan

# PLCO CANCER SCREENING TRIAL QUALITY ASSURANCE PLAN

The main objectives of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial Quality Assurance program are collection of high quality data and consistency of data collection across Screening Centers and for the duration of the trial. The responsibility for quality assurance activities belongs to all participating institutions and groups, i.e., the National Cancer Institute, the Coordinating Center, each Screening Center, the Laboratory, the Biorepository and the Monitoring and Advisory Panel. This document provides a description of the components of the quality assurance program including standardization of study protocols and procedures, training and certification of examiners, monitoring adherence to the study protocol, and data editing and analyses.

## 1. Standardization and Maintenance of Study Protocol

- **Steering Committee and Subcommittees**

The Steering Committee is made up of the National Cancer Institute (NCI) Project Officers, the Principal Investigators of the Screening Centers (SC), the Laboratory and the Coordinating Center (CC). This committee provides overall scientific direction for the study and serves as the major decision-making body for the operational aspects of the study. Several subcommittees have been designated to address specific aspects of the trial. These subcommittees are described below:

Protocol Subcommittee - The Protocol Subcommittee will address development issues regarding eligibility determination, randomization, central pathology review, central death data review and quality assurance. This subcommittee will also review major protocol changes and monitor operational aspects of the trial.

Prostate Subcommittee - The Prostate Subcommittee will develop the protocols for the screening examinations related to the prostate and monitor these protocols on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the prostate examinations. It will also regularly review data regarding the prostate examination and prostate cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses and produce manuscripts.

Lung Subcommittee - The Lung Subcommittee will develop the protocols for the screening examination related to the lung and monitor this protocol on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the lung examination. It will also regularly review data regarding the chest x-ray examination and lung cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses and produce manuscripts.

Colon/Colorectum Subcommittee - The Colon Subcommittee will develop the protocols for the screening examination related to the colon and monitor this protocol on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the colon examination. It will also regularly review data regarding the colon/colorectal examination and colon/colorectal cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses and produce manuscripts.

Ovary Subcommittee - The Ovary Subcommittee will develop the protocols for the screening examinations related to the ovaries, and monitor these protocols on an ongoing basis. This subcommittee will resolve questions regarding the protocol, procedures and forms for the ovary examinations. It will also regularly review data regarding the ovarian examinations and ovarian cancer ascertainment, evaluate the progress and quality of these activities, and make suggestions for additional investigation and/or protocol revisions. This committee will initiate ideas for publications, direct supporting data analyses and produce manuscripts.

Ancillary Studies Subcommittee - The Ancillary Studies Subcommittee will review and approve/disapprove letters of intent for ancillary studies that will use PLCO participants and/or PLCO data.

Publications Subcommittee - The Publications Subcommittee will facilitate preparation of manuscripts and peer reviews of papers prior to publication. This subcommittee will also evaluate publications and presentations about the PLCO Trial.

Modeling and Simulation Subcommittee - The Modeling and Simulation Subcommittee will serve to coordinate mathematical and statistical modeling projects involving PLCO data. This subcommittee will serve as a resource for PLCO investigators interested in utilizing modeling techniques to address questions of scientific or public health interest and act to encourage such utilization where appropriate. The subcommittee will help to disseminate the results of modeling efforts among the investigators.

- **PLCO Monitoring and Advisory Panel**

The PLCO Monitoring and Advisory Panel is an oversight committee composed of outside experts in mass screening, clinical trials, appropriate medical specialties, medical ethics, biostatistics and other appropriate disciplines who meet periodically during the course of the trial to review its progress. They specifically address issues such as success of participant recruitment and results of other screening trials or medical research which might impact on the appropriateness of the screening protocols. They review suggested protocol changes and may also suggest such changes as appropriate. As the trial progresses, their function includes data monitoring to determine whether significant benefit or harm has been demonstrated for any of the screening modalities. They also provide advice regarding the possible termination of any aspect of the trial should this be deemed necessary.

- **Development of the PLCO Manual of Operations and Procedures (MOOP) - Protocol, Procedures and Forms**

An initial protocol document developed by NCI outlined the activities of the trial and the PLCO Concept Statements. It also served as the basis for the development of the MOOP. The Coordinating Center then drafted procedures and data collection forms for all activities such as eligibility determination, obtaining informed consent, randomization, screening, and follow-up. All procedures and data collection forms related to eligibility determination and randomization were reviewed by the Protocol Subcommittee. Individual protocols and data collection forms drafted for each screening examination and medical record abstraction activities were reviewed by the appropriate organ subcommittees. All procedures and forms were approved and finalized by NCI. The protocols and procedures became the basis for Chapters 1-18 of the MOOP. The data collection forms and specifications for their completion, the system reports, and other miscellaneous items, such as sample introduction letters or consent forms, were incorporated into Appendices A-M of the MOOP. The first version of the MOOP was issued in September, 1993. Since 1993, the MOOP has been updated nine times (usually on an annual basis).

- **PLCO MOOP Updates**

The Coordinating Center provides all holders of the MOOP with updated pages which reflect changes to protocols, procedures, data collection forms and specifications, as detailed in the PLCO Decision Logs, as well as correction of errors, such as typographical errors. With the distribution of each update, MOOP holders are requested to replace the appropriate pages in their MOOP. All pages are dated, and a list of effective pages for the entire MOOP (chapters and appendices) is distributed with each MOOP update. Unless instructed otherwise by NCI, the Coordinating Center will update the MOOP at least annually.

- **PLCO Decision Logs**

The Coordinating Center organizes and documents all protocol, procedural, and forms questions, suggestions for changes and Screening Center or laboratory administrative and management issues in a numbered and dated list (Issues for PLCO Decision Log) for review by NCI. NCI provides an immediate resolution or recommends that a particular question or issue be addressed by a subcommittee or consultant. The Coordinating Center coordinates distribution of the issue to the subcommittee members and/or consultant, and arranges and conducts conference calls, as necessary. The Coordinating Center coordinates and develops a final resolution which is presented to NCI for approval. Upon NCI approval, resolutions are documented in a numbered, dated list (PLCO Decision Log) and distributed regularly to all study collaborators.

- **Forms Revisions**

Changes in protocol resulting from pilot evaluations, as well as comments and suggestions from the Screening Centers, Principal Investigators, Coordinators and Data Managers and from the Monitoring and Advisory Panel may prompt revisions to the data collection forms.

Revisions to opscan forms - The Coordinating Center organizes and documents all suggested revisions, drafts a new version of the form using Design Expert (a tool for designing opscan forms), and presents them to the Screening Centers, appropriate subcommittees, and NCI for review and approval.

Revisions to non-opscan forms - The Coordinating Center organizes and documents all suggested revisions, drafts a new version of the form using a word processor, and presents them to the Screening Centers, appropriate subcommittees, and NCI for review and approval.

For both opscan and non-opscan forms, the specifications for completion of the form are also revised. The Coordinating Center sends the updated forms and specifications with an explanatory memo to the Screening Center Principal Investigators and Coordinators. The revised forms and specifications are incorporated into the PLCO MOOP with the annual update.

## 2. **Screening Center Systems Development and Maintenance**

- **Development - Data Management Plan, Study Management System (SMS) Functional Requirements, SMS Specifications, Data Entry and Editing System (DEES) Specifications, DEES System Documentation, SMS/DEES Configuration Management Plan and Tracking, PLCOnet Design and Implementation Plan, SMS, DEES, and Network User's Guides**

The Coordinating Center designs and implements all systems following the Federal Information Processing Standards and provides the documents for NCI review and comment prior to development. All decisions, approaches, algorithms, etc. are documented. Following programming, all systems are tested by a third party testing group

that has not been involved in the programming. Programs are tested against requirements and for functionality. The results of all tests are documented, along with any actions taken to address issues and the final acceptance test. User documentation is produced in conjunction with each release of software. All software is released in runtime versions only—no source code is made available to Screening Centers. On the network, Screening Centers cannot access the directories that carry code without leaving an audit trail and they do not have write access.

- **Maintenance - Configuration Management Plan (Software Change Request Forms, Mainframe Request Forms, Access Control Forms, Hardware Change Request Form, Screening Center-Specific Software: Change Request Form)**

All requests for changes from NCI, Screening Centers, and the Coordinating Center are documented and logged into a tracking system, according to a strict Configuration Management Plan. Prior to decisions on whether to incorporate the change or not, impacts are considered. Each request is then prioritized and assigned a version for inclusion (or marked as “no action necessary”). When critical systems issues are identified in the field, they go through the same process but with a Very High priority. An interim upgrade is released, if necessary, to correct the problem. Reports listing each request, its status, assigned version/priority, and testing status are reviewed regularly by systems and project staff.

In conjunction with each system update, the system version number is changed and full documentation listing all changes associated with the upgrade are distributed to the screening centers.

- **Randomization System - Blinded, Variable Blocking, Stratified on Age/Gender.**

The software is provided in a runtime version (compiled) only - no source code is ever made available to Screening Centers. Blocking factors and stratification algorithms are contained only in the protected code and blocking tables are password protected. Design and specification documents have never been given to Screening Centers for review and the blocking factors are not known to them. On the network, Screening Centers cannot access the directories that carry code without leaving an audit trail. Systems went through full third-party testing before release and prior to release of any upgrades.

- **Optical Scanning**

Optical mark readers with an error read rate of less than 0.1% have been placed at all screening centers. The error rate is significantly better than a data entry error rate that is typically 1-2% if full double entry verification is employed. Standards for ongoing maintenance, calibration, and scanner diagnostics have been established to ensure that the scanner performs optimally at all times. Following the scanning of each form, computer edits are run detailing inconsistencies, misreads, non-responses, skip errors, etc.

- **Screening Center System Security - Documented in the Network Users Guide to include: Automatic virus checks, automatic disk checks, encrypted/password protected tables with Privacy Act considerations, password protected data tables, password controlled access to network, appearance of Privacy Act notifications on all reports carrying a name, address, phone, household members, contacts, and/or social security number, periodic diagnostics on**

**network, protected PSA/CA125 data, protected administrator functions on network and within applications.**

System security has been implemented by the Coordinating Center within all screening center networks, as described in the cited document. Specifically, screening centers are unable to change functions associated with system administration, programs, or data that is not generated at the center (e.g., UCLA blood test results). All information covered by the Privacy Act of 1974 (P.L. 93-579) is accessible only by ID/password and any hardcopy reports that are printed carrying this information automatically carry a Privacy Act disclaimer on both the top and bottom of each page of the report. Names and SSNs are carried only in a table that is physically separate from other data, is password protected (in addition to the login password), and encrypted. All backups are further protected by a second encryption before writing to the removable device. Systems are also in compliance with requirements of the Computer Matching and Privacy Protection Act of 1988 (P.L. 100-503). The study arm (intervention or control) is similarly protected (password protected, encrypted, read-only access to screening centers) to ensure that, once assigned, no revisions can be made.

- **Training/Retraining**

To ensure that systems are used properly and that the data contained in the system correctly represents study activities, staff at all screening centers received a 3-day on-site training session on the systems, including the interpretation and use of edits and other reports. The training included hands on experience using the equipment in place at the center. Training was supported by a Training Manual that included exercises, a User's Guide for the Study Management System, a User's Guide for the Data Entry and Editing System, and a PLCOnet User's Guide.

Retraining is conducted after major system changes, emphasizing system changes in support of protocol changes and new features. A full refresher course is also included.

- **User Helpline**

Emergency systems assistance from Coordinating Center staff is available from 9:00 a.m.- 6:00 p.m. Monday through Friday. In addition, screening centers can call the Helpline with questions on use of the system, interpretation of reports or edits, requests for ad hoc data summaries, diagnosis of computer problems, or any other issues regarding the computer support systems from 1:00 p.m.- 6:00 p.m. Monday through Friday.

- **Audit Trails**

Numerous auditing features have been incorporated into the applications provided to the screening centers including, but not limited to: tables carrying information on every form deleted including the staff ID of the person who deleted it and the date, date of last update (and staff ID) for every record in every table, date of creation for most tables, tables logging the access (and duration of use) by staff members, ID of the person who performed randomization as well as the ID of the person who approved eligibility, date and time of randomization, flags indicating that computer edits have been run against the record and whether or not it passed those edits, etc.

### **3. Training and Retraining**

- **Initial Training of Screening Center Coordinators on Protocols, Procedures and Forms**

The initial training of Screening Center Coordinators was conducted September 20-24, 1993. The main objective of the week-long training session was to give the

Screening Center Coordinators a thorough understanding of the trial objectives, protocol, and schedule, including the Biorepository component of the trial. Sessions concentrated on implementation of the PLCO protocol for recruitment, eligibility determination, randomization, scheduling screening visits, performing screening examinations, reporting results to participants and physicians, and cancer and vital status ascertainment. It also included training on forms completion. The foundation for these training sessions was the Manual of Operations and Procedures (MOOP) which was initially presented at the training. Discussions of quality assurance measures and administrative matters were included in every training session.

During the initial training session, the medical personnel who were to supervise the collection and processing of blood for the PSA/C125 assays and for the Biorepository, were trained in the proper collection and processing procedures.

- **Periodic Retraining on Revised Protocols, Procedures and Forms**

Periodic in-person retraining of Screening Center coordinators on protocols, procedures and forms is conducted in conjunction with annual Steering Committee meetings or in separate meetings, as necessary. In addition, each change to PLCO protocols, procedures, and forms is documented in the Decision Log or in a memo to the Screening Centers. The Coordinating Center staff reviews these changes with the Screening Center coordinators prior to or upon implementation.

- **Directed Retraining on Problem Areas**

When problems are identified at the Screening Centers, the Coordinating Center determines whether retraining of the SC staff is needed. If the problem is identified at a number of Screening Centers, the retraining may be conducted as part of a conference call with all Screening Centers, during the annual Steering Committee Meeting, or during a separate meeting. If the problem is individual to one center, the Coordinating Center staff retrains the Screening Center staff by phone, or if possible during a site visit to the Screening Center.

#### **4. Security Issues**

- **Consent Form**

The PLCO consent form(s) (individual to each center), outline the voluntary nature of participation, the lack of penalty for non-participation and the assurance of confidentiality. An individual may not be enrolled into the Trial unless s/he or his/her legal guardian has understood and signed the consent form.

- **Privacy Act**

All documents containing Privacy Act data (such as names, addresses, and social security numbers) are maintained in participant files in locked cabinets or a locked room at the Screening Centers. The following warning and disclosure statement is printed on all reports containing Privacy Act data:

"This report contains data protected under the Privacy Act of 1974. Distribute only to authorized staff and store and dispose in a proper manner."

All Privacy Act data are maintained at the Screening Centers and are not transmitted to the NCI or to the Coordinating Center.

- **Requirements for Screening Center Security**

All participant files are maintained in a locked area at the Screening Center (such as a locked cabinet or a locked room). Access is limited to the staff working on the study, and the Screening Center Coordinator controls access to this area.

Each Screening Center maintains fire protection equipment such as fire extinguishers and sprinklers as required by their local jurisdiction.

- **Requirements for Coordinating Center Security**

Access to study documents is restricted to Coordinating Center personnel working on the study. Files are maintained in a secure building at the Coordinating Center.

## 5. Communication

- **Scheduled Calls**

The Coordinating Center conducts regularly scheduled (weekly or bi-monthly) calls to the Screening Centers. The purpose of these calls is to:

- Collect and document information regarding Screening Center performance of study procedures. For example: Poll Screening Center to collect information regarding the issues that arise when determining eligibility based on Screener data, medical record data, or interview data. Determine if all Screening Centers are faced with same issues and if they are all making decisions in the same way.
- Obtain information regarding protocol violations and procedural errors.
- Convey changes in policy and procedures.
- Maintain telephone logs.
- Prepare monthly status sheet for Screening Centers to document calls and operational issues.

- **Daily Communication Via Telephone, FAX, E-Mail to Convey Information, Answer Questions, Resolve Problems, etc.**

- **Periodic Conference Calls to Discuss Screening Center Coordinator Issues, Address Problem Issues as Identified Through Regular Monitoring Reports, Forms Review, and Communication.**

On a periodic basis (bi-monthly), the Coordinating Center conducts conference calls with the Screening Center coordinators and NCI. The agenda for these calls is proposed jointly by the Screening Center coordinators and by the Coordinating Center, and is approved by NCI. The first part of each call is devoted to one or more issues of concern to the coordinators (e.g., how to increase the enrollment of women, how to present detailed examination findings to participants, etc.). The coordinators describe the procedures at their centers and exchange ideas for improvement. In the second part of each call, the Coordinating Center addresses problem issues, and may retrain the coordinators on various study procedures.

- **Steering Committee Meetings**

On at least an annual basis, NCI, the Coordinating Center, the Screening Center Principal Investigators and Coordinators, as well as other supporting staff from the Screening Centers, convene to discuss the progress of the trial and to resolve issues related to the PLCO protocol, ancillary studies, and data analysis and publications.

- **Subcommittee Meetings and Conference Calls**

When issues arise that are related to the procedures for recruitment and enrollment, the screening examinations, medical record abstracting, or cancer or death ascertainment, the appropriate subcommittee (Protocol, Prostate, Colorectal, Ovarian, or Lung) convenes in person or by telephone for discussion and resolution of the issues. In addition, the Ancillary Studies subcommittee meets (in person or by phone) on an as-needed basis to review and evaluate ancillary study proposals. The Publications

Subcommittee meets (in person or by phone) on a regular basis to review proposed publications.

## 6. On-Site Monitoring

Site visits to the Coordinating Center, the Laboratory and the Screening Centers are conducted at least annually by NCI staff and designated consultants. The rationale and a detailed description of on-site monitoring of Screening Centers is given here:

- **History and Purpose**

- Background

As the world's largest sponsor of randomized clinical trials, the National Cancer Institute (NCI) must ensure that research data generated under its sponsorship are of high quality, reliable, and verifiable. NCI's monitoring policies for clinical trials have been evolving since the late 1950's.

- Clinical Trial Quality Assurance

Because clinical trials are generally implemented through more than one institution (e.g., laboratories, clinics, and repositories) and are located at more than one site, quality assurance efforts must target all groups and sites. In addition, because clinical trials involve a large variety of activities (e.g., staff training, preparation of a manual of operations and procedures, protocols, rules and practices, certification of examiners, and data management) quality assurance efforts must cover all aspects of the trial.

- **Conduct of On-site Monitoring**

- Purpose

The purposes of on-site monitoring are:

- 1) to enhance the delivery of accurate and reliable clinical trials data and results;
- 2) to verify the accuracy of data and to monitor protocol compliance using source documents on-site;
- 3) to verify adherence to regulatory requirements, including protection of human subjects and handling of biomaterials;
- 4) to verify adherence to established procedures through observation; and
- 5) to provide education and support to clinical centers regarding data management and protocol adherence.

- Process Assumptions, Definitions, and General Comments

A critical element of quality assurance for a clinical trial is on-site monitoring. On-site monitoring includes two basic processes: 1) auditing primary data records, and 2) observing trial practices and procedures. This document describes the on-site monitoring processes used for the PLCO trial.

The record audit includes a review of those records which are related to all aspects of a site's responsibility. For example, for a clinical center the audit includes a review of records dealing with all aspects of participant involvement, from recruitment to screening to follow-up.

Study participant source documents generally form the basis for clinical trial record audits. Documents related to all major study endpoints are carefully reviewed. These generally include eligibility screeners, baseline questionnaires, consent forms, examination results forms, medical record abstracts, and biomate-

rials inventories as appropriate for the various institutions (screening centers, laboratories, and repositories).

- Composition of the PLCO On-site Monitoring Team

Monitoring team composition will vary according to the elements of the site visit.

Record audits may be done independently by NCI project managers as part of site visits, by Coordinating Center staff as part of site visits (to Screening Centers), and by special audit teams under contract. The elements of the record audit in all three cases are the same, but the intensity of the audit may differ depending upon specific needs or concerns.

NCI project managers include project officers, project coordinator, and affiliated scientific staff. Coordinating center staff conducting audits could include coordinators, data managers, and the network administrator. Independent contractors doing audits must include professionals with extensive experience in conducting screening trials. Experience in coordination, data management, and screening practices is essential.

As needed, consulting specialists may be included on on-site monitoring teams for specific purposes.

- On-site Monitoring of the Primary Institution

All institutions are monitored on-site and audited at least once every 12 months but are at risk for random selection audit at any time.

Clinical Centers are monitored on-site and audited no longer than 18 months after entry of the first participant to ensure that performance standards are being met and as an educational experience for the new investigators and their staff. The initial monitoring and audit may be sooner if feasible, based on accrual. Clinical Centers remain at risk for audit even if their membership in the trial is terminated since they have made a commitment to long term follow-up of participants on study with provision of good quality data according to the protocol.

- On-site Monitoring of the Affiliate Institution

Affiliate institutions are monitored and audited as if they were primary institutions.

- **Preparation for On-site Monitoring**

- Notification

The institutions/investigators to be monitored on-site are notified not more than 3 months prior to the selected date. Upon notification of the institutions, the monitoring team meets to establish a general plan for the visit and highlight the areas of priority for the audit. Team members are aware of individual responsibility according to their expertise. A detailed agenda is prepared and distributed to all team members and the institution.

Institutions being audited do not know in advance which case records will be audited.

- Selection of Cases for Audit

Fixing a percentage of cases to be audited would be inappropriate. Cases are randomly selected by the audit team in sufficient numbers to assure compliance with protocol requirements. In case selection for audit, an emphasis is placed on accruals since the previous audit. Additional cases for audit may also include those

identified (through quality review) with missing, inconsistent and inaccurate data and those with associated protocol violations.

- Selection of Material for Audit

Complete participant files are audited for eligibility, data entry, missing data, date consistencies, proper referral, and follow-up. Consent forms must be reviewed at all clinical centers.

- **Elements of On-Site Monitoring**

A series of standard checklists have been developed for record audits and observation of study procedures and processes to ensure that all elements are reviewed. The PLCO Manual of Operations and Procedures (MOOP) is the reference point for all audits and the checklists are maintained from this document. Any problems or discrepancies found such as protocol violations, record errors or missing information are noted on the checklist, and the checklist is signed by the chief monitor and included as an attachment to the site visit report.

During audits, forms appropriate to the case which are listed in the Manual of Operations and Procedures (MOOP) are reviewed. Attention is given to accuracy, completeness, consistency, and the overall quality of record keeping. Missing forms are sought from Screening Center coordinators since these may be separated from a file for data entry, retrieval or follow-up. The inability of a Screening Center coordinator to find missing records is noted. Consent forms must be present, dated, and signed by the participant.

Auditors verify adherence to established trial procedures through observation of recruitment, randomization, screening and follow-up activities such as obtaining and abstracting medical records and obtaining death certificates. Forms processing, results reporting and data entry and editing procedures are observed. Auditors also observe Screening Center practice of procedures for maintaining data security in the following areas: 1) personnel control; 2) physical object control; 3) disaster preparedness; 4) control of data access; and 5) telecommunications and hardware.

The responsible investigator and staff should be available throughout the visit to answer questions and help the monitors to locate necessary information and charts.

At the conclusion of the visit, the team conducts an exit interview with the responsible investigator and staff to review the preliminary findings and to discuss any recommendations of the team. This interview provides the opportunity for immediate dialogue and feedback and/or clarification by personnel at the institution.

- **On-site Monitoring Reports**

- Internal Review and Actions

A written report is submitted by monitoring team members to NCI and shared with the monitored institution through NCI. All research and regulatory elements described in "Elements of On-site Monitoring" noted above must be addressed in the report.

Where the findings indicate significant protocol deviations for non-compliance with regulations, the monitored institution may take a variety of actions depending on the scope and severity of the findings: 1) the responsible investigator and staff are notified of the problems and instructed in ways to improve performance; 2) a re-audit may be performed to evaluate improvement; and 3) in cases where severe multiple problems are noted, recruitment or other activities may be suspended pending a more in-depth review or until the institution has demonstrated that it has effectively modified its practices to correct these deviations. If NCI is

not satisfied that the problems are correctable, it may choose to terminate the contract of the institution.

- NCI Notification

A final single report summarizing the findings of the monitoring team and recommendations must be submitted to NCI within 1 month of the audit.

Major headings for this report are: Name of Institution, Contract Number, Principal Investigator, Date of Monitoring, Names and Affiliations of Monitors, Names and Responsibilities of Investigator Staff and Institutional Representatives, Records Audited (by PID), Major Findings, and Recommendations. Signed checklists are attached to the report.

- Follow-up

All protocol violations, record errors, and instances of missing data or forms are followed up by NCI, and thorough and complete explanations and evidence of corrections of both instances and contributing practices provided by the institution.

## **7. Monitoring Protocol Violations**

Screening Centers are required to report all protocol violations in a Screening Center Report Protocol Violation form to Coordinating Center. The completed report describes the error, the circumstances, the method of discovery, recommended corrections or actions, and steps that will be taken to prevent the error in the future. Upon receipt of the report, the Coordinating Center contacts the Screening Center to make the appropriate corrections in the Screening Center database, as necessary, or to give detailed instructions for the Screening Center to make the appropriate corrections in its database. If the requested correction does not follow protocol guidelines, the Coordinating Center must obtain NCI approval before making any changes to the Screening Center database.

Protocol violations are identified by the Screening Centers or by the Coordinating Center or NCI during data review or on-site monitoring. The Coordinating Center logs all violations, assists with investigation and resolution and documents appropriate follow-up and closure.

## **8. Screening Examination Quality Assurance**

Standard protocols were developed for each screening examination by the organ subcommittees to the Steering Committee. Specific guidelines were documented in the PLCO MOOP for each of the following areas:

- Examiner, Trainer Qualifications
- Training and Certification
- Equipment Specifications and Maintenance
- Preparation of Participant for the Examination
- Performance of Examination Procedures
- Quality Assurance of Examination Procedures (Repeat Examinations)
- Reporting of Examination Results
- Acquisition of Information Regarding Diagnostic Follow-Up for Positive Screening Exams
- Cancer Confirmation

Each Screening Center was required to develop a Quality Assurance Plan describing how it would meet the requirements of the screening examination protocols. The plans were reviewed by the Coordinating Center and submitted to NCI with a

summary of the review for NCI approval. NCI gave conditional approval for use of Screening Center QA plans during the pilot phase and subsequent years until implementation of a final PLCO QA plan.

Because of the wide variety of approaches to QA documented by the Screening Centers, a Quality Assurance Subcommittee was assembled to oversee screening exam quality assurance. The Quality Assurance Subcommittee met to develop structural, procedural, and outcome measures to monitor and evaluate examiner performance and Screening Center adherence to the examination protocols. Each plan addressed the following areas:

- Examiner, Trainer Qualifications;
- Examiner Training and Certification;
- Equipment Specifications and Maintenance;
- Repeat Examinations;
- Central Audit; and
- Data Analyses

Individual QA plans for each screening examination modality are given as Attachments to this document. All Screening Centers are expected to comply with the requirements of the attached screening examination QA plans.

## **9. Blood Collection and Analysis**

### **• Screening Center Quality Assurance**

Standard protocols were developed for blood collection, processing, storage and shipment and are described in chapter 10 of the PLCO MOOP. Each Screening Center was required to develop a QA plan which included minimum qualifications of the examiner, completion of training, monitoring of examiner performance and quality control of equipment and supplies. All plans were reviewed, revised as necessary, and finally approved by NCI. As the trial progresses, SCs must submit any proposed revisions to NCI for approval prior to implementation. SCs must also complete an ECT for all new phlebotomists, blood processors, trainers and/or supervisors and receive NCI approval before the new staff member begins work. Minimum qualification for blood collection and processing staff are provided in Chapter 10 of the PLCO MOOP. Current versions of each SC blood QA plan and examiner credentials are kept on file at NCI, the Coordinating Center and the Screening Centers.

### **• UCLA Quality Assurance**

The UCLA laboratory maintains strict QC procedures for PSA and CA-125 assays. Assays are performed by licensed technologists who have satisfied training and performance requirements. Assay procedures are performed as specified by the manufacturer.

Each test run includes both a reagent kit control and a Bio-Rad tumor marker bi-level control, which are commercially prepared specifically for use in tumor marker testing. Samples with out of range results are retested.

QC data for assay runs are stored, and control statistics are reported in a report to NCI each quarter.

## **10. Biorepository QC**

Procedures for the Screening Center collection, aliquoting, temporary storage, and shipment of biologic samples to the Biorepository are described in Chapter 10 of the MOOP. Procedures

for receipt, inventory, storage, and discrepancy resolution are described in the Manual for Receiving Frozen Blood Component Samples at the Biorepository (NOVA Research Company, May 1995).

Management systems are in place to monitor and resolve discrepancies in identification number for receipted vials. Samples received by the Biorepository that are not in conformance with established protocol are identified by special code and retained by the Biorepository for non-study use by NCI.

Receipted material is monitored to identify incompletely filled or incomplete vial sets. Patterns of incompleteness have been identified by Screening Centers, and, as needed, modifications to the collection protocol are being implemented to meet study requirements.

## **11. Quality Assurance of Medical Record Abstracting**

### **• Overview**

The National Cancer Institute, the Coordinating Center (CC) and Screening Centers (SCs) will implement procedures to monitor the quality of cancer ascertainment activities. The main goals of the medical records quality assurance (MRQ) program are:

- to ensure that medical records abstractors and Certified Tumor Registrars (CRTs) or CTR-eligible individuals utilize standard procedures;
- to ensure a high level of accuracy for critical data elements;
- to evaluate the quality of data abstracted in the cancer ascertainment process;
- to continuously improve the quality of data abstracted by providing feedback and training to SCs in areas where problems are identified.

The MRQ program will use a multi-level approach to achieve the goals outlined above. The following are the components of the MRQ program:

- Regular Communication
  - Registration, Training and External Quality Assurance
    - Review of qualifications
    - Training
    - External Quality Assurance
  - Internal Quality Assurance
  - Workshops and Conference Calls
  - Problem Resolution
  - Response to Medical Record Abstraction (MRA) Issues
- ### **• Regular Communication**

The SC will appoint a Lead Abstractor. The responsibilities of the Lead Abstractor will include staffing, training, quality assurance, and communicating with SC staff (Coordinator, PI, Collaborating Physicians) and the CC. The CC will appoint a MRA Coordinator. The responsibilities of the MRA Coordinator will include review and tracking of SC abstractor and nosologist credentials, training, external quality assurance, responding and coordinating the resolution process of all SC MRA issues and communicating all MRA issues and decisions to the SCs through documentation.

- **Registration, Training and External Quality Assurance**

- Review of Qualifications

The Coordinating Center will review the qualifications of all abstractors and nosologists to ensure they meet the criteria described below. NCI will approve the credentials of all medical record abstractors and nosologists after the CC review. In addition, the abstractor at the CC who is completing the key for the external quality assurance abstracts will possess all of the qualifications of Medical Record Abstractor and Nosologist.

The Record of Credentials for Medical Record Abstractor and Nosologist Registration form (CAN) is the form used to verify and document the credentials of abstractors. The CAN is to be completed by the SC Principal Investigator or Coordinator for all individuals who are to perform medical record abstraction and/or medical coding for the PLCO trial. The CAN form and specifications for its completion can be found in appendix A-17-10 of the MOOP.

The following sections describe the qualifications for medical record abstractors.

- Minimum Qualifications of Abstractors

The abstractor should have a medical background, including knowledge of medical terminology, anatomy and physiology, and concepts of disease, in addition to basic medical coding instruction and a minimum of 2 years experience abstracting and coding medical records. The abstractor should also be trained on the PLCO medical record abstraction forms.

The abstractor should also possess at least one of the following credentials from each list below for ICD-9-CM and ICD-O-2 coding:

For ICD-9-CM coding (in order of desirability):

- 1) Certified Coding Specialist (CCS) - This individual has obtained sufficient coding expertise either through education, experience, or a combination of the two to pass an advanced coding exam and become certified.
- 2) Registered Health Information Technician (RHIT) - A RHIT has at least an Associate's degree in Medical Record Science and has passed an accreditation exam. This individual must meet RHIT continuing education requirements to maintain accreditation.
- 3) Registered Health Information Administrator (RHIA) - A RHIA has at least a Bachelor's degree in Medical Record Science and has passed a registration exam. This individual must meet RHIA continuing education requirements to maintain registration. If a person is a RHIA and is currently doing medical coding, then he/she may be qualified to conduct medical coding. If, however, a RHIA is doing supervisory work, then he/she may not be up-to-date on medical coding.

For ICD-O-2 coding and TNM staging:

Certified Tumor Registrar (CTR or CTR-eligible) - A CTR is an individual who has passed the Certification Examination for Cancer Registrars, which is offered by the National Cancer Registrars Association (NCRA). To maintain a certified status, a CTR must meet current continuing education requirements of the National Cancer Registrars Association (NCRA). To be eligible to take the Certification Examination, an individual must meet *one* of the following requirements as of the test date:

- 1) Two years full-time equivalent experience in the cancer registry field.

- 2) Successful completion of a college level curriculum in cancer data management/cancer registry, and a work experience component composed of 120 hours in a CTR staffed computerized cancer registry or 240 hours in a non-CTR staffed computerized cancer registry.
  - 3) One year full-time equivalent experience in the cancer registry field and successful completion of college level curriculum in medical records, nursing, or other allied health field.
  - 4) One year full-time equivalent experience in the cancer registry field and credentialed or licensed status in a recognized allied health field as determined by NBCR.
- Approval Process for Abstractors and Nosologists

The process for the review and approval of abstractor and nosologists qualifications is as follows:

- 1) For each abstractor and nosologist, the SC completes a separate CAN form and sends one copy to the MRA Coordinator and one copy to NCI.
- 2) The MRA Coordinator reviews the qualifications and forwards the documentation to NCI with any comments.
- 3) NCI reviews the qualifications and comments and sends an approval/disapproval letter to the SC Coordinator.
- 4) If the staff member is disapproved, but the SC wishes to use him/her for abstracting or coding, the SC PI must send a letter to NCI documenting the individual's pertinent qualifications and requesting a special exception. NCI will give conditional approval for an abstractor or nosologist requiring that their work be checked by a qualified staff member until they have successfully completed an External Quality Assurance cycle and/or qualifications are met.
- 5) If a CTR-eligible individual is approved by NCI, it is expected that this individual will sit for and pass the next certification examination, which is given by the NCRA. SCs who would like exemption from this requirement must submit a letter to NCI and a copy to the CC discussing the justification for this exemption.

#### New Abstractor Training

New Abstractor Training at the SC involves two phases as outlined below:

- The SC Lead Abstractor will train new abstractors on PLCO procedures and forms. The CC has recommended that a standard case should be used for training on each form type.
- 100% of the abstractor's work will be checked by a qualified staff member until ten forms of each type with a non-cancer diagnosis and five forms of each type with a cancer diagnosis meet the criteria outlined below:
  - 1) All critical data elements on each form type (DEP, DEL, DEC, DEO, TIP, TIL, TIC, TIO and OCF) are without error (See Attachments F-1 through F-5 for a listing of critical data items), and
  - 2) the total error rate for all remaining non-critical data elements on each form type does not exceed 20%.

Checking may be review, re-abstractation or independent verification of coding. The CC recognizes that the SCs receipt more medical records with a non-cancer diagnosis than those with a cancer diagnosis. Consequently, checking

requirements are different for both types of medical records. In addition, the abstractor or nosologist may complete training for one form type before requirements for all form types are met.

The CC will conduct an annual 1-day training session for new abstractors. This training session will cover the goals and the protocol for the PLCO medical records abstraction process. The specifications for all medical record abstraction data collection forms will be reviewed. A standard case will be presented for each form type. All new abstractors must attend this training within the first year of work on PLCO. The Lead Abstractors from each SC must also attend this training. Nosologists are not required to attend the training sessions conducted by the CC.

- External Quality Assurance

There will be three External Quality Assurance cycles per year. The CC will annually provide a MRA External Quality Assurance Schedule, which will list the dates relevant to each cycle as well as the types of cases to be completed during each cycle. Throughout one year, all PLCO cancers will be covered. The External Quality Assurance package for each cycle will include 5 medical records and 7 data collection forms as follows:

<b>Type of Medical Record</b>	<b>Data Collection Forms to be Completed</b>
2 records representing participants with a PLCO cancer	2 Diagnostic Evaluation Forms 2 Treatment Information Forms
2 records representing participants who underwent a workup for a positive screen, but PLCO cancer was not diagnosed	2 Diagnostic Evaluation Forms
1 record representing a participant who was diagnosed with a non-PLCO cancer	1 Other Cancer Confirmation Form

On an annual basis, the CC will request a pre-determined amount of cases from each SC to establish a case library from which to select cases for the EQA cycles. SCs will be asked to submit records for the case library and to remove the identifiers from the records.

All PLCO abstractors and nosologists must complete the quarterly PLCO External Quality Assurance process. Each abstractor will receive a packet of test abstractions for completion from the CC. Each abstractor or nosologist should complete separate abstract forms for each case. While the abstract forms should be completed independently by the abstractor or nosologist, individual SC abstractors may discuss completion of the specific items with other abstractors at their SC for clarification or item resolution. Abstractors or nosologists who are not available to complete the External Quality Assurance cycle on schedule, should notify the SC Lead Abstractor and Coordinator. The SC should contact the MRA Coordinator regarding abstractors or nosologists who will not be able to complete abstract forms within the time period for that cycle. The SC and the CC will determine another reasonable schedule for the abstractor to complete the test abstractions.

When the abstractor has completed the External Quality Assurance abstracts, the completed forms should be submitted to the CC for evaluation and determination of successful completion of test records. The CC will develop the key for each

External Quality Assurance abstract with support from PLCO subcommittee experts and NCI as needed. A successful abstract is one in which the total error rate for all data elements on each form type does not exceed 20%.

The CC will provide a detailed report of test abstraction results for each abstractor or nosologist to the SC Coordinator and Lead Abstractor who will review the results with individual abstractors and nosologists. If the performance of an abstractor or nosologist is not successful, the Lead Abstractor will provide re-training on forms that were not successfully abstracted. Re-abstraction, by a qualified staff member, will be required for each type of form that was not successfully abstracted. Five cases per form type with a non-cancer diagnosis and two cases per form type with a cancer diagnosis should be re-abstracted until the total error rate for all data elements does not exceed 20%:

If the Lead Abstractor at the SC does not successfully complete abstraction of test records, the SC Coordinator and Principal Investigator will need to evaluate performance problems and develop a plan to maintain quality assurance of medical record abstraction at their SC. The SC Principal Investigator is required to document, in a memo to NCI and the CC, the plan for proposed corrective action.

On a semi-annual basis, the CC will send the abstractor or nosologist the summary of his or her qualifications as reported to the CC. The abstractor or nosologist will be requested to update the information with additional experience or certifications received since the last update.

- **Internal Quality Assurance**

The SC Coordinator and Lead Abstractor should use results of the External Quality Assurance Process to monitor the Internal Quality Assurance process at the SC. Lead Abstractors should evaluate systematic errors by abstractors at their SC to guide in-service training and/or seminars.

- **Workshops and Conference Calls**

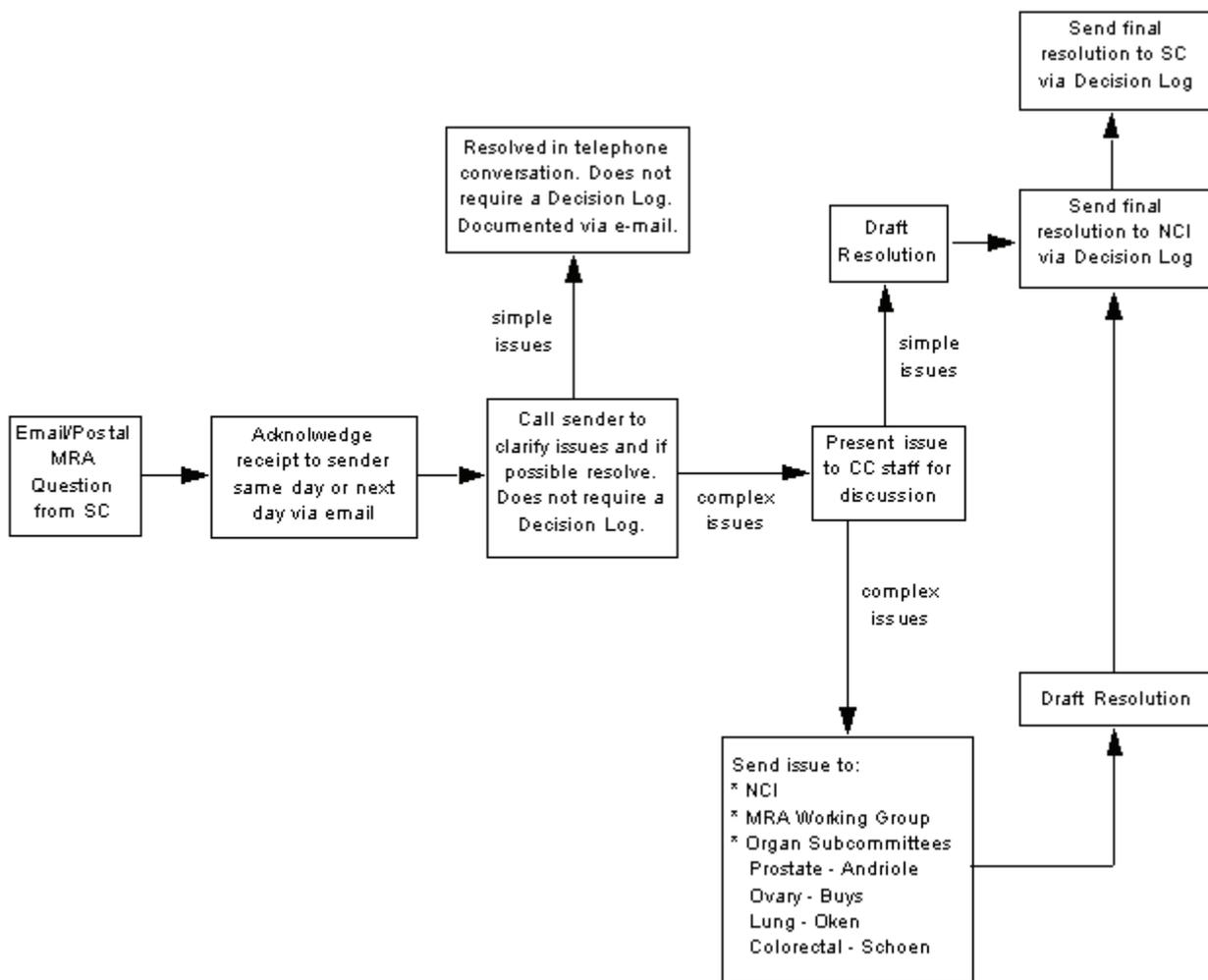
The CC will conduct an annual 1-day workshop for current abstractors that will take place the day after the new abstractor training. This workshop will be an opportunity for abstractors to share information, ask questions, and raise issues in order to improve the medical record abstraction process. This workshop may involve some training on changes in the protocol and NCI decisions since the previous workshop. Workshops will also be the forum for invited guest speakers to provide information to abstractors on issues of medical relevance. Attendance at this workshop is open to all abstractors, but attendance is mandatory for the SC Lead Abstractor.

There will be quarterly abstractor conference calls. The times and topics for these calls will be determined with the input of the SC medical record abstracting staff and representatives from NCI and the CC.

- **Problem Resolution**

The SC Abstractor should discuss all questions and/or problems internally with the Lead Abstractor, SC Coordinator, PI, and Collaborating Physicians. If the question and/or problem cannot be resolved internally, then the Lead Abstractor should contact the CC. The Lead Abstractor should direct all questions to the MRA Coordinator at the CC if there are forms completion issues or procedures. The MRA Coordinator at the CC will coordinate the problem resolution through various groups, (i.e., MRA Working Group; NCI Project Officers, Consultants, Collaborators, CTR; CC CTR, PA-C, Data Management; PLCO Subcommittees). The CC will document and distribute all resolutions to the SC Coordinators and Lead Abstractors through e-mail or a Decision Log. Systems Issues and Edit Issues should be directed to User Support at the CC.

- **Response to MRA Issues**



## 12. Central Pathology Review (NCI)

Development of procedures for central review of all cancer pathology is under discussion at NCI.

## 13. Central Death Data Review (NCI)

The procedures for the central death data review are provided in Chapter 9 of the MOOP entitled Vital Status Ascertainment and the Central Death Review Process.

## 14. Monitoring Reports

### Reports

The Coordinating Center develops SAS reports to monitor Screening Center progress and performance in recruitment, enrollment, screening and follow-up activities on a monthly, quarterly or semi-annual basis. These reports are reviewed by the Coordinating Center and NCI and copies are sent to Screening Centers each quarter. Problems are identified and Screening Centers are contacted for explanation and resolution.

## 15. Coding Decision Logs

Each Screening Center maintains a Coding Decision Log to document decisions made in editing forms (in particular Baseline Questionnaires). On this log, the Screening Center staff record the date, the PID, the form type, the item number, what the participant recorded, and what they coded or changed.

On a quarterly basis, each Screening Center sends its Coding Decision Log to the Coordinating Center for review. Coordinating Center staff review the logs to determine whether the decisions are appropriate and provide written and verbal feedback to the Screening Center. The Screening Center may be asked to send supporting documentation to the Coordinating Center for review.

The Coordinating Center also determines whether a decision made at one Screening Center should become a study-wide decision. If such a determination is made, the decision is reviewed by NCI and incorporated into the PLCO Decision Log which is distributed to all Screening Centers.

Review of Screening Center Coding Decision Logs was discontinued early in Year 3. Coding decisions are now reviewed during Screening Center site visits.

## 16. WORKING DATA QUALITY ASSURANCE PLAN

- **DATA QA INITIATED BY THE SC**

- Scan OPSCAN Forms in DEES

At the end of a scanning/data entry session, the SCs run the DEES edits and duplicates report. The edits are reviewed and updates made, as appropriate. Any changes made to the data collection form as a result of the computer edits are marked directly on the original form and the form is rescanned. After a form is rescanned, the computer edit is regenerated. Once the SC Coordinator is satisfied that the form is as clean as possible, a final disposition code (final complete or final incomplete) is assigned. The system will automatically assign final disposition of FCM (final complete) to forms with no errors at the end of an edit session.

It may not always be possible to correct the errors flagged by the DEES edit programs. An edit is intended to be a signal to the SC to investigate and determine the cause of the error. If, for example, the examiner simply could not ascertain a piece of information and left it blank on the form, a DEES error will be generated, but will not be able to be fixed, and the form should be coded "Final Incomplete." If, on the other hand, the examiner did not follow a skip pattern correctly, the DEES errors should alert SC staff to contact the examiner to correct the form.

- Run Production Edits Reports in SMS
  - SMS intra-forms edit report
  - SMS inter-forms edit report

The SCs run production edit reports in the SMS that list errors and inconsistencies within a single data collection form and among forms of different types. For optimal data quality, SCs should run production edits, at a minimum, before their monthly data transmission.

- DEES/SMS Quality Assurance Reports

The SC coordinator is responsible for monitoring all data collection activities including the quality assurance of the data. This is done using several reports generated from DEES/SMS.

- **WESTAT MONITORING OF SC DATA QA**

- Semi-Annual Data Editing Reports to CC

Beginning in FY 99, Westat requested each SC to generate the following data edit reports on a semi-annual basis for review at Westat.

- DEES DEES/SMS Comparison Report - identifies discrepancies between like fields in DEES and SMS data for opscan forms only
- SMS Inter-form Edits Report - lists errors and inconsistencies among forms of different types
- SMS Intra-form Edits Report - lists errors and inconsistencies within a single data collection form
- DEES Duplicates Report - identifies duplicate forms of the same form type
- DEES Match Forms Report - identifies forms scanned in DEES and not receipted in SMS and forms receipted in SMS and not scanned in DEES
- DEES Final Disposition Report - identifies forms scanned into DEES that do not have a final disposition

The objective of generating these reports is to provide an additional mechanism to ensure the quality of the data. Westat reviews and summarizes the data semi-annually.

- Reports Generated for Site Visit

As part of the onsite monitoring, SCs are asked to generate specific reports from the DEES and SMS for review at the site visit. Westat provides feedback to the SCs during the site visit as well as written documentation summarizing the output from these reports and recommended follow up.

- **WESTAT DATA QA ACTIVITIES**

To ensure the integrity, consistency and accuracy of the PLCO trial data, Westat performs and oversees numerous data investigation activities and data changes. A detailed description of each data QA activity is below.

- Quarterly Data Investigation Forms (DIFs)

Westat has programmed a variety of quality assurance reports over the course of the trial. Data anomalies that have been identified as a result of this reporting have been investigated to resolve the discrepancies on a quarterly basis. These errors may have been the result of protocol changes, changes to form completion specifications and additional edit checks added to forms processing. It was decided to formalize the process of identifying and correcting these errors using data investigation forms. Specific reports have been and will continue to be designed to identify potential errors for items of high importance that we feel additional data checks are warranted.

Reports are (or will be) reviewed for data errors and inconsistencies using data from the SMS and DEES. Following identification of errors or inconsistencies, DIFs are completed and sent to SCs for resolution. Some reports have been discontinued because the data have been cleaned and the SMS and DEES functions have been modified to eliminate the introduction of new errors or the SCs have the tools to run similar reports to identify and correct errors. Westat tracks the resolution and follow-up of these DIFs in an Access database at the SC level.

- **Medical Complications Investigation and Cleanup**

The PLCO trial generates a large volume of verbatim data including medical complications verbatim data. The medical complications data are presented annually to the MAP. In preparation for the MAP meeting, the medical complications verbatim responses on exam, QA exam, DE, and TI forms are reviewed and cleaned through the DIF process.

- Data from Exam, QA Exam Forms

Each verbatim medical complication response on the Exam and QA forms is reviewed: 1) to identify mismatches of expected verbatim responses and vice versa, 2) to determine if each verbatim response meets the definition of a medical complication, and 3) to assess the necessity for recoding the responses. Westat provides recommendations to the SC to review and cleanup the verbatim responses. The verbatim exam medical complications are cleaned at the SCs through the DIF process. After the SCs complete data cleanup, the remaining verbatim responses are grouped according to coding schemes Westat developed. Upon completion of the data cleanup initiative, Westat collaborates with a MAP member, NCI and IMS to develop data tables summarizing the medical complications data in preparation for the annual MAP meeting.

- Data from DE Forms

Each verbatim medical complication response on the DE form is reviewed: 1) to identify mismatches of expected verbatim and vice versa, 2) to determine if each verbatim response meets the definition of a medical complication as defined by the version 3 DE specifications, and 3) to assess the necessity for recoding the responses. Data cleanup occurs through the DIF process. Westat provides recommendations to the SC for data cleanup for each verbatim response. If it is determined that the verbatim is a medical complication according to the version 3 DE specifications, the SC is instructed to document the number corresponding to the complication in the other "specify" field using the r### coding scheme. It was also decided to leave the verbatim response "as is" in the database, if it does not comply with the version 3 specifications to minimize SC burden.

Beginning in 2004, Westat is systematically reviewing and cleaning all the codes to ensure they comply with the coding scheme in preparation for data analysis. Cleanup will occur through the DIF process. During analysis, only properly coded verbatim responses will be summarized and the remaining verbatim text will be ignored.

- Data from TI Forms

As of August 2001, TI medical complications data are no longer being collected; therefore, no DIFs related to TI medical complications have been sent to the SCs.

- **Forms Completion and Finalization**

With the completion of baseline data collection on July 31, 2002, Westat implemented a plan to complete and finalize all the baseline data forms, including the baseline questionnaires, TO exam forms, TO DE and TI forms, as well as the DHQ and DQX.

- Baseline Questionnaires

1) *Completeness.* All BQs should either be receipted or MDFs entered for all expectations. DIFs for all outstanding BQs are sent to the SCs in for them to investigate participants' BQ status and receipt MDFs as needed.

- 2) *Finalized*. All BQs without a final disposition are identified and DIFs sent to the SCs. The purpose of this DIF is to investigate and finalize BQ data.
  - 3) *Mismatched verbatim*. All BQs with expected verbatim but none listed and vice versa are identified and DIFs sent to the SCs. DIFs are separated for those with a final disposition and those without.
  - 4) *Targeted review of "Other Specify" verbatim*. Once the mismatched verbatim DIFs are returned, discrepant or invalid relative gender/cancer type codes are identified. The inconsistent data are cleaned up through the DIF process.
  - 5) *Westat reviews the data identified for cleaning and prepare the DIFs based on the priorities set by NCI*. The DIFs are then sent to the SCs.
  - 6) *Rerun the regularly scheduled DIFs specifically related to the BQs*. DIFs are sent to the SCs.
- T0 Exam Forms
    - 1) *Completeness*. All T0 exam forms are receipted or MDFs entered for all expectations. DIFs for all outstanding T0 exam forms are sent to the SCs in for them to receipt MDFs.
    - 2) *Finalized*. All T0 exam forms without a final disposition are identified and DIFs are sent to the SCs..
    - 3) *Mismatched verbatim*. All T0 exam forms with expected verbatim but none listed and vice versa are identified and DIFs sent to the SCs. DIFs are separated for those with a final disposition and those without.
    - 4) *Westat reviews the data identified for cleaning and prepares the DIFs*. Then the DIFs are sent to the SCs.
    - 5) *Rerun the routinely scheduled DIFs specifically related to the exams*.

**Note:** medical complications data for T0 exam forms have been addressed in previous DIFs.
  - T0 DE/TI/OCF
    - 1) *Completeness*. All T0 DE/TI/OCF forms are either receipted or MDFs entered for all expectations. DIFs for all outstanding T0 DE/TI/OCF forms are sent to the SCs for them to receipt MDFs.
    - 2) *Finalized*. All T0 DE/TI/OCF forms without a final disposition are identified and DIFs sent to the SCs.
    - 3) *Mismatched verbatim*. All T0 DE/TI/OCF forms with expected verbatim but none listed and vice versa are identified and DIFs sent to the SCs. DIFs are separated for those with a final disposition and those without.

**Note:** medical complications data for T0 DE/TI forms have been addressed in previous DIFs.

    - 4) *Westat reviews the data identified for cleaning and prepares the DIFs*. Then the DIFs are sent to the SCs.
    - 5) *Rerun the routinely scheduled DIFs specifically related to DE/TI/OCF forms*.
  - DHQ/DQX
    - 1) *DQX Completeness*: All DQXs are either receipted or MDFs entered for all expectations. A memo identifying all outstanding DQXs is sent to the SCs for them to receipt MDFs.

- 2) *DQX DR for Selected Items*: All items requiring DR are identified and DIFs are sent to the SCs.
- 3) *DHQ Completeness*: All DHQs are either receipted or MDFs entered for all TO expectations. DIFs for all outstanding DHQs are sent to the SCs.
- 4) *DHQ DR for Selected Items*: All items requiring DR are identified.

This initiative will be systematically repeated for exam and MRA forms in the remaining study years.

## **17. Cancer Related Data Investigation and Cleanup Activities**

- **Cancer Related Data Problems**

In early 2002, NCI prioritized categories of cancer related data problems for intervention participants that require cleanup. These data problems include biopsy with no biopsy date; no biopsy but expected; problem diagnosis dates; missing diagnosis dates; missing TNM/stage, type, grade, and Gleason Score; and mismatched expectations for flexible sigmoidoscopy and colonoscopy. The cleanup effort begins with TO data in the following site specific order: colon, lung, ovary, and prostate.

Westat identifies PIDs with discrepant data for a specific PLCO site, reviews each case using a Problem Category Information Form (PCIF) and synthesizes recommendations for cleanup. The PCIF provides a chronological history of events for each PID requiring review. It includes screening, diagnostic, as well as treatment procedures and results. The PCIFs and the corresponding recommendations are then sent as DIFs to the SCs.

Westat continues to work with IMS and NCI to identify data problems that require cleanup.

- **Cancer Related Verbatims**

Starting in Yr 11, NCI prioritized the cleanup of all cancer related verbatim data in Section C of the version 1 and 2 DE form as well as other "specify" diagnostic/staging procedures. The verbatim procedures will be recoded when possible according to the version 3 specifications using the r### coding scheme. This cleanup initiative occurs in conjunction with the cleanup of cancer related data problems described above. A PCIF is generated for each PID with cancer related verbatims. Westat proceeds to develop recommendations to cleanup inappropriate or inconsistent verbatims through the DIF process.

- **Data Inquiry Process**

In response to data inquiries received from Principal Investigators working on PLCO publications, Westat has developed a process to track and respond to these requests. All inquiries will initially be sent to NCI for review, and any that require accessing the original source of data are forwarded to Westat. Westat proceeds to gather the pertinent information to respond to each inquiry. The inquiry is subsequently logged in a tracking spreadsheet and its resolution is monitored.

The data inquiry is then incorporated into a data investigation form (DIF) that is sent to the SCs. The SCs are instructed to investigate the data in question, document their findings on the DIF and return it to Westat. The findings are subsequently forwarded to the investigator and Westat logs the date the data were sent. Additional requests for information often follow the initial data inquiry and are processed in a similar manner.

In 2003, Westat received a high volume of requests for data investigations and cleanup from the site specific Subcommittees as they prepared TO papers for publication. The DIFs were sent to the SCs in an expedited manner to meet the Subcommittees' tight deadlines. All the expedited DIFs that resulted from the data inquiries are being incorporated into the cancer related data cleanup initiative for the remaining study years.

- **Monitoring data activities with DIMS**

As previously mentioned, Westat performs and oversees numerous data investigation activities and data changes to ensure the integrity, consistency and accuracy of the PLCO trial data. These data investigation activities are electronically monitored by Westat at the SC level. However, Westat is developing the Data Investigation and Management System (DIMS), a comprehensive application and database that will provide organizational and system support for documenting and tracking Westat's data QA activities at the PID/study year level. The status of each data QA investigation will be monitored in the database, as well as the outcome for auditing and reporting purposes. Tracking outcomes will enable Westat to verify whether the data have in fact been corrected for each case, based on its recommendations.

DIMS will provide automated support for DIF communications between Westat and the SCs. Previously, hardcopy DIFs were sent to the SCs, the SCs documented their outcomes on the forms, and returned the completed DIFs to Westat. With the implementation of DIMS, DIFs will be sent to the SCs, the SCs will enter the outcome of each investigation in the electronic document and email it back to Westat. The outcomes are then imported into DIMS for auditing and reporting purposes. A substantial amount of historical data that have already been investigated and cleaned through the DIF process will also be stored in DIMS.

## **18. DATA REVIEW INITIATED BY OTHER SOURCES**

- **Review of Potential Problems with Cancer Related Data**

In early 2002, NCI prioritized categories of cancer related data problems that require cleanup. These data problems were identified in analysis programs generated by IMS and include biopsy with no biopsy date; no biopsy but expected; problem diagnosis dates; missing diagnosis dates; missing TNM/stage, type, grade, and Gleason Score; and mismatched expectations for flexible sigmoidoscopy and colonoscopy. For each of the identified data problems, DIFs were developed and sent to the SCs.

Participant profiles were generated for each PID with discrepant cancer related data. In its review of each participant profile, Westat identified and highlighted the discrepant cancer related data, as well as inconsistent verbatim (specify) procedures and any other discrepant information. Recommendations were then synthesized to clean up the discrepant data.

To document and track this cleanup initiative, Westat developed a spreadsheet listing the PIDs requiring cleanup, the discrepant data corresponding to the PIDs, and its recommendations for data cleanup. The PIDs were organized in the spreadsheets according to screening center, cancer type, and problem type. Westat also instructed the SCs to report their cleanup efforts on the spreadsheet. As additional analyses are brought to our attention, Westat will continue to work with NCI to identify data problems that require clean up.

- **Cancer Related Verbatim Responses in Section C**

NCI has also prioritized the cleanup of all cancer related verbatim data. Westat will work with IMS to identify all the cancer related verbatim responses in Section C on

the version 1 and 2 DE forms, as well as verbatim diagnostic/staging procedures. Westat will then review all the verbatim responses and develop recommendations to cleanup inappropriate or inconsistent information. The verbatim responses will be cleaned up through the DIF process. Each DIF will include participant profiles, which provide a complete case history including screening, diagnostic, as well as treatment procedures and results for the PIDs in question. This initiative will be organized by study year starting with 10 and cancer type in the following order: colon, lung, ovary, and prostate to verify that the data have been changed in accordance with the screening center's documentation.

A QA process for the participant profiles has been developed. Upon completion of the participant profile, DIFs for a specific cancer site and a sample of participant profiles with an unresolved data problem will be rerun. The data on the participant profiles will be compared with the screening center's documented clean-up efforts. Any data discrepancies will be rectified at the SCs through the DIF process.

- **Data Inquiry Process**

In response to data inquiries received from Principal Investigators working on PLCO publications, Westat has developed a process to track and respond to these requests. All inquiries will initially be sent to NCI for review, and any that require accessing the original source of data are forwarded to Westat. Westat then faxes a data inquiry request form to the investigator to gather the pertinent information. The information can also be collected over the phone. Once the form has been reviewed for completeness and any missing information retrieved, the inquiry is logged in a tracking spreadsheet.

The information on the form is then incorporated into a data investigation form (DIF) that is sent to the SCs. The SCs are instructed to investigate the data in question, document their findings on the DIF and return it to Westat. The findings are subsequently forwarded to the investigator and Westat logs the date the data were sent. Additional requests for information often follow the initial data inquiry and are processed in a similar manner.

**APPENDIX L: ATTACHMENT A**  
**QUALITY ASSURANCE—CHEST X-RAY EXAMINATION (XRY)**  
**(11-01-99)**

**A. Using Structural Measures to Assess Technician/Radiologist Qualifications:**

The following sections describe current protocol requirements for chest x-ray technicians and radiologists and measures for assessing the extent to which Screening Center staff conform to the written protocol.

**1. The Radiologist, Interpreter and QA Examiner:**

The protocol indicates that the radiologist who interprets the chest x-ray is an ABR board certified or board eligible radiologist. (Protocol for Chest X-Ray Examination, Item 1.E.2).

**2. The Technician:**

The protocol specifies the following minimum requirement, the technician will be an ARRT certified radiologic technician. (Protocol for Chest X-Ray Examination, Item 1.E.1).

**3. Minimum Training/Certification Requirements:**

Not Applicable.

**4. Registration of Radiologists:**

Screening Centers submit a completed Record of Experience, Credentials and Training (ECT) with copies of relevant board certificates to NCI. NCI reviews submitted documentation to determine if the proposed staff member credentials meet protocol requirements. If there is any deviation from the protocol, NCI transmits copies of the ECT and board certificates to a designated member of the Ovarian/Lung Subcommittee. The subcommittee member informs NCI about the adequacy of the documents submitted to establish each radiologist qualifications. NCI conveys the subcommittee member's judgments to Screening Center Coordinators, and to the Coordinating Center. The Coordinating Center maintains a central register of qualified trainers. This register includes the identity (name) of Radiologists and Technicians, the date of board certification, the date of registration by the Coordinating Center, and the identification number assigned at the Screening Center. A physician may not function as a radiologist until approved by NCI, and registered by the Coordinating Center.

**5. Initial Registration/Certification of Technicians:**

Screening Centers submit a completed ECT along with copies of relevant diplomas, certificates, and/or licenses to NCI. NCI reviews submitted documentation to determine if the proposed technician credentials meet protocol requirements. If there is any deviation from the protocol, NCI transmits copies of these documents to a designated member of the Ovarian/Lung Subcommittee. The subcommittee member informs NCI about the adequacy of documents submitted to establish each technician's qualifications and preparation. NCI conveys the subcommittee member's judgments to the Screening Center Coordinators, and to the Coordinating Center. The Coordinating Center maintains a central register of technicians. This register includes the identity (name) of technicians, the date of graduation, certification or licensure, the type of document establishing minimum qualifications, the date of registration by the Coordinating Center, and the technician identification number assigned at the Screening Center. An individual may not function as a chest x-ray technician until approved by NCI, and registered by the Coordinating Center.

## **B. Using Structural Measures to Assess Adherence to Protocol for Equipment Use and Maintenance:**

The equipment: The chest x-ray is taken using dedicated high-kV equipment (approximately 110-149 kV) at a tube-to-film distance of 6 to 10 feet. The Screening Center uses a wide latitude film with a 12 to 1 standard grid or higher.

Quality control of the equipment is assured by individual institutions, all of which are state licensed. Quality control also includes yearly documentation of kV calibration within 5 percent, radiation output assessed by use of an anatomic tomcat phantom, documentation of film-screen contact, demonstration that the x-ray spectrum is free of low-energy contaminants through use of half-value layer, collimation, dose exposure, and function of automatic exposure control.

The Screening Center sends to NCI documentation of equipment used for the chest x-ray, including film type used (e.g., symmetric or asymmetric film-screen combinations, etc.), and a record of maintenance and quality checks as demanded by state licensing requirements. NCI reviews documentation for completeness, then submits it to the appropriate Ovarian/Lung Subcommittee member for review and approval. NCI conveys Ovarian/Lung Subcommittee approval to the Screening Center.

## **C. Monitoring Technician Performance Using Outcome Performance Measures:**

Every quarter, the Coordinating Center prepares monitoring reports summarizing the performance of each Screening Center and Screening Center technicians and radiologists. These reports are distributed to NCI and individual Screening Centers. Using these reports, NCI judges the adequacy of each Screening Center performance. See items 1 and 2 below for a summary of outcome performance measures. For those Screening Centers judged to have inadequate performance in one or more areas, NCI will communicate with the Screening Center Principal Investigator to resolve performance problems. The Screening Center Principal Investigator is required to document, in a memo to NCI, his/her interpretation of the data and proposed corrective action. If necessary, NCI will arrange for a designated expert to visit the Screening Center and consult on problem issues.

### **1. Positive and Inadequate Exams**

The prevalence of positive (Abnormal Suspicious) chest x-ray examinations is reported by screening center, radiologist and three-month time interval. The prevalence of inadequate chest x-ray examinations is reported by screening center, technician, reason for inadequate exam, and three-month time interval.

The Coordinating Center distributes these displays to NCI and the Principal Investigator at each Screening Center. The Principal Investigator shares these analyses with radiologists and technicians. NCI uses these data for decisions regarding performance of Screening Centers and Screening Center technicians and radiologists.

### **2. Agreement Between Two Examiners**

Using the protocols, procedures, and definitions developed for the trial, a second designated qualified radiologist (QA examiner) reinterprets chest x-ray films for 9 participants each month. These chest x-ray films are reviewed by a second radiologist within 3 weeks of the first interpretation. In SCs where there is a QA system in place where some examiners review their own film, a letter should be submitted to NCI explaining this system and justifying the level of blinding. The number of subjects and method for the selection are determined by NCI through consultation with the individual Screening Centers.

If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should

not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams. If upon QA review of an "adequate" exam, the QA examiner determines that it was actually inadequate, the X-ray procedure should not be repeated, that is, a new X-ray should not be obtained.

Only chest x-ray radiologists registered with the Coordinating Center performs the second confirmatory interpretation of the chest x-ray. Second radiologists are blinded to the results of the initial interpretation. The second radiologist completes the Chest X-ray Screening Examination Quality Assurance Form. Screening Centers base referral recommendations on the most abnormal examination test result.

NCI performs statistical analyses which compare the screening test results provided by the primary and secondary radiologists. The results of these analyses are shared with the Screening Centers.

#### **D. Centralized Review of Chest X-Rays**

A centralized audit of chest x-rays is under consideration.

**APPENDIX L: ATTACHMENT B**  
**QUALITY ASSURANCE—DIGITAL RECTAL EXAMINATION OF THE PROSTATE**  
**(DRE)**  
**(11/01/99)**

**A. Using Structural Measures to Assess Examiner/Trainer Qualifications:**

The following sections describe current protocol requirements for digital rectal examination of the prostate (DRE) examiners and trainers, and measures for assessing the extent to which Screening Center staff conform to the written protocol.

**1. The Trainer:**

The protocol indicates that the trainer is *a board certified urologist. (PLCO MOOP, Appendix J, Protocol for Digital Rectal Examination of the Prostate Item 1.G.1). For any individual who is not a board certified urologist, the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.*

**2. The Examiner:**

The protocol specifies the following minimum requirement, the examiner is an R.N., Certified Physician's Assistant, Nurse Practitioner, Physician or equivalent (*PLCO MOOP, Appendix J, Protocol for Digital Rectal Examination of the Prostate, Item 1.E.1*). Equivalency is to be determined by the Screening Center Principal Investigator and documented in a letter to be submitted with a completed ECT to NCI.

**3. The QA Examiner:**

The protocol specifies the following minimum requirement, the QA examiner is any licensed physician who is adequately trained and experienced in the digital rectal examination as determined by the Screening Center Principal Investigator or a certified PLCO DRE examiner (*PLCO MOOP, Appendix J, Protocol for Digital Rectal Examination of the Prostate, Item 1.F.1*). *For any individual who is not a PLCO DRE examiner or a board certified urologist, the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.*

**4. Minimum Training/Certification Requirements:**

A non-physician examiner must successfully perform at least 15 of 30 examinations, including 10 examinations with abnormal findings, under the supervision of a trainer (*PLCO MOOP, Appendix J, Protocol for Digital Rectal Examination of the Prostate, Item 1.H.*).

**5. Registration of Trainers:**

Screening Centers submit a completed Record of Experience, Credentials and Training (ECT) with copies of relevant board certificates to NCI. NCI reviews submitted documentation to determine if the proposed staff member's credentials meet protocol requirements. If there is any deviation from the protocol, NCI transmits copies of the ECT and board certificates to a designated member of the Prostate/Colorectal Subcommittee. The subcommittee member informs NCI about the adequacy of the documents submitted to establish each trainer qualifications. NCI will convey the subcommittee member's judgments to Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of qualified trainers. This register includes the identity (name) of trainers and examiners, the date of board certification, the date of registration by the Coordinating Center, and the identi-

fication number assigned at the Screening Center. An individual may not function as a trainer until approved by NCI, and registered by the Coordinating Center.

**6. Initial Registration/Certification of Examiners and QA Examiners:**

Screening Centers submit a completed ECT along with copies of relevant diplomas, certificates, and/or licenses to NCI. Also, a registered trainer prepares, signs, and submits a letter which affirms satisfactory completion of minimum training requirements. NCI reviews submitted documentation to determine if the proposed examiner's credentials and training meet protocol requirements. If there is any deviation from the protocol, the NCI transmits copies of these documents to a designated member of the Prostate/Colorectal Subcommittee. The subcommittee member informs NCI about the adequacy of documents submitted to establish each examiner's qualifications and preparation. NCI conveys the subcommittee member's judgments to the Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of certified examiners and QA examiners. This register includes the identity (name) of examiners, the date of graduation, certification or licensure, the type of document establishing minimum qualifications, the date of registration by the Coordinating Center, and the examiner identification number assigned at the Screening Center. An individual may not function as DRE examiner or DRE QA examiner until approved by NCI, and registered by the Coordinating Center.

**B. Using Structural Measures to Assess Adherence to Protocol for Equipment Use and Maintenance:**

Not applicable.

**C. Monitoring Examiner Performance Using Outcome Performance Measures:**

Every quarter, the Coordinating Center will prepare monitoring reports summarizing the performance of each Screening Center and Screening Center examiner. These reports are distributed to NCI and individual Screening Centers. Using these reports, NCI judges the adequacy of each Screening Center performance. See items 1 and 2 below for a summary of outcome performance measures. For those Screening Centers judged to have inadequate performance in one or more areas, NCI communicates with the Screening Center Principal Investigator to resolve performance problems. The Screening Center Principal Investigator is required to document, in a memo to NCI, his/her interpretation of the data and proposed corrective action. If necessary, NCI arranges for a designated expert to visit the Screening Center and consult on problem issues.

**1. Positive and Inadequate Exams**

The prevalence of positive (Abnormal Suspicious) DRE examinations is reported by Screening Center, DRE examiner, and three-month time interval. The prevalence of inadequate DRE examinations is reported by Screening Center, DRE examiner, reason for inadequate exam, and three-month time interval. The Coordinating Center distributes these displays to NCI and the Principal Investigator at each Screening Center. The Principal Investigator shares these analyses with trainers. NCI uses these data for decisions regarding performance of Screening Center and Screening Center examiners.

**2. Agreement Between Two Examiners**

The protocol developed for the pilot phase of the PLCO Cancer Screening Trial recognizes the importance of direct measurements of the reliability of DRE physical examinations.

Using the protocols, procedures, and definitions developed for the trial, a second examiner attempts to repeat the examination for 7 participants each month. The

number of subjects and method for selection are determined by NCI through consultation with the individual Screening Centers.

If in the process of selecting exams for QA repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

Only DRE QA examiners or trainers registered with the Coordinating Center may perform the second confirmatory DRE examination. Second examiners are blinded to the results of the initial examination. The second examiner will complete the DRE Quality Assurance Form. Screening Centers base referral recommendations on the most abnormal examination test result.

NCI performs statistical analyses which compares the screening test results provided by the primary and secondary examiners. The results of these analyses are shared with the Screening Centers.

**D. Central Audit**

Not applicable.

**APPENDIX L: ATTACHMENT C**  
**QUALITY ASSURANCE—FLEXIBLE SIGMOIDOSCOPY EXAMINATION (FSG)**  
**(11/01/99)**

**A. Using Structural Measures to Assess Examiner/Trainer Qualifications:**

The following sections describe current protocol requirements for flexible sigmoidoscopy examiners and trainers and measures for assessing the extent to which Screening Center staff conform to the written protocol.

**1. The Trainer:**

The protocol indicates that the trainer is *a board certified gastroenterologist*. (Protocol for Flexible Sigmoidoscopy Examination, Item 1.G.1). For any individual who is not a board certified gastroenterologist, the Principal Investigator must document and certify adequate training and experience in a letter to be submitted with a completed ECT to NCI.

**2. The Examiner:**

The protocol specifies the following minimum requirement, *the examiner is an R.N., certified Physician's Assistant, Nurse Practitioner, Physician or equivalent* (Protocol for Flexible Sigmoidoscopy Examination, Item 1.E.1). Equivalency is to be determined by the Screening Center Principal Investigator and documented in a letter to be submitted with a completed ECT to NCI.

**3. The QA Examiner:**

The protocol specifies the following minimum requirement, the QA examiner is either a PLCO FSG trainer or a PLCO FSG examiner who has performed at least 240 PLCO FSG examinations in the prior 12 months (average 20 per month) and achieved 50+cm insertion depth in at least 85 percent of cases with adequate bowel preparation (Protocol for Flexible Sigmoidoscopy Examination, Item 1.F.1). For any individual who is not a board-certified gastroenterologist, the Principal Investigator must document and certify adequate training and experience in a letter to be submitted with a completed ECT to NCI. FSG QA examiner status must be renewed at annual intervals.

**4. Minimum Training/Certification Requirements:**

A non-physician or physician who is not a board certified gastroenterologist or who does not have hospital privileges to perform flexible sigmoidoscopies or colonoscopies must successfully perform at least 25 examinations under the supervision of a trainer (Protocol for Flexible Sigmoidoscopy, Item 1.F).

**5. Registration of Trainers:**

Screening Centers submit a completed Record of Experience, Credentials and Training (ECT) with copies of relevant board certificates to NCI. NCI reviews submitted documentation to determine if the proposed staff member credentials meet protocol requirements. If there is any deviation from the protocol, the NCI transmits copies of the ECT and board certificates to a designated member of the Prostate/Colorectal Subcommittee. The subcommittee member informs NCI about the adequacy of the documents submitted to establish each trainer qualifications. NCI conveys the subcommittee member's judgments to Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of qualified trainers. This register includes the identity (name) of trainers and examiners, the date of board certification, the date of registration by the Coordinating Center, and the identification

number assigned at the Screening Center. A physician may not function as a trainer until approved by NCI, and registered by the Coordinating Center.

**6. Initial Registration/Certification of Examiners and QA Examiners:**

Screening Centers submit a completed ECT along with copies of relevant diplomas, certificates, and/or licenses to NCI. Also, a registered trainer prepares, signs, and submits a letter which affirms satisfactory completion of minimum training requirements. NCI reviews submitted documentation to determine if the proposed examiner credentials and training meet protocol requirements. If there is any deviation from the protocol, NCI transmit copies of these documents to a designated member of the Prostate/Colorectal Subcommittee. The subcommittee member inform NCI about the adequacy of documents submitted to establish each examiner's qualifications and preparation. NCI will convey the subcommittee member's judgments to the Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of certified examiners and QA examiners. This register will include the identity (name) of examiners, the date of graduation, certification or licensure, the type of document establishing minimum qualifications, the date of registration by the Coordinating Center, and the examiner identification number assigned at the Screening Center. An individual may not function as a flexible sigmoidoscopy examiner or an FSG QA examiner until approved by NCI, and registered by the Coordinating Center.

**B. Using Structural Measures to Assess Adherence to Protocol for Equipment Use and Maintenance:**

The equipment: The equipment is a flexible endoscope with capability to 60 cm and a light source.

Screening Centers are required to submit the following documentation for scope and light source: make, model number, serial number and type of scope/light source. Screening Centers submit documentation of video equipment. In addition, Screening Centers submit a description of the cleaning and disinfection procedures that are performed according to standard medical practice and pertinent federal and local regulations. The documentation is submitted to NCI to review for completeness. NCI submits the documentation to a designated member of the QA subcommittee for approval. NCI conveys the subcommittee member's approval to the Screening Center.

**C. Monitoring Examiner Performance Using Outcome Performance Measures:**

Every three months, the Coordinating Center prepares monitoring reports summarizing the performance of each Screening Center and Screening Center examiner. These reports are distributed to NCI and individual Screening Centers. Using these reports, NCI judges the adequacy of each Screening Center performance. See items 1 and 2 below for a summary of outcome performance measures. For those Screening Centers judged to have inadequate performance in one or more areas, NCI communicates with the Screening Center Principal Investigator to resolve performance problems. The Screening Center Principal Investigator is required to document, in a memo to NCI, his/her interpretation of the data and proposed corrective action. If necessary, NCI arranges for a designated expert to visit the Screening Center and consult on problem issues.

**1. Positive and Inadequate Exams**

The prevalence of positive (Abnormal Suspicious) flexible sigmoidoscopy examinations is reported by Screening Center, examiner, and three-month time interval. The prevalence of inadequate exams is reported by Screening Center, examiner, reason for inadequate exam and three-month time interval. The Coordinating Center distributes these displays to NCI and the Principal Investigator at each Screening Center. The Principal Investigator shares these analyses with trainers and examiners. NCI

uses these data for decisions regarding performance of Screening Center and Screening Center examiners.

## **2. Agreement Between Two Examiners**

Using the protocols, procedures and definitions developed for the trial, a second examiner performs a quality assurance review of the flexible sigmoidoscopy examination using one of the following methods: 1) review videotapes of flexible sigmoidoscopy examinations; 2) repeat flexible sigmoidoscopy examinations, or 3) real-time observation. Although they may be ideal, repeat FSGs are not practical within the context of the study. Review of videotape and real-time observation have potential biases, but either method will be an acceptable option for FSG QA.

A sample of 4 participants will be selected each month. The number of subjects and method for selection are determined by NCI through consultation with the individual Screening Centers.

If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

Only flexible sigmoidoscopy QA examiners or trainers registered with the Coordinating Center may perform the QA review. Second examiners are blinded to the results of the initial examination to the extent possible. The second examiner completes the Flexible Sigmoidoscopy Screening Examination Quality Assurance Form. Screening Centers base referral recommendations on the most abnormal examination test result.

NCI performs statistical analyses which compares the screening test results provided by the primary and secondary examiners. The results of these analyses are shared with the Screening Centers.

## **D. Centralized Review of FSG Tapes**

Centralized review will be considered if at some point all Screening Centers have videotape capability.

**APPENDIX L: ATTACHMENT D**  
**QUALITY ASSURANCE—PHYSICAL EXAMINATION OF THE OVARIES (OVR)**  
**(11-01-99)**

**A. Using Structural Measures to Assess Examiner/Trainer Qualifications:**

The following sections describe current protocol requirements for ovarian palpation examiners and trainers and measures for assessing the extent to which Screening Center staff conform to the written protocol.

**1. The Trainer:**

The protocol indicates that the trainer *is a board certified gynecologist or gynecologic oncologist. (PLCO MOOP, Appendix J, Protocol for Ovarian Palpation Examination, Item 1.G.1)*. For any individual who is not a board certified gynecologist or gynecologic oncologist, the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.

**2. The Examiner:**

The protocol specifies the following minimum requirement, the examiner is a clinical nurse *specialist, R.N., certified Physician's Assistant, or equivalent (PLCO MOOP, Appendix J, Protocol for Ovarian Palpation Examination, Item 1.E.1)*. Equivalency is to be determined by the Screening Center Principal Investigator and documented in a letter to be submitted with a completed ECT to NCI.

**3. The QA Examiner:**

The protocol specifies the following minimum requirement, the QA examiner is any licensed physician with adequate training and experience in the ovarian palpation examination as determined by the Screening Center Principal Investigator or a PLCO certified PLCO OVR examiner *(PLCO MOOP, Appendix J, Protocol for Ovarian Palpation Examination, Item 1.F.1)*. For any individual who is not a board certified gynecologist or gynecologic oncologist, or a PLCO certified OVR examiner the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.

**4. Minimum Training/Certification Requirements:**

A non-physician must spend at least two full work days with a trainer and must successfully perform at least 40 examinations in post-menopausal women, including 10 examinations with abnormal findings.

**5. Registration of Trainers:**

Screening Centers will submit a completed Record of Experience, Credentials and Training (ECT) with copies of relevant board certificates to NCI. NCI reviews submitted documentation to determine if the proposed staff member's credentials meet protocol requirements. If there is any deviation from the protocol, NCI transmits copies of the ECT and board certificates to a designated member of the Ovarian/Lung Subcommittee. The subcommittee member informs NCI about the adequacy of the documents submitted to establish each trainer qualifications. NCI conveys the subcommittee member's judgments to Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of qualified trainers. This register includes the identity (name) of trainers and examiners, the date of board certification, the date of registration by the Coordinating Center, and the identification number assigned at the Screening Center. An individual may not function as a trainer until approved by NCI, and registered by the Coordinating Center.

**6. Initial Registration/Certification of Examiners and QA Examiners:**

Screening Centers submit a completed ECT along with copies of relevant diplomas, certificates, and/or licenses to NCI. Also, a registered trainer will prepare, sign, and submit a letter which affirms satisfactory completion of minimum training requirements. NCI reviews submitted documentation to determine if the proposed examiner's credentials and training meet protocol requirements. If there is any deviation from the protocol, NCI transmits copies of these documents to a designated member of the Ovarian/Lung Subcommittee. The subcommittee member informs NCI about the adequacy of documents submitted to establish each examiner's qualifications and preparation. NCI conveys the subcommittee member's judgments to the Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of certified examiners and QA examiners. This register includes the identity (name) of examiners, the date of graduation, certification or licensure, the type of document establishing minimum qualifications, the date of registration by the Coordinating Center, and the examiner identification number assigned at the Screening Center. An individual may not function as an OVR examiner or OVR QA examiner until approved by NCI, and registered by the Coordinating Center.

**B. Using Structural Measures to Assess Adherence to Protocol for Equipment Use and Maintenance:**

Not applicable.

**C. Monitoring Examiner Performance Using Outcome Performance Measures:**

Every three months, the Coordinating Center prepares monitoring reports summarizing the performance of each Screening Center and Screening Center examiner. These reports are distributed to NCI and individual Screening Centers. Using these reports, NCI judges the adequacy of each Screening Center performance. See items 1-3 below for a summary of outcome performance measures. For those Screening Centers judged to have inadequate performance in one or more areas, NCI communicates with the Screening Center Principal Investigator to resolve performance problems. The Screening Center Principal Investigator is required to document, in a memo to NCI, his/her interpretation of the data and proposed corrective action. If necessary, NCI arrange for a designated expert to visit the Screening Center and consult on problem issues.

**1. Positive and Inadequate Exams**

The prevalence of positive (Abnormal Suspicious) or inadequate ovarian examinations is reported by screening center, ovarian examiner, reason for inadequate exam, and six-month time period. The Coordinating Center distributes these displays to NCI and the Principal Investigator at each Screening Center. The Principal Investigator shares these analyses with trainers and examiners. NCI uses these data for decisions regarding performance of Screening Center and Screening Center examiners.

**2. Correspondence Between Physical Examination and Transvaginal Ultrasound Findings**

The protocol blinds the ovarian physical examiner to the results of the transvaginal ultrasound examination. The protocol also blinds the transvaginal ultrasonographer to the results of the ovarian physical examination. The independence of these two examinations allow study of the correspondence between manual detection of the ovaries and visualization of the ovaries, stratified according to screening site, ovarian physical examiner, and/or time.

At three month intervals, the Coordinating Center displays correspondence measures on comparisons between the manual detection of the ovaries and visualization of the ovaries. Separate displays allow comparisons across screening centers, across ovarian

examiners, and across time periods. The Coordinating Center distributes these displays to NCI and the principal investigator at each screening center. The principal investigator shares these analyses with trainers and examiners. NCI uses these data for decisions regarding performance of Screening Centers and Screening Center examiners.

### **3. Agreement Between Two Examiners**

Using the protocols, procedures, and definitions developed for the trial, a second examiner attempts to repeat the examinations for 14 participants each month. The number of subjects and method for selection are determined by NCI through consultation with each Screening Center. Only OVR QA examiners or trainers registered with the Coordinating Center may perform the second confirmatory physical examination. Second examiners are blinded to the results of the first examination. The second examiner completes the Ovarian Palpation Screening Examination Quality Assurance Form. Screening Centers base referral recommendations on the most abnormal examination test result.

NCI performs statistical analyses, which compare the screening test results provided by the primary and secondary examiners. The results of these analyses are shared with the Screening Centers.

### **D. Central Audit:**

Not applicable.

**APPENDIX L: ATTACHMENT E**  
**QUALITY ASSURANCE—TRANSVAGINAL ULTRASOUND EXAMINATION (TVU)**  
**(11/01/99)**

**A. Using Structural Measures to Assess Examiner/Trainer Qualifications:**

The following sections describe current protocol requirements for transvaginal ultrasound examiners and trainers/supervisors and measures for assessing the extent to which Screening Center staff conform to the written protocol.

**1. The Trainer/Supervisor:**

The protocol indicates that the trainer/supervisor is a board certified radiologist with specific training in ultrasonography (*PLCO MOOP, Appendix J, Protocol for Transvaginal Ultrasound Examination, Item 1.G.1*). For any physician who is not a board certified radiologist with specific training in ultrasonography, the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.

**2. The Examiner:**

The protocol indicates the following minimum requirement, the examiner is a sonographer certified by the American Registry of Diagnostic Medical Sonographers (ARDMS) who has passed the OB/GYN section of the ARDMS certification examination. The examiner may also be a physician who is adequately trained (and experienced) in transvaginal ultrasonography as determined by the Screening Center Principal Investigator. Examiners should be supervised by a PLCO qualified Trainer/Supervisor (*PLCO MOOP, Appendix J, Protocol for Transvaginal Ultrasound Examination, Item 1.E.1*). For any individual who is not a sonographer registered by ARDMS, the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI.

**3. The QA Examiner:**

The protocol indicates the following minimum requirement, the QA examiner is either a PLCO TVU trainer or a PLCO TVU examiner who has performed at least 240 PLCO TVU examinations in the prior 12 months (average 20 per month) and detected one or both ovaries in at least 60 percent of those examinations deemed adequate (*PLCO MOOP, Appendix J, Protocol for Transvaginal Ultrasound Examination, Item 1.F.1*). For any individual who is not a board certified radiologist with specific training in ultrasonography, the Screening Center Principal Investigator must document adequate training and experience in a letter to be submitted with a completed ECT to NCI. The TVU QA examiner status should be renewed at annual intervals.

**4. Minimum Training/Certification Requirements:**

All examiners should have prior experience performing 50 to 100 examinations to be certified.

**5. Registration of Trainers/Supervisors:**

Screening Centers submit a completed Record of Experience, Credentials and Training (ECT) with copies of relevant board certificates to NCI. NCI reviews submitted documentation to determine if the proposed staff member's credentials meet protocol requirements. If there is any deviation from the protocol, the NCI transmits copies of the ECT and board certificates to a designated member of the Ovarian/Lung Subcommittee. The subcommittee member informs NCI about the adequacy of the documents submitted to establish each trainer qualifications. NCI conveys the subcommittee

member's judgments to Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of qualified trainers/supervisors. This register includes the identity (name) of trainers/supervisors and examiners, the date of board certification, the date of registration by the Coordinating Center, and the identification number assigned at the Screening Center. A physician may not function as a trainer until approved by NCI, and registered by the Coordinating Center.

**6. Initial Registration/Certification of Examiners and QA Examiners:**

Screening Centers submit a completed ECT along with copies of relevant diplomas, certificates, and/or licenses to NCI. Also, a registered trainer will prepare, sign, and submit a letter which affirms satisfactory completion of minimum training requirements, including centralized training. NCI reviews submitted documentation to determine if the proposed examiner's credentials and training meet protocol requirements. If there is any deviation from the protocol, the NCI transmits copies of these documents to a designated member of the Ovarian/Lung Subcommittee. The subcommittee member informs NCI about the adequacy of documents submitted to establish each examiner's qualifications and preparation. NCI conveys the subcommittee member's judgments to the Screening Center Coordinators and the Coordinating Center. The Coordinating Center maintains a central register of certified examiners and QA examiners. This register includes the identity (name) of examiners, the date of graduation, certification or licensure, the type of document establishing minimum qualifications, the date of registration by the Coordinating Center, and the examiner identification number assigned at the Screening Center. An individual may not function as a TVU examiner or TVU QA examiner until approved by NCI, and registered by the Coordinating Center.

**B. Using Structural Measures to Assess Adherence to Protocol for Equipment Use and Maintenance:**

Equipment must be a 5-7.5 MHz transvaginal probe. A photograph, computerized image, or thermal printout is obtained for documentation. It is acceptable to store transvaginal ultrasound images on thermal paper and radiographic film. Digital storage is also acceptable but a back-up copy should also be maintained. The storage method should meet requirements of 20-year storage with no decrease in the quality of the image and with capability to retrieve a film or paper image at any time during the 20-year storage period.

Screening Centers are required to submit to NCI the following documentation for transvaginal ultrasound equipment: make, model, serial number and type of transducer; and type, name, and manufacturer of documentation material. In addition, Screening Centers submit a description of cleaning and disinfection procedures that are performed according to standard medical practice and pertinent federal and local regulations. NCI reviews submitted documentation to determine if the equipment specifications meet protocol requirements. If there is any deviation from the protocol, NCI transmits copies of these documents to a designated member of the Quality Assurance Subcommittee. The subcommittee member informs NCI about the adequacy of the equipment. NCI conveys the subcommittee member's judgments to the Screening Center Coordinators.

**C. Monitoring Examiner Performance Using Outcome Performance Measures:**

Every three months, the Coordinating Center prepares monitoring reports summarizing the performance of each Screening Center and Screening Center examiner. These reports are distributed to NCI and individual Screening Centers. Using these reports, NCI judges the adequacy of each Screening Center performance. See items 1-4 below for a summary of outcome performance measures. For those Screening Centers judged to have inadequate performance in one or more areas, NCI communicates with the Screening Center Principal Investigator to resolve performance problems. The Screening Center Principal

Investigator is required to document, in a memo to NCI, his/her interpretation of the data and proposed corrective action. If necessary, NCI arranges for a designated expert to visit the Screening Center and consult on problem issues and train sonographers.

### **1. Positive and Inadequate Exams**

The prevalence of positive (Abnormal Suspicious) or inadequate transvaginal ultrasound examinations is reported by screening center, examiner, reason for inadequate exam, and three-month time interval. The Coordinating Center distributes these displays to NCI and the Principal Investigator at each Screening Center. The Principal Investigator shares these analyses with trainers/supervisors. NCI uses these data for decisions regarding performance of Screening Center and Screening Center examiners.

### **2. Correspondence Between Physical Examination and Transvaginal Ultrasound Findings**

The protocol blinds the ovarian physical examiner to the results of the transvaginal ultrasound examination. The protocol also blinds the transvaginal ultrasonographer to the results of the ovarian physical examination. The independence of these two examinations allow study of the correspondence between palpation of the ovaries and visualization of the ovaries, stratified according to screening site, transvaginal ultrasound examiner, and/or time.

At three-month intervals, the Coordinating Center displays correspondence measures on comparisons between the manual detection of the ovaries and visualization of the ovaries. Separate displays allow comparisons across screening centers, across ovarian examiners, and across time intervals. The Coordinating Center distributes these displays to NCI and the principal investigator at each screening center. The principal investigator shares these analyses with trainers/supervisors and examiners. NCI uses these data for decisions regarding performance of Screening Centers and Screening Center examiners.

### **3. Agreement Between Two Examiners**

The protocol developed for the pilot phase of the PLCO Cancer Screening Trial recognizes the importance of direct measurements of the reliability of transvaginal ultrasound examinations.

Using the protocols, procedures, and definitions developed for the trial, a second examiner attempts to repeat the examination for 14 participants each month. The number of subjects and method for selection are determined by NCI through consultation with the individual Screening Centers.

If in the process of selecting exams for QA review/repeat, an exam with a result of Inadequate (IN) is chosen, the QA exam should not be performed. Such exams should not be selected for QA because the original reason for inadequacy may be out of the examiner's control and lead to further inadequate exams.

Only TVU trainers/supervisors or QA examiners registered with the Coordinating Center may perform the second confirmatory TVU examination. Second examiners are blinded to the results of the initial examination. The second examiner completes the Transvaginal Ultrasound Screening Examination Quality Assurance Form. Screening Centers base referral recommendations on the most abnormal examination test result.

NCI performs statistical analyses which compare the screening test results provided by the primary and secondary examiners. The results of these analyses are shared with the Screening Centers.

#### **4. Additional Analyses**

Additional outcome quality measures recommended for the TVU exam include:

- 1) tracking the proportion of exams in which one or both ovaries are identified;
- 2) monitoring the mean ovarian size recorded by each of the examiners and comparing it to the mean for all examiners; and
- 3) monitoring the proportion of ovaries with small cyst as a corollary to presence of the ovary.

#### **D. Centralized Review of TVU Films:**

There are currently no plans to conduct a centralized review of TVU films.

## ATTACHMENT F-1

<b>CRITICAL DATA ITEMS FOR DEP</b>	
<b>PART A</b>	<b>DIAGNOSTIC EVALUATION AND STAGING</b>
A.1	Diagnostic Procedures Performed
A.8	Medical Complications of Diagnostic Evaluation and Staging
A.9	Result of Diagnostic Evaluation for Prostate Cancer
<b>PART B</b>	<b>DIAGNOSIS INFORMATION FOR SPECIFIC CONDITION OTHER THAN PROSTATE CANCER</b>
B.10	Specific Prostate Diagnosis
B.11	Other Cancer Diagnosis
<b>PART C</b>	<b>PRIMARY CANCER DIAGNOSIS INFORMATION</b>
C.12	Date of Primary Prostate Cancer Diagnosis
	ICD-O-2 Cancer Classification
C.14a	Topography
C.14b	Morphology
C.14c	Behavior
C.14d	Grade
C.16	Histopathologic Type for Primary Prostate Cancer
C.17	Histopathologic Grade for Primary Prostate Cancer
C.18	Gleason Score
	TNM Staging for Primary Prostate Cancer
C.19a	TNM Clinical Staging
C.19b	TNM Pathologic Staging

<b>CRITICAL DATA ITEMS FOR TIP</b>	
<b>PART A</b>	<b>INITIAL TREATMENT INFORMATION</b>
A.1	Radiation Treatment for Prostate Cancer
A.2	Surgical Treatment for Prostate Cancer
A.3	Hormonal Treatment for Prostate Cancer

## ATTACHMENT F-2

<b>CRITICAL DATA ITEMS FOR DEL</b>	
<b>PART A</b>	<b>DIAGNOSTIC EVALUATION AND STAGING</b>
A.1	Diagnostic Procedures Performed
A.4	Medical Complications of Diagnostic Evaluation and Staging
A.5	Result of Diagnostic Evaluation for Lung Cancer
<b>PART B</b>	<b>DIAGNOSIS INFORMATION FOR SPECIFIC LUNG CONDITIONS</b>
B.6	Specific Lung Diagnosis
B.7	Other Cancer Diagnosis
<b>PART C</b>	<b>PRIMARY CANCER DIAGNOSIS INFORMATION</b>
C.8	Date of Primary Lung Cancer Diagnosis
	ICD-O-2 Cancer Classification
C.10a	Topography
C.10b	Morphology
C.10c	Behavior
C.10d	Grade
C.12	Primary Tumor Location
C.13	Histopathologic Type for Primary Lung Cancer
C.14	Histopathologic Grade for Primary Lung Cancer
	TNM Staging for Primary Lung Cancer
C.15a	TNM Clinical Staging
C.15b	TNM Pathologic Staging

<b>CRITICAL DATA ITEMS FOR TIL</b>	
<b>PART A</b>	<b>INITIAL TREATMENT INFORMATION</b>
A.1	Radiation Treatment for Lung Cancer
A.2	Surgical Treatment for Lung Cancer
A.3	Chemotherapeutic Treatment for Lung Cancer

## ATTACHMENT F-3

<b>CRITICAL DATA ITEMS FOR DEC</b>	
<b>PART A</b>	<b>DIAGNOSTIC EVALUATION AND STAGING</b>
A.1	Diagnostic Procedures Performed
A.6	Medical Complications of Diagnostic Evaluation and Staging
A.7	Result of Diagnostic Evaluation for Colorectal Cancer
<b>PART B</b>	<b>DIAGNOSIS INFORMATION FOR CANCERS OTHER THAN COLORECTAL CANCER</b>
B.8	Other Cancer Diagnosis
<b>PART C</b>	<b>PRIMARY COLORECTAL CANCER DIAGNOSIS INFORMATION</b>
C.9	Description of Colorectal Carcinoma
C.10	Date of Primary Colorectal Cancer Diagnosis
	ICD-0-02 Cancer Classification
C.12a	Topography
C.12b	Morphology
C.12c	Behavior
C.12d	Grade
C.14	Histopathologic Type for Primary Colorectal Cancer
C.15	Histopathologic Grade for Primary Colorectal Cancer
	TNM Staging for Primary Colorectal Cancer
C.16a	TNM Clinical Staging
C.16b	TNM Pathologic Staging

<b>CRITICAL DATA ITEMS FOR TIC</b>	
<b>PART A</b>	<b>INITIAL TREATMENT INFORMATION</b>
A.1	Surgical Treatment for Colorectal Cancer
A.2	Radiation Treatment for Colorectal Cancer
A.3	Chemotherapeutic Treatment for Colorectal Cancer

## ATTACHMENT F-4

<b>CRITICAL DATA ITEMS FOR DEO</b>	
<b>PART A</b>	<b>DIAGNOSTIC EVALUATION AND STAGING</b>
A.1	Diagnostic Procedures Performed
A.5	Medical Complications of Diagnostic Evaluation and Staging
A.6	Result of Diagnostic Evaluation for Ovarian Cancer
<b>PART B</b>	<b>DIAGNOSIS INFORMATION FOR SPECIFIC CONDITIONS OTHER THAN OVARIAN CANCER</b>
B.7	Specific Ovarian Diagnosis
B.8	Other Cancer Diagnosis
<b>PART C</b>	<b>PRIMARY OVARIAN CANCER DIAGNOSIS INFORMATION</b>
C.9	Date of Primary Ovarian Cancer Diagnosis
	ICD-O-2 Cancer Classification
C.11a.	Topography
C.11b	Morphology
C.11c	Behavior
C.11d	Grade
C.13	Histopathologic Type for Primary Ovarian Cancer
C.14	Histopathologic Grade for Primary Ovarian Cancer
	TNM Staging for Primary Ovarian Cancer
C.15a	TNM Clinical Staging
C.15b	TNM Pathologic Staging

<b>CRITICAL DATA ITEMS FOR TIO</b>	
<b>PART A</b>	<b>INITIAL TREATMENT INFORMATION</b>
A.1	Surgical Treatment for Ovarian Cancer
A.2	Radiation Treatment for Ovarian Cancer
A.3	Chemotherapeutic Treatment for Ovarian Cancer

## ATTACHMENT F-5

CRITICAL DATA ITEMS FOR OCF	
<b>PART A</b>	<b>CONFIRMATION OF CANCER</b>
A.6	Result of Confirmation of Reported Non-PLCO Cancer
A.6a	Type of PLCO Cancer
A.7	Date of Cancer Diagnosis
	ICD-O-2 Cancer Classification of Primary Cancer
A.8a	Topography
A.8b	Morphology
A.8c	Behavior
A.8d	Grade
A.10	Basis of Diagnosis
A.12	Reported Metastatic Sites

**L-2**

Central Review of Cancer Diagnosis and Staging  
Data

# **CENTRAL REVIEW OF CANCER DIAGNOSIS AND STAGING DATA**

## **Introduction**

The primary objective for the proposed central review of cancer diagnosis and staging data is to ensure a high level of accuracy for TNM staging of PLCO cancers. Individuals from the Coordinating Center (CC) will make up the Cancer Data Review Committee (CDRC). The SCs will provide medical records and the CC will review the records and independently stage and code cancers as well as coordinate the activities of the SCs. The request for and review of the medical records will be done quarterly. Descriptions of the CDRC and the proposed procedures for the central review of cancer diagnosis and staging data are described in the following sections.

## **Central Review**

The CDRC will be composed of Certified Tumor Registrars (CTRs) and one physician from the CC. The CC CTRs and the CC physician are actively staging cancers for the PLCO Screening Trial.

The responsibility of each CDRC member is to review, code, and stage Prostate, Lung, Colorectal, and Ovarian cancer cases accurately. Coding will be done according to the ICD-O-2 guidelines and in accordance with all related PLCO specifications. The TNM staging will be done according to AJCC TNM Cancer Staging guidelines for clinical and pathologic staging. Cases that have been previously selected and reviewed will also be excluded to avoid a repeat review.

## **Qualifications of Committee Members**

The CTR representatives from the CC are actively involved in cancer staging of cases for the PLCO Screening Trial and are certified by an exam which is offered by the National Board for Certification of Registrars (NBCR), a component of the National Cancer Registrars Association (NCRA). Active certified status for CTRs should be annually maintained by meeting the continuing education requirements of the NCRA. The CC physician is board certified in Internal Medicine and has been staging PLCO cancers for over 2 years.

## **Selection of Cases for Review**

While Phase 1 Staging Pilot study showed strong concordance in staging when comparing the original data to the results of the PLCO Cancer Staging Committee, NCI decided to continue to monitor and review cancer staging data for the duration of the trial. To get an adequate sampling of the cancer staging work completed by SC CTRs, the selection of medical records for review will come from all Screening Centers and from all study years.

One additional task that will be performed as a component of the central review will be the verification of the cancer coding for each case. Cancer site and type verification is an integral component of cancer staging and uses the same health record reports that are used in cancer staging, resulting in minimal additional effort. The CDRC will review cases with a diagnosis of prostate, lung, and colorectal cancer for which a finalized Diagnostic Evaluation (DE) form is completed. Since only a sample of cases is being used, NCI will develop the sample selection criteria. The CC will then identify the cases for review and will notify the SCs. The number of cases to be reviewed each year will be approximately 225, with 55-60 cases to be reviewed each quarter. The number of cases per organ site per year will be:

- 100 Prostate Cancer Cases
- 50 Lung Cancer Cases
- 50 Colorectal Cancer Cases
- 20-25 Ovarian Cancer Cases

The quarterly review will include cases from the same PLC organ site and approximately 5-10 ovarian cases. In this plan, all lung cases will be reviewed in one quarter, all colon cases in another, and the prostate cases will be divided among two separate quarters. Since the number of ovarian cases is relatively small, all will eventually be reviewed, at a rate of 5 to 10 cases each quarter.

### **Collection of Medical Records**

Following receipt of the list of cancer cases selected for review, the SC will edit the case documentation and delete any personal identifying information. The SC will make a copy of the medical records and submit a labeled copy. The SC will also send a copy of screen view of the DEES Data View for each case. All case documentation will be batched and shipped to the CC.

### **Receipt and Preparation of Cancer Coding and Staging Materials**

Upon receipt of the case documentation from the SCs, the copy of DEES Data View from the SC completed DE form will be removed and retained in a separate file. The medical records will be forwarded to a CC CTR who will review each case to ensure that all required information is present and that all identifiers have been deleted. The CC will produce copies of each case for internal use as needed. A blank copy of Part C of the organ specific DE form will be included with each case for the reviewer to document the cancer stage and coding.

### **CDRC Review of Cases**

A CC CTR will review the cancer cases and independently complete Part C of the DE form for each case. This staff will code and stage each case as appropriate. If additional information is needed to complete the review of a case, a request for the information will be sent to the SC. The CC CTR will complete the quarterly review of cases within a six-week time period.

### **Evaluation of CDRC Results**

Another CC staff will review the results from the re-coding and re-staging of each case and compare to the data in the DEES Data View that the SC had sent. If there are no discrepancies, the review is complete. If there are any discrepancies, a different person at the CC, either the physician or a second CTR, will re-abstract the case. This will also be compared to the initial re-abstract to check for consistency. The CC staff who is assigned to review and adjudicate any differences for each case will review the results from the two re-abstracts and mediate any differences through a meeting. This meeting will serve the purpose of further review and open discussion of discordant responses and to develop a final result that will be used for comparison to the original SC data. Differences will be resolved each quarter.

### **Reporting Results of the CDRC Review to the SC**

The CC will compare the final staging and coding results of the CDRC review to the SC data for each case. Discordant results will be provided to the SC with recommended changes. If the SC agrees with the recommendations, the SC will edit and rescan the DE form. If the SC CTR disagrees with the CDRC recommendations, the CC will arrange a teleconference to dis-

discuss the results to reach an agreement for any differences. If the differences cannot be resolved, the CC will refer the issue to the appropriate sub-committee for further review and recommendations. The SC CTR will be expected to reconcile the data from this review and update the database.

### **Reporting and Evaluation**

The CC will produce regular reports of the progress of the cancer data review. The reports will include the number of cases per SC that are being reviewed, the status of the request for copies of the medical records, the number of cases that have been reviewed, and the number of cases that must be adjudicated.

## **APPENDIX M**

### **Appendix M: PLCO Policy**

**M-1**

**PLCO Review Policy for Etiologic Studies**  
(Under Review)

**M-2**

PLCO Publication Policy

## **PUBLICATION AND PRESENTATION POLICY**

The PLCO trial is a contract-based randomized screening trial directed by the National Cancer Institute. By law, by delegation from the Contracting Officer, the Project Officer is responsible for the scientific direction and daily management of the trial.

The Steering Committee and its subcommittees provide substantial scientific input. The Publications Subcommittee of the Steering Committee plays a key role in decisions regarding the release of information about the trial. The independent Monitoring and Advisory Panel (the PLCO data and safety and monitoring board) advises NCI on the timing and content of data publication. The NCI Project Officer is ultimately responsible for decisions regarding publication of data and other information regarding the trial.

The PLCO trial is dually focused. The primary clinical/public health goal of the trial is to determine the mortality impact of screening for PLCO cancers. Critical associated clinical/public health goals include assessment of quality of life and cost implications.

The accumulation of clinical data and collection of additional biologic materials facilitates, through the collaboration of the Division of Cancer Epidemiology and Genetics with the Division of Cancer Prevention, an integral and important basic and applied science focus on behavioral/environmental and molecular research regarding cancer etiology and early detection.

### **1. Publication Opportunities:**

PLCO investigators are encouraged to collaborate in all phases of analysis and publication deriving from the trial and to initiate publication ideas.

Several avenues for the proposal of publications are available. All subcommittees of the PLCO trial have as one of their goals development of analysis questions and publication ideas and the appointment of writing teams to develop analysis outlines and manuscripts. Individual investigators may also propose ideas, and, in order to assure wide collaboration and appropriate coordination, should make every effort to pass ideas through subcommittees. Publication proposals are expected also from PLCO approved ancillary studies.

The National Cancer Institute established for the PLCO trial an Analysis Plan which provides a time line of analysis and associated publications to be developed from PLCO data. This Plan is not exhaustive, but provides a framework for data analysis and publication in a timely fashion according to a projected calendar of anticipated availability of appropriate, quality checked and stable clinical and behavioral data. This plan is included in the MOOP and reflects both the clinical/public health and etiology/molecular markers foci of the trial. All proposals will be reviewed against these references and the availability of resources for prioritization of data analysis.

The two different foci of the PLCO trial provide distinctly different opportunities for publication. The Analysis Plan provides a fairly clear topical perspective regarding the clinical/public health focus. And the periodic reviews of accumulating clinical and behavioral data by investigators naturally facilitate the development of additional analysis questions. But, due to the more basic and highly dynamic nature of etiology/molecular markers research, specificity for this focus is not provided in the Analysis Plan. In fact, the continuing scientific development of this focus is the work of a team of intramural NCI scientists. The Etiology/Early Markers Research Policy provided in the MOOP clarifies how investigators can participate in and initiate research activity leading to scientific publication within this focus.

## **2. Responsibilities of the Publication Subcommittee:**

- a. To ensure that abstracts, presentations, and manuscripts (collectively, publications) are accurate and objective and do not compromise the scientific integrity of the trial.
- b. To maintain a complete and up-to-date list of PLCO publications (proposed, approved, and in print) available to all investigators.
- c. Further Responsibilities of the Chair of the Publications Subcommittee:
  1. To expedite timely presentations of pertinent data from the trial to the scientific and clinical communities.
  2. To assure all investigators opportunity to participate and be recognized in trial publications.

## **3. Formulation of a Publication Proposal:**

Proposed publications must be approved by the Project Officer and the Chair of the Publications Subcommittee. A rapid response will be provided to the proposing investigator. Approved proposals may include recommendations for refinements, enhancements, or deletions. In these instances, proposals should be resubmitted for final approval with suitable responses.

The final publication format will be dictated by the specific journal or other venue of publication. For internal discussion, the following format is recommended:

1. Title
2. Authorship/writing team
3. Introduction/background
4. Analysis plan and methods (including table shells and proposed graphs)
5. Anticipated results/conclusions
6. Anticipated time line
7. References
8. Initiating author's name and affiliation

## **4. Data Analysis:**

The PLCO Chief Statistician is responsible for coordinating/overseeing the analysis of data sets established and refreshed periodically from accumulated trial data through collaboration with the PLCO Coordinating Center (Westat), and the PLCO Computing Support Center (IMS). This assures that publications are based on standardized quality controlled and reliable data sets at all points in time.

Publication of screening center specific data will be subordinate to publication of trial-wide data. This will ensure that an accurate picture of overall trial results will precede any local subset into the public domain, thus avoiding possible misinterpretations. This does not preclude the publication of screening center specific data that clearly will not misrepresent or otherwise adversely affect the trial.

For etiology/early marker research, data derived from ad hoc laboratory analyses of biological samples are key. The analysis of biological specimens requires approval of the Biorepository Scientific Review Group (see Etiology/Molecular Markers Research Policy). Analysis of resulting data is the responsibility of the investigators conducting the research.

## **5. Authorship:**

Authorship should be as broad as practicable. This is especially important since the PLCO trial is a huge endeavor requiring major long term investments of a great many people. However, authorship requires demonstrated substantial contribution to the publication. Recognition of the broader PLCO trial team is expected on all publications by explicit acknowledgment that the authors are writing "for the PLCO Investigators."

Team members who fail to sustain an active intellectual investment in the project may be asked to leave the team. If preparation of the manuscript languishes, the writing team may be reorganized. Such decisions will fall primarily to the writing team and only secondarily to the Project Officer and the Chair of the Publications Subcommittee, as appropriate.

Lead authorship by other than PLCO investigators/staff will require explicit exception by the Project Officer and Chair of the Publications Subcommittee.

## **6. Tracking:**

The NCI PLCO Information Officer, for the Publications Subcommittee, will maintain an up-to-date list of publications and their status. It is the responsibility of the lead author as head of the writing team to keep the Publications Subcommittee informed on progress.

## **7. Approval for Publication:**

Final approval for submission of manuscripts, abstracts, and presentations must be obtained from the Project Officer, the Chair of the Publications Subcommittee, and the Chair of the Monitoring and Advisory Panel prior to submission. For this purpose, final documents must be submitted at least one month prior to the scheduled submission date to ensure that thorough review is possible. All submissions will be reviewed by Chair-assigned members of the Publications Subcommittee. The Publications Subcommittee will have 14 days to complete its review. The NCI Project Officer will have 30 days to obtain all necessary NCI reviews. All comments will be sent to the first author. The writing group is encouraged to incorporate reviewers' comments into the publication, but may offer counter arguments. In addition to comments, reviewers will classify publications as one of the following:

- a. Approved
  1. as written
  2. with suggested revisions
  3. with required revisions
- Or
- b. Not approved
  1. lacks scientific merit or content
  2. inadequate data analysis
  3. writing defects
  4. premature or misrepresents the trial

If not approved, correspondence with the first author will include adequate detail for revision and resubmission.

## **8. Archival Publications:**

The NCI PLCO Information Officer, for the Publications Subcommittee, will maintain an archive of all final publications. This will include abstracts, presentations, and manuscript

reprints. Beyond these scientific publications, archival holdings will include copies of news letters, news articles, and scientific publications referencing PLCO.

# Using the Browsable MOOP



---

**Quick  
Reference**

[Print selected pages from the MOOP](#)

[Copy/paste text from the MOOP](#)

[Find text in the MOOP](#)

[Navigating the MOOP](#)

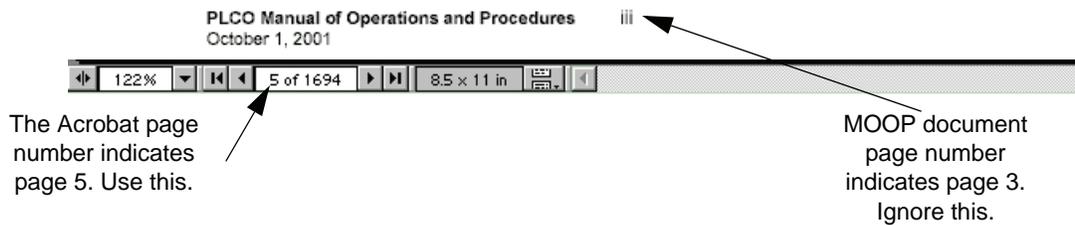
---

Go directly to the [PLCO MOOP 12](#)

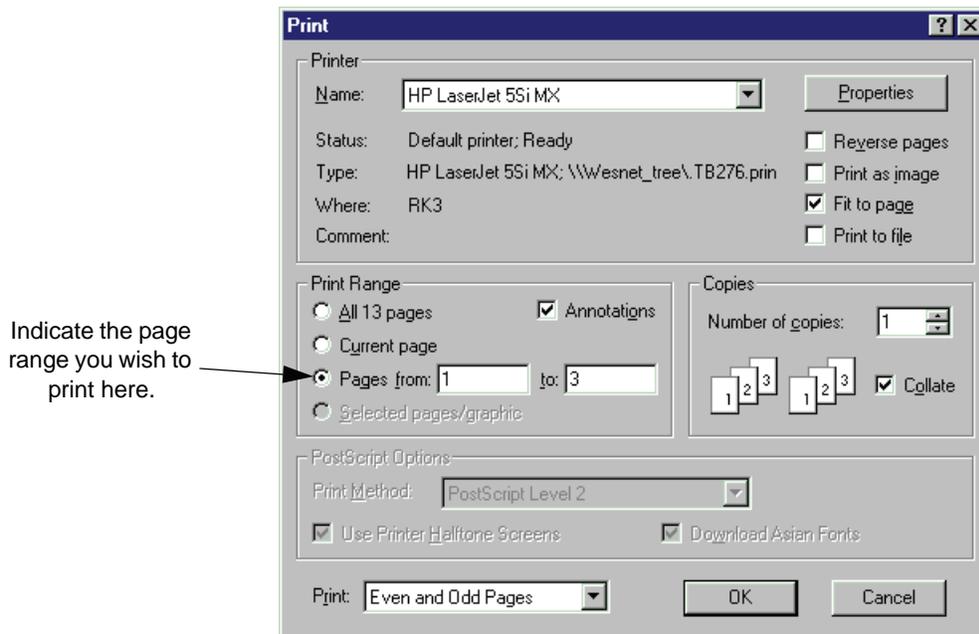
# Print selected pages from the MOOP

1. You must first determine the print range that you desire. To do this, rely upon the Acrobat page numbers located at the bottom of the Acrobat window. *Ignore the page numbers on the MOOP itself.*

<b>8.0</b>	<b>Ascertainment of Cancer Status</b> .....
8.1	Overview .....
8.2	Methods to Ascertain Cancer Status .....
8.2.1	Reports for Tracking Cancer Suspicions .....
8.2.2	Updating Cancer Status to "Suspected" in the SMS .....
8.3	Collection of Medical Records .....
8.3.1	Collection of Medical Records for Confirmation of PLCO Cancers .....
8.3.2	Collection of Medical Records for Confirmation of Non-PLCO Cancers .....
8.3.3	Tracking the Medical Records Collection Process (Epi-Info) .....
8.3.4	Acquisition of the Histopathology/Cytopathology Report .....
8.4	Abstraction of the Medical Record .....



1. Click the **Print** icon on the Acrobat toolbar.  
The **Print** window will appear.



2. Select the **Pages** button, and type the page range into the **from** and **to** boxes.
3. Click **OK**.

# Copy/paste text from the MOOP

You can easily copy text from the MOOP and paste into a word processing document.

1. Click the **Text Select Tool** on the Acrobat toolbar at the top of the window.



The Text Select Tool

2. Select the desired text with the mouse.
3. From the **Edit** menu, select **Copy**.
4. Open the target application (e.g., Microsoft Word).
5. From the **Edit** menu of the target application, select **Paste**.

## Find text in the MOOP

The MOOP is a very large document. One of the advantages of the browsable MOOP is that you can quickly find any desired text.

1. Click the **Find** icon on the Acrobat toolbar at the top of the window.



The Find icon

The **Find** window will appear.



2. Type the text you wish to find in the **Find What** box.
3. Click **Find**.
4. To find the same word or phrase again, press the **F3** key on the keyboard. Continue pressing the **F3** button to find additional instances of the same word or phrase.

NOTE: If you want to find the exact word (i.e., **Chapter**, but not **Chapters**), select the **Match Whole Word Only** box.

# Navigating the MOOP

In addition to finding specific text, the browsable MOOP allows you to go directly to a desired Chapter, Section, or Appendix with a single mouse click. There are several ways to do this.

## Using in the Navigation bar

You can always go directly to a specified destination by clicking an entry in the Acrobat Navigation bar on the left side of the screen. Use the Navigation bar as you would a table of contents that is always visible on the screen.

## Using the Table of Contents

The browsable MOOP contains a Table of Contents similar to the print version. However, the entries in the browsable MOOP's Table of Contents are active links. Click an entry to go directly to the named Section, Chapter, or Appendix.

## Using cross-references

The MOOP contains hundreds of cross-references to other Chapters, Sections, and Appendices. In the browsable version, these cross-references are active links identified by blue, underlined text. Clicking a cross-reference takes you to the named destination.

## Returning to the starting point using the Back button

The active links in the browsable MOOP found in the Navigation bar, Table of Contents, and cross-references behave just like hypertext links on a web page. You may find that you wish to return to a previous Section, Chapter, or Appendix in the MOOP after having clicked a link. To return to a previous location, just click the **Back** button on the Acrobat toolbar.



The Acrobat **Back** button

## Navigating through pages

You can also browse through the pages of the MOOP one at a time or go directly to the first or last page using the **Page** buttons on the Acrobat toolbar shown below.



First | Previous | Next | Last