

June 15, 2018

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swog.org

TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS

FROM: Patricia O'Kane (E-mail: pokane@swog.org)

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

(√) No review required

Protocol changes

(√) Data Submission / Forms changes / Vital Status Update Form

MEMORANDUM

Vital status is collected annually for 5 years on the **S1204** Annual Vital Status Update Form per protocol Sections 4.3h and 8.4e. As a reminder for submission of this form, form expectations have been posted and forms are due within 28 days after the 2, 3, 4 and 5 year time points (based on **S1204** patient registration date). Note that the Annual Vital Status Update Form will now require you to select the time point for which the vital status update is being submitted. The version of the form has changed from 1.2 to 1.3.

This memorandum serves to notify the NCI and the SWOG Statistics and Data Management Center.

cc: PROTOCOL AND INFORMATION OFFICE
Debbie Delaney-FHCRC
Karma Kreizenbeck-FHCRC

Distribution Date: October 15, 2017
Version Date: September 27, 2017

TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS

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FROM: Patricia O'Kane (E-mail: pokane@swog.org)

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REVISION #6

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

(√) Expedited review allowed

Protocol changes

(√) Editorial / Administrative changes

Per CTMB Guidelines, the protocol updates and/or informed consent changes must be approved by local IRBs within 90 days of distribution of this notice. The changes in this revision are effective upon approval by the local IRB; however, any changes to eligibility become effective 6 weeks after distribution of this notice. If local approval is not granted within 6 weeks, accrual must be suspended until approval is obtained.

REVISION #6

The secondary objectives of the above-noted study have been updated to reflect the current data analysis plans. (Note: This study remains closed.)

Specific changes are outlined below:

1. The version date has been updated.
2. **Section 1.2b:** The word "evaluate" was changed to "describe", the text "timing and" was deleted and the phrase "and alterations to therapy (if any)" was added after the phrase "type of treatments received".
3. **Section 1.2c:** The word "Evaluate" was changed to "Describe", the phrases "and rate" and "cancer treatment-related" were deleted, and the phrase "possibly attributable to the patient's viral status" was added after "adverse events".

4. **Section 6.3b (Secondary Objective 2):**

Changes in the first paragraph:

The text “with HIV” was changed to “who are identified as having HIV”, the text “evaluate timing and type” was changed to “describe the type” and the phrase “and alterations to therapy (if any)” was added after the phrase “type of treatments received”.

Changes in the second paragraph:

- In the first sentence, the phrase “prescribed within 6 months of registration” was added after “anti-viral therapies”.
- The third sentence was deleted.
- In the fourth sentence, the words “and dose” were deleted.
- The fifth sentence was deleted.

Changes in the third paragraph:

In the second sentence, the phrase “known infection” was changed to “viral infection,” and the phrase “the planned treatment will be compared with standard of care” was changed to “the recorded changes in planned treatment at 6 months following registration due to the patient’s viral status will be described”.

Changes in the fourth paragraph:

The first sentence was deleted. In the second sentence, the phrase “Among patients with newly diagnosed infections” was deleted and the phrase “by previously known versus newly diagnosed infections” was added at the end of the sentence.

5. **Section 6.3c (Secondary Objective 3):**

Changes in the first paragraph:

The word “estimate” was changed to “evaluate”, the phrase “cancer treatment-related” was deleted, the phrase “possibly attributable to the patient’s viral status” was added after the words “adverse events”, and the text “among persons with HIV” was changed to “in patients with HIV”.

Changes in the second paragraph:

In the first sentence, the phrases “cancer-treatment-related” and “using the specific question on the **S1204** Six-month Follow-up Form” were deleted.

Changes in the third paragraph:

In the first sentence, the phrase “cancer-treatment-related” was deleted.

Model Consent Form

The version date of the model informed consent has been updated to match the protocol version date; however, no changes were made in the consent.

An updated version of the protocol and consent can be accessed from the protocol abstract page on the SWOG website (www.swog.org) or CTSU website (www.ctsu.org).

This memorandum serves to notify the NCI and the SWOG Statistics and Data Management Center.

cc: PROTOCOL AND INFORMATION OFFICE
Debbie Delaney-FHCRC
Karma Kreizenbeck-FHCRC

CLOSED EFFECTIVE 02/15/2017

Distributed: February 1, 2017
E-mailed: January 23, 2017

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STATUS UPDATE

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required
- Expedited review allowed
- No review required

Status Change

- IRB Review only
- Activation
- Closure
- Reactivation

Protocol changes

- Eligibility changes
- Treatment / Dose Modification / Study Calendar changes
- Informed Consent changes
 - Patient notification not required
 - Patient notification required
- Scientific / Statistical Consideration changes
- Specimen Submission changes
- Data Submission / Forms changes
- Editorial / Administrative changes
- Other: Viral Status Information Sheet - update

PERMANENT CLOSURE

This is to inform participating sites that the above-referenced study will reach its accrual goal by the middle of February 2017. Therefore, please be advised that this study will **close to patient accrual, effective February 15, 2017 at 11:59 p.m. Pacific Standard Time.**

The **S1204** Monthly Summary of Newly Diagnosed Cancer Patient Visits form for February 2017 should reflect the status of all patients first seen in the clinic that month, through February 15, 2017. Similarly, the December 2016 and January 2017 Monthly Summary forms reporting on the patients first seen in clinic those months should reflect patient status through February 15, 2017. There is no need to track unregistered patients past February 15 for the purposes of completing the December, January or February Monthly Summary forms. The February 2017 Monthly Summary form will be the final Monthly Summary form to be submitted. Contact Katie Arnold with any questions about the Monthly Summary form: karnold@fredhutch.org or (206) 667-7685.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Debbie Delaney-FHCRC
Karma Kreizenbeck-FHCRC

CLOSED EFFECTIVE 02/15/17

August 15, 2016

TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS

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MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required
- Expedited review allowed
- No review required

Status Change

- IRB Review only
- Activation
- Closure
- Reactivation

Protocol changes

- Eligibility changes
- Treatment / Dose Modification / Study Calendar changes
- Informed Consent changes
 - Patient notification not required
 - Patient notification required
- Scientific / Statistical Consideration changes
- Specimen Submission changes
- Data Submission / **Forms changes**
- Editorial / Administrative changes
- Other: Viral Status Information Sheet - update

MEMORANDUM

The Viral Status Information Sheet and **S1204** Viral Status Form have been updated.

The Viral Status Information Sheet (Version dated 8/15/2016) has been updated to include a description of “best practice” for screening for HIV, HBV and HCV, as well as links to CDC resources for testing guidelines and recommendations.

The **S1204** Viral Status Form (v1.4) has been updated to include the option of “Other or Unknown type of test” for the HCV screening tests. The lab results for HCV testing often do not specify which type of screening test was done. Sites should attempt to follow-up with the lab to request the methodology for the immunoassay performed. However, if the site is unable to confirm methodology with the lab, then the option of “Other or Unknown type of test” may be used. This option was added to facilitate data submission, based upon further discussion among the Study Chairs and feedback from the sites.

The updated **S1204** Viral Status Form (which is part of the forms set) and the Viral Status Information Sheet are accessible on the protocol abstract page on the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Debbie Delaney-FHCRC
Karma Kreizenbeck-FHCRC

CLOSED EFFECTIVE 02/15/11

Distribution Date: June 1, 2016
DCP Submission Date: May 18, 2016

TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS

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REVISION #5

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required (for institutions that have not previously received full board review).
- Expedited review allowed
- No review required

Status Change

- IRB Review only
- Activation
- Closure
- Reactivation

Protocol changes

- Eligibility changes
- Treatment / Dose Modification / Study Calendar changes
- Informed Consent changes
 - Patient notification not required
 - Patient notification required
- Scientific / Statistical Consideration changes
- Specimen Submission changes
- Data Submission / Forms changes
- Editorial / Administrative changes
- Other: Translation Certification for **S1204** materials, Form updated

REVISION #5

The following changes have been made in the protocol referenced above:

1. Title page: The version date of the protocol has been updated.

2. Section 3.1a, Page 12: The following note was added to define “first clinic visit”: “NOTE: The “first clinic visit” is the patient’s first visit at the clinic after a new cancer diagnosis, e.g., the first visit on or after the cancer diagnosis date.”
3. Section 4.3e, Page 14: The following sentence was added: “NOTE: Source documentation must support the data submitted on all forms, specifically, upload the source documentation to support the entries on the **S1204** Viral Status Form.”
4. Section 4.3h, Page 14: the following was added: “NOTE: The **S1204** Annual Vital Status Form can be submitted upon death of a patient rather than waiting a full year before submitting the form.”
5. Section 8.4b, Page 26: The following sentence was added after **1204** Viral Status Form: “NOTE: Upload source documentation to support the data submitted on this form.”
6. Section 8.4e, Page 26: The following sentence was added: “NOTE: Submit this form at any time upon the death of a patient rather than waiting a full year before submitting the form.”
7. Section 9.1g.1, Page 28: The Data Operations Center phone number has been updated. The correct number is 206/652-2267.

Forms Update

8. The **S1204** Viral Status Form has been updated. (Typographical error corrected; HIV DNA is now HIV RNA.)
9. The **S1204** Viral Risk Survey-Spanish Version was moved to be part of the **S1204** forms set.

The version date on the Model Consent Form has been updated to match the protocol version date, however no changes were made at this time.

Certifications of Spanish Translations and back translations for **S1204** materials have been posted to the protocol abstract page on the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Debbie Delaney-FHCRC
Karma Kreizenbeck-FHCRC

December 15, 2015

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MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required (for institutions that have not previously received full board review). Reason:
 - Initial activation (should your institution choose to participate)
 - Increased risk to patient
 - Complete study redesign
 - Addition of tissue banking requirements
 - Study closure due to new risk information
- Expedited review allowed
- No review required

MEMORANDUM

The **S1204** Monthly Summary Data Collection Training document and **S1204** Viral Risk Survey – Spanish form have been updated on the protocol abstract page on the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Joseph Unger, Ph.D.
Kathryn B. Arnold, M.S.
Monica Yee, B.A.
Debbie Delaney-FHCRC
Karma Kreizenbeck-FHCRC

November 1, 2015

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MEMORANDUM

The purpose of this memorandum is to inform **S1204** approved sites of required training for research staff responsible for data submission on this study. Approved clinics are noted in the table below. **Effective October 23, 2015** no new site applications will be accepted. (Sites who have already been approved may request to add additional clinics.) All participating clinic staff must receive training on the Monthly Summary data collection and reporting. In order to complete this training, all site staff must review the "**S1204** Monthly Summary Data Collection Training" document found on the **S1204** protocol abstract page on the SWOG website (www.swog.org). Your site must submit confirmation that the training has been completed to Lisa Headlee (lheadlee@swog.org) and include names of staff and the NCI codes for clinics covered by these staff members in the e-mail.

It is strongly recommended that site staff review these materials prior to beginning recruitment, if possible.

Any site staff who have questions or wish to receive additional training on the Monthly Summary data collection and submission may contact Katie Arnold (karnold@fredhutch.org). Please direct all other study-related questions to cancercontrolquestion@crab.org.

Institution Name	Clinic SWOG Site #	Clinic NCI code	Clinic Name	Received training?*
San Antonio, U of TX	2400	TX059	Univ of Texas Health Science Center at San	YES
	11159	TX098	Cancer Therapy & Research Center	YES
Columbus NCORP	10987	OH122	Licking Memorial Hospital	
	10988	OH182	Adena Regional Medical Center	
	12844	OH246	Grant Medical Center	
	15131	OH428	Knox Community Hospital	
	16282	OH245	Southern Ohio Medical Center	
	19041	OH268	Columbus Oncology & Hematology	
	23905	OH110	OhioHealth Marion General Hospital	
Dayton NCORP	11075	OH085	VA Medical Center - Dayton	
Loyola University	11145	IL016	Edward J. Hines, Jr. VA Hospital	
	18055	IL060	Weiss Memorial Hospital	
	18057	IL205	West Suburban Medical Center/River Forest	
Boston Medical Ctr	10635	MA043	Boston Medical Center	YES
Bay Area NCORP	13765	CA463	Contra Costa Regional Medical Center	YES
Sutter Cancer RC	11269	CA164	Alta Bates Medical Center	YES
Hawaii MU-NCORP	11033	HI010	Tripler Army Medical Center	YES
Gulf South MU-	10992	LA041	LSU Health Baton Rouge-North Clinic	YES
	10993	LA035	Mary Bird Perkins Cancer Center	
	10997	LA029	Interim LSU Public Hospital	
	13521	LA017	Louisiana State University Health Sciences	
	13523	LA068	University Health Conway	
	22885	LA101	Louisiana Hematology Oncology Associates	YES
	22887	LA074	Medical Oncology LLC	YES
	22888	LA086	North Shore Hematology Oncology	YES
	22889	LA057	Oncology Center of The South Incorporated	YES
22893	LA123	Women's Cancer Care-Covington	YES	
22894	LA117	Mary Bird Cancer Center/Saint Tammany	YES	
Greenville NCORP	16175	SC053	Greenville Health System Cancer Inst-	YES
	16179	SC054	Greenville Health System Cancer Inst-	YES
Montana NCORP	11039	MT002	Billings Clinic Cancer Center	
	11046	MT006	St. James Community Hosp & Cancer	
VAMC Kansas City	11138	MO029	VA Medical Center - Kansas City	
	12169	KS007	VAMC Eastern Kansas Healthcare Sys-	

Institution Name	Clinic SWOG Site #	Clinic NCI code	Clinic Name	Received training?*
Desert Hospital	11205	CA075	Desert Hospital	
MD Anderson CC	13508	TX325	Lyndon B. Johnson General Hospital	YES
Harrington CC	11446	TX068	Don & Sybil Harrington Cancer Center	YES
Kaiser Perm NCORP	13658	CA162	Kaiser Permanente, Oakland	YES
	13661	CA223	Kaiser Permanente, Roseville	YES
	13664	CA197	Kaiser Permanente, San Francisco	YES
	14128	CA753	Kaiser Permanente Medical Center -	YES
	15655	CA039	Kaiser Permanente, Harbor City	
	19238	CO125	Kaiser Permanente - Lone Tree	
	22660	OR035	Kaiser Permanente	
Columbia MU-NCORP	18743	NY024	Columbia University Minority Underserved	YES

* Clinics marked as "YES" either participated in the **S1204** run-in or they have already received training on the Monthly Summary data collection and reporting via the SWOG Statistical Center.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
 Scott D. Ramsey, M.D., Ph.D.
 Rohit Loomba, M.D., MHSc.
 Rashmi Chugh, M.D.
 Dawn L. Hershman, M.D., M.S.
 Jessica P. Hwang, M.D.
 Joseph Unger, Ph.D.
 Kathryn B. Arnold, M.S.
 Monica Yee, B.A.
 Debbie Delaney-FHCRC
 Karma Kreizenbeck-FHCRC

CLOSED

October 1, 2015

TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS

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RUN-IN PHASE: LIMITED TO THE FOLLOWING INSTITUTIONS: BOSTON UNIV, COLUMBIA UNIV MU-NCORP, GREENVILLE NCORP, TRIPLER ARMY MEDICAL CENTER, LBJ HOSPITAL, ST. LUKE'S MOUNTAIN STATES TUMOR INSTITUTE AND CONTRA COSTA REGIONAL MEDICAL CENTER

FROM: Patricia O'Kane, Protocol Coordinator (E-mail: pokane@swog.org)

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
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IRB Review Requirements

- () Full board review required (for institutions that have not previously received full board review). Reason:
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 - () Addition of tissue banking requirements
 - () Study closure due to new risk information
- () Expedited review allowed (for sites that have previously received full board review/approval)
- (√) No review required

MEMORANDUM – Updated S1204 Worksheet for Monthly Summary

The **S1204** Worksheet for Monthly Summary (version 5.0) has been updated and can be accessed from the **S1204** protocol abstract page of the SWOG website (<http://swog.org>).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE Joseph Unger, Ph.D.
Scott D. Ramsey, M.D., Ph.D. Kathryn B. Arnold, M.S.
Rohit Loomba, M.D., MHSc. Monica Yee, B.A.
Rashmi Chugh, M.D. Debbie Delaney-FHCRC
Dawn L. Hershman, M.D., M.S. Karma Kreizenbeck-FHCRC
Jessica P. Hwang, M.D.

August 1, 2015

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TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS

RUN-IN PHASE: LIMITED TO THE FOLLOWING INSTITUTIONS: BOSTON UNIV, COLUMBIA UNIV MU-NCORP, GREENVILLE NCORP, TRIPLER ARMY MEDICAL CENTER, LBJ HOSPITAL, ST. LUKE'S MOUNTAIN STATES TUMOR INSTITUTE AND CONTRA COSTA REGIONAL MEDICAL CENTER

FROM: Patricia O'Kane, Protocol Coordinator (E-mail: pokane@swog.org)

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required (for institutions that have not previously received full board review). Reason:
 - Initial activation (should your institution choose to participate)
 - Increased risk to patient
 - Complete study redesign
 - Addition of tissue banking requirements
 - Study closure due to new risk information
- Expedited review allowed (for sites that have previously received full board review/approval)
- No review required

MEMORANDUM

The following forms for the above-noted protocol have been modified as follows:

S1204 Registration Worksheet:

- Removed the question regarding projected start of treatment

S1204 Onstudy Form:

- Replaced "Date of first clinic visit" with "Date patient first presented for evaluation or treatment of a new cancer malignancy at clinic"

S1204 Viral Status Form

- Reduced the number of screening test options for each virus and clarified remaining screening test descriptions
- Added “millions” place value in the viral load fields for all viruses
- Clarified that “Negative” is “non-reactive” and “Positive” is “reactive” as appropriate for screening test results

S1204 Baseline Laboratory Values Form

- Added millions place for platelet count

S1204 Annual Vital Status Update

- Added "Date of medical record review"

Notice of Death form has been removed from the **S1204** forms.

The forms can be accessed from the Master Forms Set link on the **S1204** protocol abstract page of the SWOG website (<http://swog.org>).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Scott D. Ramsey, M.D., Ph.D.
Rohit Loomba, M.D., MHSc.
Rashmi Chugh, M.D.
Dawn L. Hershman, M.D., M.S.
Jessica P. Hwang, M.D.
Joseph Unger, Ph.D.
Kathryn B. Arnold, M.S.
Monica Yee, B.A.
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CLOSED EFFECTIVE 02/15/17

June 1, 2015

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MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fredhutch.org

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MEMORANDUM

A slide show that can be used for training and informing study staff about **S1204**, an updated **S1204** Site Application Form, and a revised version of the **S1204** Staff FAQ have been posted on the **S1204** protocol abstract page of the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE Joseph Unger, Ph.D.
Scott D. Ramsey, M.D., Ph.D. Kathryn B. Arnold, M.S.
Rohit Loomba, M.D., MHSc. Monica Yee, B.A.
Rashmi Chugh, M.D. Debbie Delaney-FHCRC
Dawn L. Hershman, M.D., M.S. Karma Kreizenbeck-FHCRC
Jessica P. Hwang, M.D.

May 1, 2015

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FROM: Patricia O’Kane, Protocol Coordinator (E-mail: pokane@swog.org)

RE: **S1204**, “A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients”. Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

STATUS NOTICE

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fredhutch.org

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- No review required

RE-ACTIVATION

The above referenced study is now open for accrual **May 1, 2015, 2:00 p.m. ET**. The main study is open to all SWOG members, NCORPs, and affiliates.

In order to participate in this study, sites must agree to the site requirements outlined in Sections 4.1 and 4.2 of the protocol. All sites, even sites that participated in the run-in phase, are required to submit a **S1204** Site Application Form and be approved by the Study Chair’s office, prior to registration of any patients. Per protocol Section 4.2, the application form can be found on the protocol abstract page of the SWOG website (www.swog.org).

Forms

The following forms have been updated according to changes outlined in Revision #4 (distributed 5/1/15):

S1204 Registration Worksheet v1.1

S1204 Onstudy Form v1.2

S1204 Annual Vital Status Update Form v.1.1

S1204 Six Month Follow Up Form v1.2

S1204 Monthly Summary v.1.2

Ancillary Documents

The following ancillary document has been updated and can be found on the protocol abstract page of the SWOG website:

S1204 Staff FAQ

Spanish translation

Spanish versions of the informed consent and **S1204** Viral Risk Survey are available for this study. If your institution would like to use the Spanish versions of the consent and survey, you must obtain local Institutional Review Board (IRB) approval prior to use.

Cancer Care Delivery Research (CCDR) Protocols and Funding Status

Listed below is a list of frequently asked questions regarding CCDR status and funding for **S1204**.

WHO IS ELIGIBLE TO PARTICIPATE?

All SWOG Member sites, NCORPs, and affiliates, and former S1204 Run-In sites may participate. It is not limited to sites designated as CCDR sites.

DOES S1204 QUALIFY AS A CCDR STUDY?

No, this study is not an official CCDR study. This study is a legacy study sponsored by CTEP. This study has been developed by the SWOG CCDR Committee and is being run through this committee. **S1204** may be listed in a site's NCORP progress report and will count towards general research participation.

CAN NCORP CCDR SITES USE THEIR CCDR FUNDS TO SUPPORT THIS STUDY?

Sites cannot use CCDR funds for it because this is not an official CCDR study.

HOW WILL SITES BE REIMBURSED?

Sites will be reimbursed as detailed on the S1204 Funding Memo, which is available on the protocol abstract page of the SWOG website (www.swog.org).

The revised protocol document, forms, and ancillary documents can be found on the protocol abstract page of the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
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Dawn L. Hershman, M.D., M.S.
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Distribution Date: May 1, 2015
CTEP Submission Date: March 26, 2015

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FROM: Patricia O'Kane, Protocol Coordinator (E-mail: pokane@swog.org)

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

REVISION #4

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- (√) Full board review required (for institutions that have not previously received full board review). Reason:
 - (√) Initial activation (should your institution choose to participate)
 - () Increased risk to patient
 - () Complete study redesign
 - () Addition of tissue banking requirements
 - () Study closure due to new risk information
- (√) Expedited review allowed (for sites that have previously received full board review/approval)
- () No review required

REVISION #4

The above-noted protocol has been modified based on feedback from the run-in phase of the study. Specific changes are as follows:

1. **Title Page, Page 1:** The version date of the protocol has been updated. E-mail addresses have been updated for study chair Scott Ramsey, M.D. and the biostatisticians.

2. **Participants, Page 2:** The participants list was revised to indicate that the main study will be open to all SWOG Members, NCORPs and affiliates. All participating sites must agree to the site requirements and be approved for participation as outlined in Section 4.1 and 4.2.
3. **Table of Contents (TOC), Page 3:** Page numbers on the TOC were updated as a result of the changes made in the protocol.
4. **Cancer Trials Support Unit (CTSU) Address and Contact Information, Page 4:** The text "For treatment or toxicity related questions" was changed to "For study procedure related questions" and "study chair" was changed to "SWOG Data Operations Center".
5. **Schema, Page 5:** Reference to the "Run-in phase" was removed from the schema. The main study participants list was updated on the first line of the schema. Viral status was added under items to be collected for both negative and positive results. An omega (Ω) footnote was added that states: "All participating sites must agree to the site requirements and be approved for participation as outlined in Sections 4.1 and 4.2." The " \approx " footnote has been updated to be consistent with Section 4.1a. This footnote previously read, "In order to participate in this study, sites must agree to have viral testing as the standard of care for all new patients being seen at their center". The footnote now reads, "In order to participate in this study, all physicians at a given site, must agree to offer HIV, Hepatitis B and Hepatitis C testing to all new cancer patients being seen at their site." The " \surd " footnote was revised to be consistent with the language in Section 3.2b of the protocol.
6. **Schema, Page 6:** A schema outlining registration timelines has been added.
7. **Section 2.0 (Screening Guidelines), Page 8:** The fifth sentence of this paragraph was updated to reflect the 2014 update from the US Preventive Services Task Force regarding HBV screening.
8. **Section 2.0, Page 11:** The table for anticipated ethnicity and gender accrual has been updated to the new CTEP format.
9. **Section 3.0, Page 12:** The text "If Day 120 falls" was changed to "If Day, 90, 120 or 365 falls" in the second paragraph.
10. **Section 3.1a, Page 12:** The text "(obtained from the patient's medical record)" has been added after "Confirmed diagnosis" in the second sentence of this section. The following sentence has been added to this section: "Patients must be registered within 90 days after their first clinic visit."
11. **Section 3.2b (first paragraph), Page 12:** The sentence "Patients must have had their blood drawn for testing for HIV, HBC, and HCV prior to registration" was changed to "Patients must have had their blood drawn for viral status testing for HIV, HBV and HCV prior to registration or provide acceptable viral status documentation prior to registration."
12. **Section 3.2.b (second and third paragraphs), Page 12:** For patients who have had viral testing previously and do not wish to be retested, the window of time allowed from time of testing to registration has been expanded from 60 days to 365 days. The text "Patients who have had HIV, HBV and/or HCV testing within 60 days prior to registration..." has been changed to "Patients who have had HIV, HBV and/or HCV testing within 365 days prior to registration...". Additionally, language was added to describe/define "acceptable" viral status documentation.

13. **Section 4.1, Page 13:** The text “In order to participate in this study, sites must agree to:” has been changed to “In order to participate in this study:”
14. **Section 4.1a, Page 13:** The sentence “Include HIV, Hepatitis B and Hepatitis C testing as the standard of care for all new cancer patients being seen at their center who are eligible for S1204” has been changed to “All physicians at a given site must agree to offer HIV, Hepatitis B and Hepatitis C testing to all new cancer patients being seen at their site.”
15. **Section 4.1b, Page 13:** The following section was added: “Sites must agree to ask all newly diagnosed eligible cancer patients to participate.” The subsequent section was renumbered.
16. **Section 4.1c, Page 13:** The text “Sites must agree to” was added to the beginning of the sentence. The fourth sentence was updated to list data elements that will be collected. The sentence that previously read: “Additionally, a summary of the reasons for non-participation in S1204 will be submitted (as reported on the S1204 consent)” was deleted as this data will not be collected.
17. **Section 4.2, Page 13:** A new section entitled “Site Application and Approval for Study Participation” was added. Sites must complete and submit the survey and receive approval prior to registering patients. Subsequent sections were renumbered accordingly.
18. **Section 4.3a, Page 13:** The following was added: “Patients may be approached and registered any time within 90 days after their first clinic visit. During this time, patients must have completed consent and provided blood for viral testing per Sections 3.2b and 3.3a”. Subsequent sections were renumbered accordingly.
19. **Section 4.3b (previously Section 4.2a), Page 13:** The following sentences were deleted as “visit number” will no longer be collected: “The clinic visit (i.e., first, second, etc.) at which patient consented to participation in S1204 will be collected at the Registration Step. (Note: Multiple appointments within the clinic on the same day count as one visit).” The text “(per Section 7.0)” was added after the word “study” in the remaining sentence.
20. **Section 4.3c, Page 13:** The following sentence was added: “All patients who choose to complete the S1204 Viral Risk Survey should complete it after consent, between the first clinic visit and registration.” Subsequent points were renumbered.
21. **Section 4.3d (previously Section 4.2b), Page 13:** The text “and submit” was added after “collect” and “(see Section 9.1)” was added to the end of the sentence.
22. **Section 4.3g (previously Section 4.2e), Page 14:** The text “based on the patient’s medical record” was changed to “based on a review of the patient’s medical record”. The following sentence was added: “This data collection is based on the most recently obtainable information from the patient’s medical record and does not require a patient visit.”
23. **Section 5.0, Page 15:** In the last sentence of the first paragraph, the text “will be opened group wide within SWOG and to CTSU CCOPs” was changed to “will be opened within SWOG (run-in sites and SWOG NCORPs) provided each site can satisfy the site requirements (see Section 4.0).”

24. **Section 6.1, Page 16:** In the first paragraph under Table 2, the text in the second sentence was changed from “However, the cancer risk...” to “However, if the cancer risk...”.
25. **Section 6.2a, Page 17:** The text regarding tests not to be used to establish HBV status was removed.
26. **Section 6.2a, Page 18:** The sentence “PCR for HIV RNA or DNA could be done after positive HIV status is confirmed or if acute retroviral infection is suspected” was removed.
27. **Section 6.2, Page 18:** A sentence has been added to the statistical section (below Table 4) regarding weighted estimates of virus-specific prevalence rates.
28. **Section 7.1, Page 22:** Registration timing has been revised. The sentence that read “Patients must be registered within 14 days after obtaining patient consent and patient completion of **S1204** Viral Risk Survey” was changed to “Patients must be registered within 90 days after first clinic visit.”
29. **Section 7.2, Page 22:** The following text was added to the end of the first sentence: “and must have approval from the SWOG Operations Office to participate (see Section 4.2).”
30. **Section 8.4a, Page 26:** Section 8.4c, regarding specimen banking, was removed and instructions updated in Section 8.4a. Subsequent points were renumbered.
31. **Section 8.5a, Page 26:** The heading “MONTHLY THROUGH 1 MONTH AFTER STUDY CLOSURE” was changed to “MONTHLY THROUGH 1 MONTH AFTER STUDY IS CLOSED TO ACCRUAL.”
32. **Section 9.1g, Page 28:** Contact information has been updated for the SWOG Repository.
33. **Section 11.0, Page 30:** Bibliography reference #12 was updated.
34. **Appendix 12.0 (deleted), Page 32:** The schema in the appendix was deleted as it was duplicative.

Model Consent Form:

Institutions **must** update their local consent forms to include the changes to the Model Consent Form within 90 days of distribution of this notice.

SWOG considers that the Model Consent Form changes **do not** represent an alteration in risk/benefit ratio. Therefore, local accrual does **not** need to be suspended pending implementation of these changes.

Patients need not be informed of the following changes unless required by the local IRB.

35. **Model Consent:** The version date of the consent was updated to match the version date of the protocol.
36. **Model Consent, Page 4:** Under “What is involved?”: The bulleted item under the second paragraph that says “Information about your survival status, to be checked every year for 5 years” was moved to be the fourth bulleted item under the first paragraph.

37. **Model Consent, Page 11:** The question regarding non-participation was removed from the consent form (as this data will not be collected in the main study). This has allowed the subsequent information (the previous Page 12) to be moved to this page.

A replacement protocol is enclosed for your use.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Scott D. Ramsey, M.D., Ph.D.
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CLOSED EFFECTIVE 02/15/17

Distribution Date: January 1, 2015
CTEP Submission Date: December 12, 2014

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TO: ALL SWOG MEMBER, NCORP, AND AFFILIATE MEDICAL ONCOLOGISTS; Non-SWOG (NCORPs ONLY)

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STATUS NOTICE

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

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TEMPORARY CLOSURE AND REVISION #3

The run-in phase of the above-noted study has been completed, and the study is temporarily closed to new patient registration **effective December 15, 2014, 2:00 p.m. E.T.** The study will remain closed temporarily to assess feasibility and to evaluate potential changes for the protocol prior to opening the study group-wide.

1. **Title page, pages 1-3:** The version date of the protocol was updated on the title page and participants list updated to NCTN format. This change required moving the participants list to page 2. The Table of Contents has been updated on page 3.

2. **Consent Form:** The version date on the consent was updated to match the protocol, however no changes were made in the consent.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
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CLOSED EFFECTIVE 02/15/17

March 15, 2014

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TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS, CTSU (CCOPS ONLY)

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FROM: Patricia O'Kane, Protocol Coordinator

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MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
 Phone number: 206/667-7846
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MEMORANDUM

Due to the protocol revisions made during the run in phase and delays in IRB approvals, the **S1204** run in phase has run longer than originally anticipated. To complete the run in phase in a timely manner, the length of active recruitment has been shortened.

For sites that begin accrual on or after 3/15/2014, active **S1204** run in recruitment will last 2 months (rather than the previously specified 3 months) from the time of the site's first registration to **S1204**. An additional 6 week registration window at the end of active recruitment will provide sites an opportunity to approach patients *previously screened but not approached during their first visit*. This additional 6 week period is intended to offer sites more time to follow up and potentially register patients previously identified. This 6 week window is not to be used to identify new patients.

Sites must initiate run-in accrual by March 31, 2014. If accrual is not started by this date, sites must wait until the general study opens in order to register patients.

A protocol revision of Section 5.1 will be distributed at a later date.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
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CLOSED EFFECTIVE 02/15/17

February 1, 2014

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TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS, CTSU (CCOPS ONLY)

RUN-IN PHASE: LIMITED TO THE FOLLOWING INSTITUTIONS: BOSTON, COLUMBIA MBCCOP, GREENVILLE CCOP, HAWAII MBCCOP (TRIPLER ARMY MEDICAL CENTER ONLY), MD ANDERSON (LBJ HOSPITAL ONLY), ST. LUKE'S MOUNTAIN STATES TUMOR INSTITUTE AND BAY AREA CCOP (CONTRA COSTA REGIONAL MEDICAL CENTER ONLY)

FROM: Patricia O'Kane, Protocol Coordinator

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required (for institutions that have not previously received full board review). Reason:
 - Initial activation (should your institution choose to participate)
 - Increased risk to patient
 - Complete study redesign
 - Addition of tissue banking requirements
 - Study closure due to new risk information
- Expedited review allowed
- No review required

MEMORANDUM

The purpose of this memorandum is to inform sites that the Worksheet for **S1204** Monthly Summary of Newly Diagnosed Cancer Patient Visits has been updated. The Worksheet has been revised to include sort capabilities for each column and additional columns for identifying participants and site staff. The worksheet changed from Version 1 to Version 2 and is available on the **S1204** abstract page of the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Scott D. Ramsey, M.D., Ph.D.
Rohit Loomba, M.D., MHSc.
Rashmi Chugh, M.D.
Dawn L. Hershman, M.D., M.S.
Jessica P. Hwang, M.D.
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Kathryn B. Arnold, M.S.
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Karma Kreizenbeck-FHCRC

CLOSED EFFECTIVE 02/15/17

January 15, 2014

TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS, CTSU (CCOPS ONLY)

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FROM: Patricia O'Kane, Protocol Coordinator

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

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 - () Complete study redesign
 - () Addition of tissue banking requirements
 - () Study closure due to new risk information
- () Expedited review allowed
- () No review required

MEMORANDUM

The purpose of this memorandum is to inform sites that a Viral Status Information Sheet has been posted on the protocol abstract page. This sheet summarizes viral status for HBV, HCV and HIV based on standard test results and may be used as a reference when filling out the **S1204** Viral Status Form. The information sheet may be found on the protocol abstract page of the SWOG website (www.swog.org).

Additionally, please note the following form changes that took place with Revision #2:

The form number of the Registration Form was changed from #5878 to #20077.

The version of the **S1204** Viral Status Form (#4283) was changed to Version 1.1.

The version of the **S1204** Six Month Follow-up Form (#51531) was changed to Version 1.1.

The version of the **S1204** Onstudy Form (#7812) was changed to Version 1.1.

The updated Forms can be found in the Master Forms set on the protocol abstract page of the SWOG website.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
Scott D. Ramsey, M.D., Ph.D.
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CLOSED EFFECTIVE 02/15/17

Distribution Date: January 15, 2014
CTEP Submission Date: December 16, 2013

TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS, CTSU (CCOPS ONLY)

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FROM: Patricia O'Kane, Protocol Coordinator

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman and J.P. Hwang.

REVISION #2

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- () Full board review required (for institutions that have not previously received full board review). Reason:
 - () Initial activation (should your institution choose to participate)
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 - () Complete study redesign
 - () Addition of tissue banking requirements
 - () Study closure due to new risk information
- (√) Expedited review allowed
- () No review required

REVISION #2

In an effort to help sites implement this study, a few changes have been made in study flow. Sites now have the flexibility to present the study and obtain consent from patients at any time as long as the confirmation of diagnosis remains within the window of 120 days prior to registration. The **S1204** Viral Risk Survey no longer has to be included in the site's intake packets and the survey will be administered only to those patients who consent to participate in the study. Sites no longer have to do the blood draw for banked specimens at the same time as the blood draw for viral testing. The blood draw for the banked specimen may be done at any time convenient for the patient as long as it is obtained with permission. Specific changes are as follows:

1. **Title page:** Wichita CCOP has withdrawn as a run-in site and therefore was removed from the Title page. LBJ Hospital (component of MD Anderson) has been added as a run-in site. The version date of the protocol has been updated to 12/16/13.
2. **Schema, page 4:** The schema has been revised to reflect that the **S1204** Viral Risk Survey will not be included in the clinic's intake packet and is administered only to those participants who have consented to participation in the study. The text "Patient registered" was moved to occur after the consent process. The entry "Patients consenting to study will be asked to provide blood specimen for banking (Optional for patient)" was revised as "Patients consenting to study will be asked to fill out the **S1204** Viral Risk Survey and provide blood specimen for banking (Blood specimen is optional for site and patient)". The text "Obtain Viral Test Results" was changed to "Obtain viral test results *and documentation of viral status*" as documentation will now be required of all registered patients and submitted via a file upload in RAVE. A new screen entitled **S1204** "Source Documentation: Baseline" will appear after the patient is registered in OPEN. The reference to Section 4.1c in the asterisk footnote was changed to Section 4.1b.
3. **Section 1.2a, page 5:** A formatting error (font) was corrected in the first subpoint.
4. **Section 3.0, page 10:** The eligibility criteria were categorized under the following headings: Disease Related Criteria, Clinical/Laboratory Criteria and Regulatory Criteria.
5. **Section 3.1a, page 10:** The second sentence was revised for clarification. The text "within 120 days of registration" was changed to "within 120 days *prior* to registration."
6. **Section 3.5, page 10:** The section previously numbered Section 3.5 has been deleted. Collection of blood specimens for biobanking will be optional for sites, therefore, the requirement that patients must be offered the opportunity to provide blood has been removed. Subsequent sections have been renumbered.
7. **Section 4.1b, page 11:** This section was deleted as the **S1204** Viral Risk Survey will not be included in the site's intake forms and will be administered after the patient consents to participate in the study. The subsequent section (4.1c) was renumbered as 4.1b.
8. **Section 4.2a, page 11:** The following was added: "The clinic visit (i.e., first, second, etc.) at which patient consented to participation in **S1204** will be collected at the Registration Step. (Note: Multiple appointments within the clinic on the same day count as one visit)."
9. **Section 4.2b, page 11:** The text "for site and patient" has been added to the end after "optional".
10. **Section 4.2c, page 11:** This section was revised to include submission of documentation of viral status results via file upload found on the **S1204** Source Documentation: Baseline Form in RAVE.
11. **Section 4.2e, page 11:** The text "based on the patient's medical record" was added after "treatment information" for clarification.

12. **Section 5.1, page 12:** The first sentence was revised in order to clarify the time frame of the run-in phase. The text “3 months from IRB approval” was changed to “3 months from the time of the first registration at their study site”.
13. **Section 6.2a, pages 14 and 15:** Tables defining HCV and HIV viral status have been added. Also, the following sentence was added under the HIV table: “HIV infection is defined by a positive Western Blot test or a positive viral load (HIV RNA or DNA test).” The addition of these tables caused information from page 14 to be displaced to a newly inserted page 15. Remaining pages have been renumbered, and the Table of Contents has been updated accordingly.
14. **Section 8.4a, page 23:** The text in the parentheses “(at the time blood is drawn for viral testing)” was deleted as this is up to the institution.
15. **Section 8.4b, page 23:** This section was revised to state that sites must submit documentation supporting viral status results using file upload available on the **S1204** Source Documentation: Baseline Form in RAVE.
16. **Section 8.4c, page 23:** The number for this section has been corrected (previously duplicated 8.4b).
17. **Section 8.4e, page 24:** The following was added after **S1204** Six-Month Follow-Up Form: “(Refer to the patient’s medical record to complete this form)”.
18. **Section 8.5a, page 24:** A sentence was added to clarify the timing of submission of the **S1204** Monthly Summary Form. Also, the text in the parentheses “Section 4.1c” was changed to “Section 4.1b”.
19. **Section 9.1, page 24:** The text “(optional)” was changed to “(optional for sites and patients)” in the title heading.
20. **Appendix 12.0, pages 30 and 31:** The schema in Appendix 12 was updated as follows: The entry beginning “Clinic’s new patient intake forms include: **S1204** Viral Risk Survey” was deleted. The entry “Patients consenting to study will be asked to provide blood specimen for banking (Optional for patient)” was revised as “Patients consenting to study will be asked to fill out the **S1204** Viral Risk Survey and provide blood specimen for banking (Blood specimen is optional for site and patient)”. The “**S1204** Viral Test Results Form” was changed to the appropriate name which is the “**S1204** Viral Status Form”. The **S1204** Source Documentation: Baseline was added below the **S1204** Viral Status Form. The reference Section 4.1c in the asterisk footnote was changed to Section 4.1b.

The following section refers to a change in the Model Consent Form.

Institutions **should** update their local consent forms to include the changes to the Model Consent Form.

SWOG considers that the Model Consent Form changes **do not** represent an alteration in risk-benefit ratio. Therefore, local accrual does **not** need to be suspended pending implementation of these changes.

Patients currently on treatment need not be informed of these changes unless required by the local Institutional Review Board (IRB).

1. **Informed Consent Form, page 4:** The text in the parentheses “(allows researchers to track your survival status for several years)” was removed since it is not necessary to have the patient’s social security number in order to track their survival status. The text “(however this is optional)” was added in the parentheses.
2. **Informed Consent Form, page 7:** In the third paragraph under “Optional Sample Collections for Biobanking...”, the text “at the same time blood is drawn for general lab work” was deleted as blood can be drawn any time. In the section entitled “What is involved?”: The text “at the same time as the blood take for viral screening” was deleted as sites may draw blood for biobanking at a time that is convenient for the patient.

Ancillary Documents:

S1204 Fast Fact Sheet: In the first box under “Eligibility”, the text “prior to registration” was added to the sentence as a clarifier. The word “randomization” was changed to “registration” throughout. The **S1204** Source Documentation: Baseline was added to the list of patient data forms in the section beginning “Within 21 days after registration”. Also, “**S1204**” was added prior to Viral Risk Survey. A “Note” was added at the bottom of the sheet to clarify the timing of submission of the **S1204** Monthly Summary.

The Staff FAQ was updated to include changes noted in this revision.

Ancillary documents are located on the protocol abstract page of the SWOG website (www.swog.org).

Forms in the Master Forms Set:

S1204 Registration Worksheet

- The form now collects the clinic visit at which patient consented to study.

S1204 Viral Status Update Form (page 1)

- The form instructions were changed to “Submit this form within 21 days of registration and submit documentation supporting viral status results on the *Source Documentation: Baseline* form.”
- The first question on the form (“Are any of these test results being reported...”) was deleted.
- In the HEPATITIS C VIRUS (HCV) section, “Recombinant immunoblot assay (RIBA)” was deleted.

S1204 Six Month Follow-Up Form

- Instructions were changed from “Complete this form for viral positive patients...” to “Refer to the patient’s medical record to complete this form for viral positive patients...”.

S1204 Onstudy Form

- This form was updated to collect date of initial chemotherapy treatment.

S1204 Source Documentation: Baseline (*This is an electronic form in RAVE. There is no mock up form available for this form in the forms study set.*)

- Sites may now upload viral status result reports from this site.

Updated forms can be found in the Master forms set on the protocol abstract page of the SWOG website.

This memorandum serves to notify the NCI and the SWOG Statistical Center.

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CLOSED EFFECTIVE 02/15/17

November 1, 2013

TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS, CTSU (CCOPS ONLY)

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FROM: Patricia O'Kane, Protocol Coordinator

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients".

MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- () Full board review required (for institutions that have not previously received full board review). Reason:
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 - () Increased risk to patient
 - () Complete study redesign
 - () Addition of tissue banking requirements
 - () Study closure due to new risk information
- () Expedited review allowed
- (√) No review required

MEMORANDUM

The purpose of this memorandum is to inform sites of a change to the Master Forms Set for the above-referenced study.

The questions related to specimen consent and future contact were revised on the **S1204** Registration Worksheet to match the questions on the **S1204** Model Informed Consent form. The form number remains the same. The revision date on the Registration Worksheet form was updated to 10/18/13.

Additionally the **S1204** Staff FAQs document has been updated. In particular, formatting and administrative changes were made in items #6, 9, 20, 21, 30 and 36. The revised date is 10/1/13.

The updated Registration form, which is part of the **S1204** forms set and the staff FAQs document can be found on the protocol abstract page of the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
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CLOSED EFFECTIVE 02/15/17

October 1, 2013

TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS, CTSU (CCOPS ONLY)

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FROM: Patricia O'Kane, Protocol Coordinator

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MEMORANDUM

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

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MEMORANDUM

The purpose of this memorandum is to inform sites of a change to the Master Forms Set for the above-referenced study.

Question 14 of the **S1204** Monthly Status Update Form was updated, and new Questions 15 and 16 were added. On Question Number 14, "Unknown" was removed as a response option and "I do not wish to share my information" was added. Question Number 15 was added to capture the staff's view of eligibility and enrollment issues for each participant. Question Number 16 was added to give sites the opportunity to describe reasons for non-participation to **S1204**. The form number remains the same. The form date was updated to 10/1/13.

Additionally, a **S1204** Monthly Status Update “Worksheet” has been added to the protocol abstract page to aid sites in the completion of the Status Update Form. The worksheet is not part of the forms set.

The updated form (within the S1204 forms set) and new worksheet can be found on the protocol abstract page of the SWOG website (www.swog.org).

This memorandum serves to notify the NCI and the SWOG Statistical Center.

cc: PROTOCOL AND INFORMATION OFFICE
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CLOSED EFFECTIVE 02/15/17

Distribution Date: October 1, 2013
DCP Submission Date: September 11, 2013

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FROM: Patricia O'Kane, Protocol Coordinator

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening For Human Immunodeficiency Virus (HIV)" Study Chairs: Drs. S.D. Ramsey, R Loomba, R. Chugh and D.L. Hershman.

REVISION #1

IRB Review Requirements

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

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REVISION #1

The following changes have been made to the above noted protocol and model consent form:

1. **Title page:** Boston MC MBCCOP has been added as a participant of the run-in phase. New Mexico MBCCOP has withdrawn as a run-in site participant. The participant list reflects that for non-SWOG participants, the study will be open only to CCOPs. Jessica P. Hwang, M.D. has been added as a Study Chair. The version date of the protocol has been updated to 9/11/13.

2. **Schema, page 4:** The requirement to include the **S1204** patient consent in the clinic's new patient intake forms was removed due to its length. Therefore, "**S1204** Consent" was deleted from the fourth line of the schema. The "plus sign" symbol was moved to the sixth line of the schema after the text "Patient consents to study".
3. **Section 3.6, page 10:** The prior malignancy statement was revised for clarity. The text "treated for different malignancies with the past five years" was changed to "*diagnosed with a malignancy other than the current malignancy within the past five years*". Also the text "no evidence of disease for at least five years prior to randomization" was changed to "*no evidence of disease for a prior malignancy, except as noted above, for at least five years prior to randomization*".
4. **Section 4.1b, page 11:** The requirement to include the **S1204** Patient consent in the cancer center's new patient intake forms was removed. Therefore, the first sentence was changed from "Include the **S1204** Patient Consent and the **S1204** Viral Risk Survey in the cancer center's new patient intake forms" to "Include the **S1204** Viral Risk Survey in the cancer center's new patient intake forms." Text related to optional separate consent for specimen banking was removed as this is dictated by the institutions local IRB.
5. **Section 4.2a, page 11:** The following text was added to the end of the sentence: "using the **S1204** Registration Worksheet".
6. **Section 6.2, pages 13-14:** The third sentence of the second paragraph of Section 6.2a which previously read: "HBV infection is defined by positive HbsAg and anti-HBC" was replaced by a new paragraph and table defining HBV viral status and standard HBV tests.
7. **Section 9.1a, page 23:** In the first and second sentences, "serum" was changed to "serum and whole blood" for clarity.
8. **Section 9.1c, Collecting Whole Blood, page 24:** In the last sentence, "frozen serum" was changed to "frozen whole blood" as this section relates to whole blood.
9. **Appendix 12.0 (Schema), page 29:** The requirement to include the **S1204** patient consent in the clinic's new patient intake forms was removed due to its length. Therefore, "**S1204** Consent" was deleted from the third line of the schema. The "plus sign" symbol was moved to the fifth line of the schema after the text "Patient consents to study".

The following section refers to changes in the Model Informed Consent Form.

Institutions **should** update their local consent forms to include the changes to the Model Consent Form.

SWOG considers that the Model Consent Form changes **do not** represent an alteration in risk-benefit ratio. Therefore, local accrual does **not** need to be suspended pending implementation of these changes.

Patients who sign a consent form prior to Institutional Review Board (IRB) approval and local implementation of the consent form changes, need not be informed of these changes unless required by the local IRB.

1. **Model Informed Consent, page 3:** The section entitled “What is the usual approach to use of medical information for research?” was moved above “What are my other choices if I do not take part in this study?”
2. **Model Informed Consent, page 3:** The following change concerns the first 3 paragraphs previously listed under “Why is this study being done?”.

Previously the section read: “This is not a treatment study for cancer. The purpose of this study is to find out how common human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV) infections are among new cancer patients.

Screening newly diagnosed cancer patients for HIV, HBV and/or HCV infections is very important. If a doctor treats a cancer patient without knowing that the patient has one of these viruses, it could cause severe problems or even death. The Center for Disease Control (CDC) and the American College of Physicians and US Preventive Services Task Force (USPTF) recommend HIV screening in the general population. The USPTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965. The CDC recommends Hepatitis B screening for all patients undergoing treatment with certain types of drugs that can affect the immune system (like some of the drugs used to treat cancer). Despite these recommendations, cancer centers do not always routinely screen for these viruses.

We are asking you to take part in this voluntary study so that we can find cost-effective ways for cancer centers to test patients for HIV, HBV, and HCV. We want to learn the best way to find and treat cancer patients who have these viruses.”

This was replaced with the following:

“We want to learn how often people with newly diagnosed cancer also have viral infection and the best and most effective way to find which cancer patients have these viruses.

Even if you don't think you have these viruses, your participation is very important to this study. In fact, for the purposes of this study, it will be very helpful to include those who believe they are at very low risk for having been infected by any of these viruses.”

Please note that the original paragraphs have been moved to the Consent Appendix. See item number 8 below.

3. **Model Informed Consent, page 3:** Under “What are my other choices if I do not take part in this study?”, the sentence “There will be about 3,000 people taking part in this study” was moved to be the last sentence in the section entitled “Why is this study being done?”
4. **Model Informed Consent, page 3:** The section entitled “How long will I be in this study?” was moved above the heading “What is involved?” (Page 4).
5. **Model Informed Consent, page 4:** Under “What risks can I expect from taking part in this study?”, the text “blood draws will be” was deleted.

6. **Model Informed Consent, page 5:** Under “What possible benefits can I expect from taking part in this study”, the sentence “This study will help researchers learn things that will help people in the future” was changed to “We hope that the information from this study will help doctors learn more about how viruses affect cancer and cancer care. This information could help future cancer patients”.
7. **Model Informed Consent, page 10:** A signature and date line for the researcher obtaining consent was added at the end of the informed consent form.
8. **Model Informed Consent, page 12:** An appendix has been added to the consent which contains additional language options for use in specific areas of the consent, when the local IRB is requesting more information be provided to participants. The decision to use the abbreviated language of the current consent or the comprehensive text is up to the local IRB.

Study materials added to the S1204 abstract page on the SWOG website: Fast Fact Sheet

This memorandum serves to notify the NCI and SWOG Statistical Center.

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Distribution Date: September 1, 2013
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swog.org

TO: ALL SWOG MEMBER, CCOP, AND AFFILIATE MEDICAL ONCOLOGISTS;
CTSU (CCOPS ONLY)

FROM: Patricia O'Kane, Protocol Coordinator

RE: **S1204**, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study Of Screening For Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients". Study Chairs: Drs. S.D. Ramsey, R. Loomba, R. Chugh, D.L. Hershman, and J.P.H. Wang.

STATUS NOTICE

Study Chair: Scott D. Ramsey, M.D., Ph.D.
Phone number: 206/667-7846
E-mail: sramsey@fhcrc.org

IRB Review Requirements

- Full board review required (for institutions that have not previously received full board review). Reason:
 - Initial activation (should your institution choose to participate)
 - Increased risk to patient
 - Complete study redesign
 - Addition of tissue banking requirements
 - Study closure due to new risk information
- Expedited review allowed (for institutions that have previously received full board review)
- No review required

ACTIVATION

The study referenced above is now open for participation **effective August 29, 2013**. The entire protocol is attached for your use. Note that the protocol is dated 7/22/13 and the informed consent document is dated 7/24/13.

The run-in portion of the study **is limited to the following sites**: Columbia MBCCOP (Inst. No. 18743), Greenville CCOP (Inst. No. 10879), Hawaii MBCCOP (Tripler Army Medical Center ONLY) (Inst. No.11033), St. Luke's Mountain States Tumor Institute (Inst. NO. 8081) and Wichita CCOP (Inst. No. 9017).

Once the run-in phase is complete, the study will be opened group-wide and to non-SWOG sites through the CTSU. Notification will be forthcoming.

This memorandum serves to notify the NCI and SWOG Statistical Center.

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CLOSED EFFECTIVE 02/15/17

PRIVILEGED COMMUNICATION
FOR INVESTIGATIONAL USE ONLY

Activated August 29, 2013

SWOG

A SERO-EPIDEMIOLOGIC SURVEY AND COST-EFFECTIVENESS STUDY OF SCREENING FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) AMONG NEWLY DIAGNOSED CANCER PATIENTS

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ID003/St. Lukes Mountain States Tumor Institute
CA463/Contra Costa Regional Medical Center

MAIN STUDY OPEN TO ALL SWOG MEMBER, NCORP, AND AFFILIATES *

* All participating sites must agree to the site requirements and be approved for participation as outlined in Sections 4.1 and 4.2.

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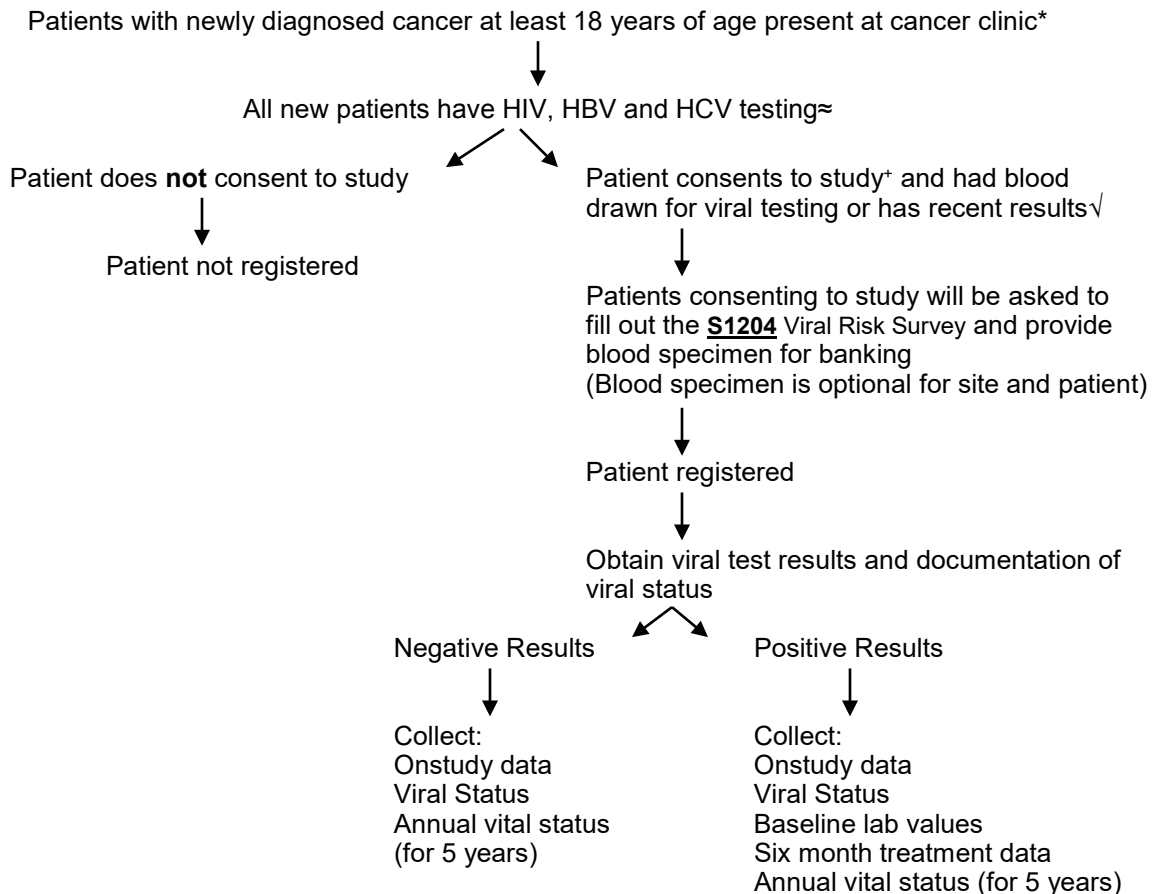
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CANCER TRIALS SUPPORT UNIT (CTSU) ADDRESS AND CONTACT INFORMATION

To submit site registration documents:	For patient enrollments:	Submit study data directly to the Lead Cooperative Group unless otherwise specified in the protocol:
<p>CTSU Regulatory Office 1818 Market Street, Suite 1100 Philadelphia, PA19103</p> <p>Fax: 215-569-0206</p> <p>Email: CTSURegulatory@ctsu.coccg.org</p> <p>For more information, call the CTSU Help Desk at 888-823-5923 or the Regulatory Help Desk at 866-651-CTSU.</p>	<p>Please refer to the patient enrollment section for instructions on using the OPEN system.</p>	<p><u>Online Data Submission:</u> This protocol will use Medidata Rave® for electronic data submission. Access Rave® using your active CTEP-IAM userid and password at the following url: https://login.imedidata.com/selectlogin</p> <p><u>Other Tools and Reports:</u> Institutions participating through the CTSU continue to have access to other tools and reports available on the SWOG Workbench. Access this by using your active CTEP-IAM userid and password at the following url: https://crawb.crab.org/TXWB/ctsulogon.aspx</p>
<p>The study protocol and all related forms and documents must be downloaded from the protocol-specific Web page of the CTSU Member Web site located at https://www.ctsu.org. Sites must use the current form version and adhere to the instructions and submission schedule outlined in the protocol.</p> <p>CTSU sites should follow procedures outlined in the protocol for Site registration, Patient Enrollment, Adverse Event Reporting, Data Submission (including ancillary studies), and Drug Procurement.</p>		
<p>For patient eligibility questions contact the SWOG Data Operations Center by phone or email: 206-652-2267 cancercontrolquestion@crab.org</p> <p>For study procedure related questions contact the SWOG Data Operations Center by phone or email (see above).</p>		
<p>For questions unrelated to patient eligibility, site requirements, logistics, or data submission contact the CTSU Help Desk by phone or e-mail: 888-823-5923 ctsucontact@westat.com</p> <p>All calls and correspondence will be triaged to the appropriate CTSU representative.</p>		
<p>For detailed information on the regulatory and monitoring procedures for CTSU sites please review the CTSU Regulatory and Monitoring Procedures policy located on the CTSU members' website: https://www.ctsu.org</p>		
<p>The CTSU Web site is located at https://www.ctsu.org</p>		

SCHEMA

Main study (open to all SWOG Member, NCORP, and Affiliates Ω)



* Consent to **S1204** is an agreement by the patient to allow the following information to be used for research purposes: demographic information, type of cancer, responses to the Viral Risk Survey, results of viral testing, cancer and viral treatment data (if patient tested positive to HIV, HBV, and/or HCV), and yearly vital status for 5 years.

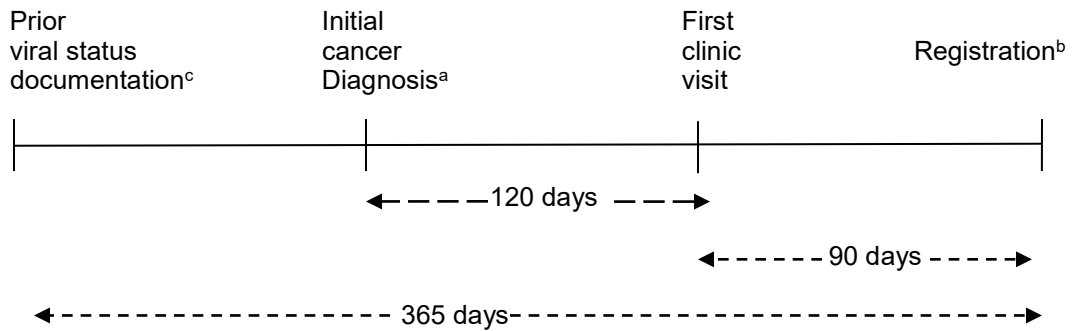
≈ In order to participate in this study, all physicians at a given site must agree to offer HIV, Hepatitis B and Hepatitis C testing to all new cancer patients being seen at their site. See [Section 4.1a](#). Sites will use institutional consent for viral testing and/or institutional confidentiality agreement for HIV testing.

* All new cancer patients age 18 years and older presenting at cancer clinic will be included in monthly summary data submitted on the **S1204** Monthly Summary of Newly Diagnosed Cancer Patient Visits form. (See [Sections 4.1c](#) and [8.5a](#).)

√ Patients who have had HIV, HBV, and/or HCV testing within 365 days prior to registration and who do not wish to be retested are eligible, providing supporting documents can be obtained confirming viral test results per [Section 3.2b](#). Patients providing acceptable viral status documentation must have blood drawn for testing prior to registration for any of the three viruses not covered by the documentation.

Ω All participating sites must agree to the site requirements and be approved for participation as outlined in [Sections 4.1](#) and [4.2](#).

SCHEMA FOR S1204 REGISTRATION TIMELINES



- a Patients must have an initial cancer diagnosis within 120 days prior to the first clinic visit.
- b Registration must be within 90 days after first clinic visit. Activities between the first clinic visit and registration include: blood draw for viral testing; consent; Viral Risk Survey completion.
- c Patients with known viral status who do not wish to be retested may submit proof of viral status, dated within 365 days prior to registration.

1.0 OBJECTIVES

1.1 Primary Objective

Among newly diagnosed cancer patients presenting to SWOG-affiliated community and academic oncology clinics, estimate the prevalence of human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection. Prevalence estimates will be further stratified: by whether infection with the virus(es) is known, as reported by patients and/or their physician prior to study testing, vs. unknown; by presenting cancer type, and by self-reported risk factors for each virus.

1.2 Secondary Objectives

- a. Evaluate known sociodemographic, clinical, and behavioral factors that are significantly associated with previously undiagnosed HIV, HBV, and/or HCV infection in a population of people with newly diagnosed cancer.
- b. Among patients who are identified as having HIV, HBV, and/or HCV, describe the type of treatments received and alterations to therapy (if any), both for the viral infections and the cancers.
- c. Describe type of adverse events possibly attributable to the patient's viral status in patients with HIV, HBV, and/or HCV infection.
- d. Using simulation modeling that is directly informed by the data obtained from this study, determine the cost-effectiveness (expressed as cost per infection detected and cost per year of life gained) of (1) routine, universal screening and (2) risk factor-directed screening of newly diagnosed cancer patients for HIV, HBV, and/or HCV vs. current care.

1.3 Tertiary Objective

Create a biorepository of stored serum for future translational medicine studies that may include identifying genomic and viral factors that increase the risk of serious adverse effects among participants infected with HIV, HBV, and/or HCV being treated for invasive cancers.

2.0 BACKGROUND

Changing Demographics of HIV, HBV and HCV

The demographics of HIV, HBV and HCV infection and the epidemiology of their complications have changed substantially over time as increasingly effective therapies have been deployed to prevent and treat these viruses. For example, while the incidence of deaths due to life-threatening infections from HIV has decreased, there has been a concomitant increase in the proportion of deaths due to cancers not previously associated with AIDS. (1) As the expected lifespan of individuals with HIV infection increases with antiretroviral therapy, more HIV patients live long enough to develop malignancies. (2) Moreover, HIV-infected patients may have twice the risk of developing cancer relative to the general population, with non-AIDS defining cancers occurring 10-15 years earlier than the general population. (2)

HIV

New HIV infections are increasingly common in older persons: it is estimated that 37% of new infections occur in people over 40 years of age. Because of this shift towards older groups, there is concern that the proportion of newly diagnosed cases that are undetected may rise if clinicians don't consider HIV when those older patients present with symptoms. At the end of 2008, it was

estimated that 20% of the 1,178,350 persons with HIV in the United States had undiagnosed infections. (3) [Table 1](#) displays the estimated prevalence of known and unknown HIV infection by age.8

Table 1

Age	Prevalence of HIV infection in the United States*		
	Total Persons (%)	Rate/100,000	% unknown
13-24	68,600 (5.8%)	134.1	58.9%
25-34	180,600 (15.3%)	440.9	31.5%
35-44	357,500 (30.3%)	846.3	18%
45-54	385,400 (32.7%)	871.3	13.8%
55-64	147,700 (12.5%)	439.3	11.9%
65+	38,400 (3.3%)	99.0	10.7%

* CDC 2008 report. (4)

HBV and HCV

Vaccination of children against HBV starting in 1991 has significantly reduced disease incidence in younger age groups but higher rates of HBV infection continue among adults, particularly among males aged 30-44 years. The estimated rate of HBV incident infection is between 4.3 and 5.6% in the US population. Chronic infection occurs in 6-10% of persons over 5 years of age. Most people with chronic HBV remain symptom free for 20 or 30 years and about 15-25% of people with chronic infection develop serious liver conditions such as cirrhosis or liver cancer.

Estimates of HCV incident infection rates are between 1.3 and 1.9% of the US population with between 2.7 and 3.9 million persons living with chronic infection. HCV is the most prevalent in persons aged 40-59 years and in this age group the prevalence is highest among African Americans (6.1%). There is no vaccine against HCV infection. Approximately 75-85% of infections with HCV result in chronic infection. HCV is the most common blood borne infection in the United States. The majority of hepatitis infections are diagnosed at the onset of a hepatitis-related illness.

Screening Guidelines

Guidelines are remarkably divergent in their recommendations regarding screening for these viruses. Shifts in the demographic composition, and the estimated 250,000 persons with undetected HIV infection have led several groups to call for universal screening of all persons for HIV. With the exception of HIV, there continues to be controversy about the value of routine universal screening. (5) The CDC, American College of Physicians and US Preventive Services Task Force (USPSTF) recommend screening for HIV in the general population. (6-11) A 2014 Bulletin from USPSTF recommends HBV screening of all patients at high risk of infection and/or with weakened immune systems. (12) In response, ASCO convened a group of experts who, in a 2010 publication, concluded that there is insufficient evidence to support universal screening of cancer patients for hepatitis B. (13) A recent cost-effectiveness study suggested that routine screening for HBV among patients being considered for cytotoxic chemotherapy was not cost-effective, although screening might be "economically favorable" in certain subgroups at increased risk. (14) The USPSTF recommends against routine screening for hepatitis C virus (HCV) infection in asymptomatic adults who are not at increased risk (general population) for infection, and found insufficient evidence to recommend for or against routine screening for HCV infection in adults at high risk for infection. (15) The CDC, ASCO, and other oncology groups have not published guidance on HCV screening in cancer patients.

Universal Screening of Cancer Patients for HIV, HBV, HCV: Pro and Con

There are several arguments in favor of universal screening of cancer patients. First, because treatments for HIV, HBV and HCV have improved dramatically over time, those who are not screened miss an opportunity to receive treatment that may substantially reduce their lifetime risk of morbidity and mortality related to infection with these viruses. New HIV and HCV infections are increasingly occurring in persons who are old enough to have higher rates of cancer. A 2006 survey found that 37% of all newly diagnosed HIV infections were in people older than 40 years. A Veterans Affairs healthcare system study showed that the prevalence of HIV in people 55 to 64 year of age was 3.5%. (16) The peak prevalence of HCV infection has now shifted to those over 40. (17) The estimated number of people in the US living with chronic HBV infection is between 800,000 and 1.4 million. The age composition of those who remain undiagnosed is unknown. While clinicians are likely to consider co-existing infection for persons with newly diagnosed cancers known to be associated with HIV, HBV and HCV (e.g., Kaposi's sarcoma, hepatocellular carcinoma, non-Hodgkin's lymphoma), it is also true that this age shift means that many (and perhaps most) infected patients now develop cancers that are not clearly defined as HIV-, HBV-, or HCV-related.

A second clinical issue in favor of screening is the risk that cytotoxic chemotherapy may pose to patients with cancer and a coexisting but undiagnosed infection. Cancer chemotherapy can lead to reactivation of HBV and HCV that may result in significant morbidity and mortality. (18) It is estimated that the rate of HBV reactivation is between 14 and 21% across all cancers and as high as 50% among certain cancers such as hematologic and breast cancers. There is some suggestion that reactivation is influenced by the type of therapy used for these cancers. For example, chemotherapy regimens containing corticosteroids or anthracycline-containing regimens have been associated with reactivation. Additionally, the anti-CD20 monoclonal antibody, rituximab has also been found to be associated with an increased risk of reactivation. Risk factors for reactivation include male gender, younger age, and HBeAg positive serology. Recent studies suggest that prophylactic anti-viral therapy can prevent reactivation of HBV and HCV during chemotherapy. Immunosuppression associated with chemotherapy can also adversely affect HIV-infected people, leading to an elevated risk of AIDS. HIV-infected individuals may also be more susceptible than uninfected individuals to myelosuppression.

There are also arguments against universal screening. Screening the 1.6 million newly diagnosed cancer patients for HIV, HBV, and HCV will increase the cost of cancer care, but may have a very low yield. In populations with a very low prevalence of infection, the likelihood of false positive tests increases, leading to additional patient anxiety and possible delays in cancer treatment. Even among those with true positive tests, potentially harmful delays in cancer treatment may occur due to concerns about viral reactivation or other issues related to the newly discovered infection. Clinicians might switch to "less toxic" cancer treatments with lower or less certain effectiveness out of fears of causing viral reactivation. Because our knowledge of the true risk of severe adverse effects related to cancer treatment in persons with latent infections remains uncertain, the putative benefits of delaying or modifying cancer treatment remain speculative, while the risk these changes pose to cancer patient outcomes are real.

Because of Fundamental Gaps in Knowledge, the Cost-Effectiveness of Universal Screening Remains Highly Uncertain

Ultimately, because we have limited knowledge of fundamental issues—the prevalence of undiagnosed infections; the risks posed to treating cancer patients with latent infections; the impact of screening on cancer therapy choices, delays in cancer treatment, and virus- and cancer-related outcomes--the effectiveness and cost-effectiveness of universal screening programs for HIV/HBV/HCV is unknown. In an era of increasingly constrained resources and rising costs of treating cancer, we cannot afford to introduce new practices that increase costs further but provide little value to patients. Not accounting for the costs of evaluating positive results, using current Medicare reimbursements for HIV, HBV and HCV testing, screening would increase the nation's cancer "spend" by nearly \$500 million annually, (although a less expensive multiplex test might reduce this cost). Conceivably, these costs could be offset by reductions in

costs resulting in improved outcomes of cancer care. Nonetheless, these issues present a strong argument in favor of a multi-center, prospective study to evaluate the prevalence of latent, undiagnosed HIV, HBV, and HCV infection among newly diagnosed cancer patients.

SWOG is a national leader among cooperative groups in treating patients with HIV and malignancy

Advances in HIV medicine require re-examination of routine exclusion of HIV-infected individuals from cancer clinical trials. (19) In the era of modern HIV therapeutics, selected HIV-infected patients tolerate cancer therapy well and have outcomes similar to their HIV not-infected counterparts. (20) In addition to improved HIV therapeutics and cancer therapy outcomes, there is uncertainty whether exclusion based on “known” HIV infection remains the best approach for eligibility screening. Indeed, there have been calls for screening all cancer patients for HIV infection who present for oncology care. (21) Accordingly, the National Cancer Institute has initiated programs to expand access to individuals with HIV infection. SWOG has taken a national leadership role in this endeavor and was the first Cooperative Group to include HIV-infected patients as a sub-cohort in a special NCI funding program. However, a better understanding of the burden of HIV in cancer patients is needed to move forward in an informed way. A formal study aimed at screening for HIV infection would be the best way of estimating the burden of both known and unknown HIV-infection in cancer patients presenting for consideration of clinical research participation and would inform this issue in critical ways. The SWOG network is an ideal setting to determine the prevalence of latent HIV, HBV and HCV infection, and also to determine best practices for treating patients with coexisting infections and malignancies.

Rationale for collection of serum for biorepository

A biorepository of stored serum for the purposes of identifying genomic and viral factors that increase the risk of serious adverse effects among HIV, HBV and HCV infected persons being treated for cancers will be valuable to researchers. It would allow researchers to further assess known cofactors among HIV, HBV, and HCV markers in the infected cancer patients that increase risk for adverse outcomes from chemotherapy. Examples might include HIV viral load, HBeAg, and HCV genotype. Finally, the biorepository would have potential value for identifying new factors—such as coinfections—that could predict treatment-related adverse events among cancer patients with HIV, HBV, and HCV

Summary

This goal of this study is to evaluate the prevalence of HIV, HBV and HCV viruses in a well-characterized, geographically and demographically diverse cohort of patients with cancer in the United States. This will allow the recognition of viral infection in patients when it may affect relevant therapies and in order to allow for assessing the need for appropriate anti-viral treatment (with concomitant cancer chemotherapy). An additional objective is to use these data to determine whether routine viral screening programs for newly diagnosed cancer patients improves patient care and outcomes such that they are cost-effective. (21)

Inclusion of Women and Minorities

This study was designed to include women and minorities, but was not designed to measure differences of intervention effects. The anticipated accrual in the ethnicity/race and sex categories is shown in the table below.

DOMESTIC PLANNED ENROLLMENT REPORT					
Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	5	6	1	1	13
Asian	23	23	3	3	52
Native Hawaiian or Other Pacific Islander	1	1	0	0	2
Black or African American	81	108	9	14	212
White	1165	1323	128	166	2782
More Than One Race	0	0	0	0	0
Total	1275	1461	141	184	3061

3.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration. Use the spaces provided to confirm a patient's eligibility. Any potential eligibility issues should be addressed to the Data Operations Center in Seattle at 206/652-2267 prior to registration.

When calculating time frame for date of diagnosis, the date that the diagnosis was made is considered Day 0. **If Day 90, 120, or 365 falls on a weekend or holiday, the limit may be extended to the next working day.**

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

3.1. Disease Related Criteria

- _____ a. Patients must be presenting for evaluation or treatment of a new cancer malignancy (including hematologic). Confirmed diagnosis (obtained from the patient's medical record) must be within 120 days prior to the first clinic visit. (NOTE: The "first clinic visit" is the patient's first visit at the clinic after a new cancer diagnosis, e.g., the first visit on or after the cancer diagnosis date.) Patients must be registered within 90 days after their first clinic visit. Patients presenting for "second opinions" of confirmed malignancies are eligible, including those who have started cancer treatment at other facilities. NOTE: Patients are allowed to participate in other clinical trials.

3.2. Clinical/Laboratory Criteria

- _____ a. Patients must be at least 18 years of age.
- _____ b. Patients must have had their blood drawn for viral status testing for HIV, HBV and HCV prior to registration or provide acceptable viral status documentation prior to registration.

Acceptable viral status documentation includes:

- Viral test results for any or all of the viruses, dated within 365 days prior to registration.
- Viral load documentation for any or all of the viruses, dated within 365 days prior to registration.

Note that patients providing acceptable viral status documentation must have blood drawn for testing prior to registration for any of the three viruses not covered by the documentation.

- _____ c. Individuals are ineligible if they have been diagnosed with a malignancy other than the current malignancy within the past five years, with the exception of basal cell or squamous cell skin cancer, in situ cervical cancer, or in situ breast cancer. Individuals are eligible if they have had no evidence of disease for a prior malignancy for at least five years prior to randomization except as noted above.

3.3 Regulatory Criteria

- _____ a. Patients must sign and give written informed consent in accordance with institutional and federal guidelines.

- b. As a part of the OPEN registration process (see [Section 7.0](#) for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

4.0 SITE REQUIREMENTS AND LOGISTICS

For study related questions, contact the SWOG Data Operations Center at cancercontrolquestion@crab.org or 206/652-2267.

4.1 Site Agreements

In order to participate in this study:

- a. All physicians at a given site must agree to offer HIV, Hepatitis B and Hepatitis C testing to all new cancer patients being seen at their site. (Institutional consent and/or confidentiality forms for viral testing should be used as needed.)
- b. Sites must agree to ask all newly diagnosed, eligible cancer patients to participate.
- c. Sites must agree to submit monthly summary data on all new cancer patients age 18 years and older presenting at the cancer clinic. These data are to be submitted to SWOG using the **S1204** Monthly Summary of Newly Diagnosed Cancer Patient Visits form. If the site is part of a large system or consortia, summary data will be required from each individual clinic registering patients to **S1204**. Summary data collected include the number of patients who had viral testing, the number of patients who are positive for each virus and type of cancer and demographics.

4.2 Site Application and Approval for Study Participation

Each site is required to have approval from the SWOG Operations office to participate in **S1204**. Sites must complete and submit the **S1204** Site Application according to the directions on the form. The **S1204** Site Application can be found on the **S1204** protocol abstract page on the SWOG website (www.swog.org).

4.3 Study Flow

- a. Patients may be approached and registered any time within 90 days after their first clinic visit. During this time, patients must have completed consent and provided blood for viral testing per [Sections 3.2b](#) and [3.3a](#).
- b. Eligible patients who consent to **S1204** will be registered to the study (per [Section 7.0](#)) using the **S1204** Registration Worksheet.
- c. All patients who choose to complete the **S1204** Viral Risk Survey should complete it after consent, between the first clinic visit and registration.
- d. All patients: staff will collect and submit a repository blood specimen from those who consent (optional for site and patient). (See Section 9.1.)

- e. All patients: staff will submit the **S1204** Onstudy Form, **S1204** Viral Risk Survey Form, **S1204** Viral Status Form and **S1204** Source Documentation: Baseline Form. **NOTE:** Source documentation must support the data submitted on all forms, specifically, upload the source documentation to support entries on the **S1204** Viral Status Form.
- f. Patients who have been diagnosed with HIV, HBV and/or HCV: baseline laboratory values will be collected on the **S1204** Baseline Laboratory Values Form.
- g. Patients who have been diagnosed with HIV, HBV and/or HCV: treatment information, based on a review of the patient's medical record, will be collected at 6-months on the **S1204** Six Month Follow-Up Form. This data collection is based on the most recently obtainable information from the patient's medical record and does not require a patient visit.
- h. All patients: annual vital status will be collected annually for 5 years on the **S1204** Annual Vital Status Form starting at one year after registration. (**NOTE:** The **S1204** Annual Vital Status Form can be submitted upon the death of a patient rather than waiting a full year before submitting the form.)

5.0 RUN-IN PHASE

This study will be conducted in two parts; a run-in phase followed by the main study. The run-in phase will be conducted in selected SWOG sites to evaluate feasibility of following the recruitment procedures, and to allow an opportunity for modification of those procedures if necessary. After the run-in phase is complete, the study procedures and materials will be evaluated and improved as needed for use in the main study. The main study will be opened within SWOG (run-in sites and SWOG NCORPs) provided each site can satisfy the site requirements and are approved to participate (see [Section 4.0](#)).

5.1 Run-in Phase

Selected SWOG sites (a combination of member, CCOP, and affiliate institutions) will conduct this study for 3 months from the time of the first registration at their study site. During the run-in phase, summary information about all new oncology patients seen at each participating site is to be submitted on a monthly basis using the **S1204** Monthly Summary of Newly Diagnosed Cancer Patient Visits form.

After the 3 month run-in phase is complete, the study will be evaluated using: (1) the total number of registrations compared to number of new patients across the participating sites and (2) the completeness of the **S1204** Viral Risk Survey forms.

5.2 Criteria For Study Evaluation of the Run-in Phase

Evaluate the ratio of registered patients to known new patient: A ratio of 0.75 or better will be considered acceptable; a ratio of 0.5 to 0.74 will indicate improvement is needed; a ration of 0.50 or less will indicate a serious problem with the study design and/or eligibility that must be addressed for the study to meet objectives.

Evaluate the rate and pattern of missing data on the **S1204** Viral Risk Survey: Consistent issues with uncompleted questions or pages will be addressed as needed. (Questions with missing responses where the "Prefer not to answer" box is checked will be counted as completed data).

6.0 STATISTICAL CONSIDERATIONS

6.1 Sample Size and Estimated Number of Persons Identified with HIV/HBV/HCV

The target accrual for this study is 3,000 eligible patients. Assuming 2% of patients will not satisfy the eligibility criteria, the total planned accrual is 3,061 to achieve 3,000 eligible patients. The sample size of 3,000 patients was chosen based on the fixed budget.

[Table 2](#) details the expected number of persons with HIV infection (known and undiagnosed) based on the age distribution of patients accrued to SWOG therapeutic trials over the past 5 years and the risk estimates from the 2008 CDC reports. (22) The sample size of 3,000 patients was chosen based on the fixed budget. In the following table E(N), E(HIV+) and E(unknown) represent the expected number of patients, number HIV-infected, number of unknown HIV infections, within each age category respectively.

Table 2

	%	E(N)	E(HIV+)	E(unknown)
18-24	1	30	0	0
25-34	4	120	1	0
35-44	12	360	3	1
45-54	25	750	7	1
55-64	29	870	4	0
65+	29	870	1	0
Total		3,000	15	2

These estimates assume that the prevalence of HIV infection among cancer patients is not different from the general US population. However, if the cancer risk among HIV-infected individuals is truly twice that of the general population, the expected numbers would be twice these values. (2)

While cancer patients are older than the general population, we use the general population prevalence estimates to estimate the expected number of cases of HBV and HCV. Taking the upper range of persons ever infected for HBV and HCV to be 5.6% and 1.9%, respectively and assuming that in 10% of persons HBV is chronic and in 80% of persons HCV is chronic, [Table 3](#) shows the expected number of cases that will be identified with a sample size of 3,000 patients:

Table 3

	HBV		HCV	
	%	N	%	N
Ever infected	5.6%	168	1.9%	57
Chronic	10.0%	17	80.0%	46

It is expected that some patients will be co-infected with HIV, HBV, and/or HCV. Given these numbers, it is expected that up to 240 participants will be infected with HIV, HBV, and/or HCV.

6.2 Analysis of Primary Objective

- a. Among newly diagnosed cancer patients presenting to SWOG-affiliated community and academic oncology clinics, estimate the prevalence of human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection. Prevalence estimates will be further stratified: by whether infection with the virus(es) is known, as reported by patients and/or their physician prior to study testing, vs. unknown; by presenting cancer type, and by self-reported risk factors for each virus.

Initially, the prevalence of each infection will be evaluated in the entire study population and by cancer type. Patients will be defined as positive or negative based on standard diagnostic criteria for each virus.

Patients with chronic HBV infection who are HBAg-positive (and also anti-HBc-positive) will be considered positive and are at highest risk of reactivation. Patients who are HBsAg-negative/anti-HBc-positive could be either convalescent from a previous infection (with anti-HBs-positive) or have isolated anti-HBc (with

anti-HBs-negative); both scenarios will be considered positive. Although this latter group is also at risk of reactivation, the risk is much lower than those who are HBsAg-positive.

Definition of HBV viral status based on HBV test results

Standard tests			HBV
HBsAg	anti-HBc*	anti-HBs	Status
Negative	Negative	Negative	Negative
Negative	Negative	Positive	Negative
Negative	Positive	Negative	Positive (prior infection; low risk of reactivation)
Negative	Positive	Positive	Positive (prior infection; low risk of reactivation)
Positive	Positive	Negative	Positive (active infection; high risk of reactivation)

* Total or IgG anti-HBc

Definition of HCV status based on HCV test results

Results of Standard Tests		
anti-HCV Screening Test (CIA or EIA)	anti-HCV Confirmatory Test (HCV RNA)	HCV Status
Negative	Not needed	Negative
Positive	Not done	Unknown (exposed, current status unknown)*
Positive	Negative	Negative (recovery from past infection)
Positive	Positive	Positive

CIA, chemiluminescence immunoassay; EIA, enzyme immunoassay.

* If a patient's HCV status is unknown, pursue further testing as appropriate or seek consultation from HCV specialist to determine positive or negative HCV status.

HCV infection is defined by a positive HCV RNA test. HCV positive patients with positive HCV RNA will be defined as having chronic HCV infection. However, we will also report the number of screen positive patients defined as a positive HCV EIA or CIA, overall and by confirmation status based on the HCV RNA test results.

Definition of HIV status based on HIV test results

Results of Standard Tests		
Antibody Test (Rapid HIV Antibody, ELISA, or EIA)	Western Blot	HIV Status
Negative	Not needed	Negative*
Positive	Negative	Negative*
Positive	Positive	Positive

EIA, enzyme immunoassay; ELISA, enzyme-linked immunosorbent assay.

* If the patient is suspected to have acute retroviral infection, viral load (by PCR) should be obtained to confirm HIV status.

HIV infection is defined by a positive Western Blot test or a positive viral load (HIV RNA or DNA test).

Previously undiagnosed infection will be defined based on a positive diagnosis and reporting no prior history of each respective virus. Previously diagnosed/known infection will be defined based on a proof of prior positive tests and/or confirmation as part of this study along with reporting prior history of each respective virus on the **S1204** Viral Risk Survey. The prevalence of previously undiagnosed HIV, HBV, or HCV infection will be evaluated excluding patients with previously diagnosed/known infection. The proportion of patients with known infection at registration will be evaluated using entire study population.

A sample size of 3,000 patients will allow us to estimate the confidence interval for the prevalence of each virus to within $\pm 25\%$ (based on the upper bound of the 95% confidence interval), if the assumed incidence is at least 2.5%. [Table 4](#) describes the relative accuracy for varying levels of prevalence.

Table 4

Assumed prevalence (p)	95% Confidence Interval	Relative Accuracy [(95% CI upper bound – p)/p]
0.5%	0.3% - 0.8%	66.2%
1.0%	0.7% - 1.4%	42.9%
2.5%	2.0% - 3.1%	25.0%
5.0%	4.3% - 5.8%	16.8%
7.5%	6.6% - 8.5%	13.3%
10.0%	9.0% - 11.1%	11.3%

Weighted estimates of virus-specific prevalence rates accounting for potential differences in demographic factors between the enrolled cohort and the general cancer treatment population will also be generated.

6.3 Analysis of Secondary Objectives

- a. Evaluate the known sociodemographic, clinical, and behavioral factors that are significantly associated with previously undiagnosed HIV, HBV, and/or HCV infection in a population of people with newly diagnosed cancer.

Risk factors will be evaluated comparing all infections (within virus), known infections, and undiagnosed infections. Moreover, risk factors will be evaluated within tumor type, although our ability to make inferences within tumor types will be limited by relatively small numbers. We will explore grouping tumors into types that are linked with behaviors that may increase risk for viral infection (e.g., lung cancer, head and neck cancer, cervical cancer). First, we will evaluate if known risk factors are found to be risk factors for the study population. Initial evaluations will be bivariate comparisons of the risk factor and infection status using logistic regression. Then a multivariable logistic model will be used to assess the independent association of risk factors with infection status.

[Table 5](#) details the minimum risk ratio under various values for the prevalence of infection, and the predictor variables (assuming binary) for two-sided testing at the 0.05 level and 80% power.

Table 5

Prevalence of predictor:	Infection Prevalence		
	<u>2%</u>	<u>1%</u>	<u>0.5%</u>
10%	2.4	3.1	4.1
20%	2.1	2.6	3.4
30%	2.0	2.4	3.2
40%	2.0	2.4	3.2
50%	2.0	2.4	3.2

The risk model will be developed using Lasso for binary outcomes including the factors identified in bivariate comparisons as being associated with viral status.

Further analyses will explore grouping tumors into types that are linked with behaviors that may increase risk for viral infection (e.g., lung cancer, head and neck cancer, cervical cancer).

- b. Secondary Objective 2: Among patients who are identified as having HIV, HBV, or HCV, describe the type of treatments received and alterations to therapy (if any), both for the viral infections and the cancers.

The type of anti-viral therapies prescribed within 6 months of registration will be described by virus type. Primary evaluations will be mainly descriptive. Types of therapies will be summarized by virus type in the entire infected population and by previously known versus newly diagnosed infections.

Summaries of cancer therapies will be descriptive in nature. Among patients with viral infection, the recorded changes in planned treatment at 6 months following registration due to the patient's viral status will be described.

We will compare the pre-diagnosis treatment plan to the post-diagnosis plan by previously known versus newly diagnosed infections. Since the expectation is that the majority of unknown infections will be either hepatitis B or C, this analysis will be mostly aimed at evaluating the impact of hepatitis diagnosis on cancer therapy.

- c. Secondary Objective 3: Evaluate type and rate of adverse events possibly attributable to the patient's viral status in patients with HIV, HBV, and/or HCV infection.

The likelihood of viral infection being associated with adverse events will be estimated. The frequency will be evaluated among all infections, within virus type, and also by whether the viral infection was previously or newly diagnosed.

With 240 total infections, the probability of adverse events can be estimated to within 6.4%. Given the expected numbers of infections stated in Tables 2 and 3, the likelihood of change in therapy can be estimated to within 7.7% for HCV, 13.2% for HBV, and to within 25.8% for HIV with 95% confidence. The relative accuracy of these estimates, assuming the true likelihood is 20% is 27.7% overall, and 33.6%, 61.4%, and 100% for HCV, HBV, and HIV, respectively. The observed probabilities for each of these categories will be summarized including 95% confidence intervals and by the relative accuracy using the observed proportions.

- d. Secondary Objective 4: Estimate the cost-effectiveness of screening for HIV, HBV, and HCV.

This evaluation will assess the cost-effectiveness of (1) universal screening for HIV/HBV/HCV and (2) risk-factor directed screening for these viruses vs. usual care (no screening). The evaluation of risk-factor directed screening will estimate the cost-effectiveness of screening for different levels of predicted risk for each virus based on the models generated in Secondary Objective 1. Specifically, using the final logistic model, subject-specific probabilities of undiagnosed HIV, HBV, and HCV will be calculated. The risk factor-directed analysis will evaluate cost-effectiveness values for various levels of predicted probabilities in different cancer patient populations and for the entire population.

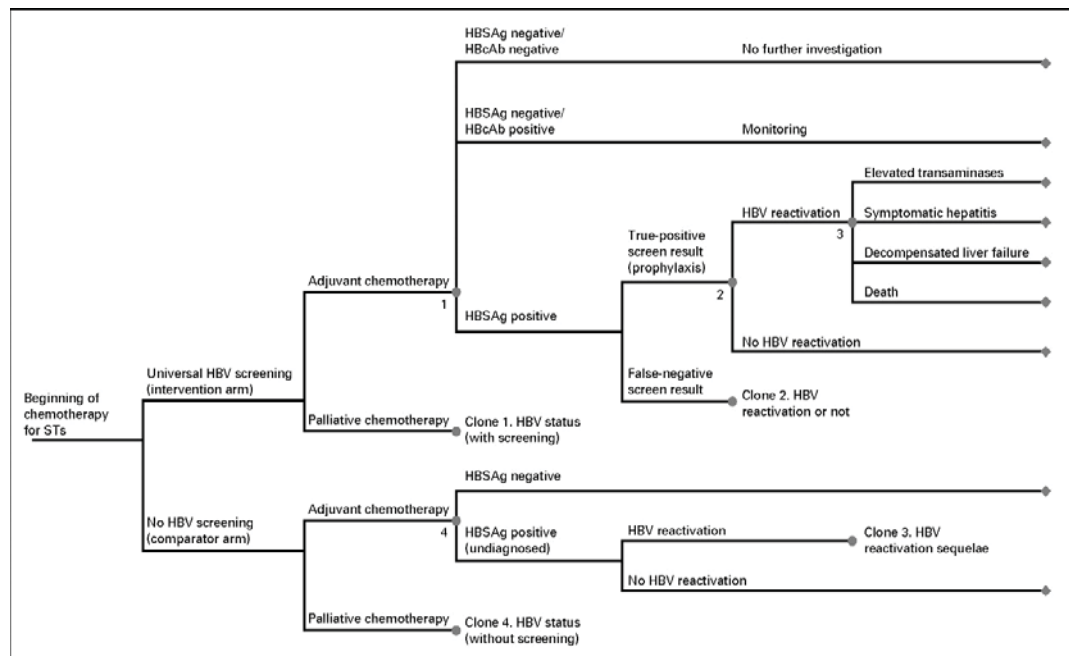
Cost-effectiveness will be measured as the change in costs of care for universal or directed screening compared to the current care (no screening) in all cancer patients and stratified by cancer type. The incremental cost-effectiveness of the screening test(s) vs. current care (no screening) is derived using the following formula:

$$\text{Incremental Cost-Effectiveness Ratio (ICER)} = (C_{\text{New}} - C_{\text{Std}}) / (E_{\text{New}} - E_{\text{Std}})$$

Where C_{New} and C_{Std} refer to average total costs, and E_{New} and E_{Std} refer to average total effectiveness for the new intervention and current care arms, respectively. Components of C_{New} include the costs of the screening tests, costs of follow-up (confirmatory) testing, costs of antiretroviral therapy, cancer treatment costs, and costs of managing adverse events related to reactivation of latent viruses. For this analysis, components of E_{new} are new carriers detected (HIV/HBV/HCV), and years of life gained.

We will compute ICERs for screening programs that test each virus alone and together (i.e. the incremental cost-effectiveness of adding HBV and HCV screening, respectively, to HIV screening). The estimates will be derived using simulation models with representative care and outcome pathways related to screening and current care. An example of a representative decision pathway is provided below, based on the Day et al cost-effectiveness study for Hepatitis B screening.

The models will be stochastic (e.g., Markov type) in that they will capture the following (1) risks of adverse effects related to providing chemotherapy to persons with unknown latent viral infections (2) risk of mortality due to the cancer (3) mortality due to the virus(es); (4) risk of other cause mortality. The models will account for costs and consequences stemming from current care and alternative viral screening programs. Data to inform the models will be based on several sources, for example: virus prevalence information from the trial; survival from the SEER cancer registry and HIV, HBV and HCV patient registries; healthcare utilization and costs from SEER-Medicare records and will build off of inputs developed for models such as Marshall et al. to determine the cost-effectiveness of screening blood donations for HBV, HCV, and HIV. (23) Standard procedures for conducting and reporting economic analyses will be followed for this analysis, including using reimbursements or true costs rather than charges, discounting of future costs and benefits, and conducting one-way and multi-way uncertainty analyses. (24) Results will be generated as cost-per virus detected and cost per life year gained. We will consider constructing quality adjusted life year estimates if the data are available from secondary sources (it will not be feasible to collect health state utility information in the course of this study). The analysis will be conducted from the health insurance perspective and from the societal perspective over 1-year, 3-year, and lifetime time horizons.



6.4 Tertiary Objectives

Create a biorepository of stored serum for the purposes of identifying genomic and viral factors that increase the risk of serious adverse effects among HIV, HBV and HCV infected persons being treated for cancer.

There are no statistical considerations for the biorepository.

6.5 Data and Safety Monitoring Committee

A Data and Safety Monitoring Committee will oversee the conduct of the run-in portion of the study. The Committee consists of four members from outside of the SWOG, 3 SWOG members, 3 non-voting representatives from the National Cancer Institute (NCI), and the Group Statistician (non-voting). The members of this Committee will receive a report on the aspects determining feasibility from the SWOG Statistical Center following completion of the run-in portion.

In addition to the above DSMC review, accrual monitoring is done routinely by the Study Coordinator, Study Statistician, and the Committee Chair. Accrual reports are generated weekly.

7.0 REGISTRATION GUIDELINES

7.1 Registration Timing

Patients must be registered within 90 days after first clinic visit.

7.2 Investigator/Site Registration

Prior to the recruitment of a patient for this study, investigators must be registered members of a Cooperative Group and must have approval from the SWOG Operations office to participate (see [Section 4.2](#)). Each investigator must have an NCI investigator number and must maintain an “active” investigator registration status through the annual submission of a complete investigator registration packet (FDA Form 1572 with original signature, current CV, Supplemental Investigator Data Form with signature and Financial Disclosure Form with original signature) to the Pharmaceutical Management Branch, CTEP, DCTD, NCI. These forms are available on the CTSU Web site (enter credentials at <https://www.ctsu.org>; then click on the Register tab) or by calling the PMB at 301/496-5725 Monday through Friday between 8:30 a.m. and 4:30 p.m. Eastern time.

Each investigator or group of investigators at a clinic site must obtain IRB approval for this protocol and submit IRB approval and supporting documentation to the CTSU Regulatory Office before they can enroll patients. Study centers can check the status of their registration packets by querying the Regulatory Support System (RSS) site registration status page of the CTSU member web site by entering credentials at <https://www.ctsu.org>.

Requirements for site registration:

- CTSU IRB Certification
- CTSU IRB/Regulatory Approval Transmittal Sheet

7.3 OPEN Registration Requirements

The individual registering the patient must have completed the appropriate SWOG Registration Worksheet. The completed form must be referred to during the registration but should not be submitted as part of the patient data.

Oncology Patient Enrollment Network (OPEN) will also ask additional questions that are not present on the SWOG Registration Worksheet. The individual registering the patient must be prepared to provide answers to the following questions:

- a. Institution CTEP ID
- b. Protocol Number
- c. Registration Step
- d. Treating Investigator
- e. Cooperative Group Credit
- f. Credit Investigator
- g. Patient Initials
- h. Patient's Date of Birth
- i. Patient SSN (SSN is desired, but optional. Do not enter invalid numbers.)
- j. Country of Residence
- k. ZIP Code
- l. Gender (select one):
 - Female Gender
 - Male Gender
- m. Ethnicity (select one):
 - Hispanic or Latino
 - Not Hispanic or Latino
 - Unknown
- n. Method of Payment (select one):
 - Private Insurance
 - Medicare
 - Medicare and Private Insurance
 - Medicaid
 - Medicaid and Medicare
 - Military or Veterans Sponsored NOS
 - Military Sponsored (Including Champus & Tricare)
 - Veterans Sponsored
 - Self Pay (No Insurance)
 - No Means of Payment (No Insurance)
 - Other
 - Unknown

- o. Race (select all that apply):
 - American Indian or Alaska Native
 - Asian
 - Black or African American
 - Native Hawaiian or other Pacific Islander
 - White
 - Unknown

7.4 Registration Procedures

- a. All site staff will use OPEN to enroll patients to this study. OPEN is a web-based application and can be accessed at <https://open.ctsu.org> or from the OPEN tab on the CTSU members' side of the website at <https://www.ctsu.org>, or from the OPEN Patient Registration link on the SWOG CRA Workbench.
 - b. Prior to accessing OPEN site staff should verify the following:
 - All eligibility criteria have been met within the protocol stated timeframes. Site staff should refer to [Section 3.0](#) to verify eligibility.
 - All patients have signed an appropriate consent form and HIPAA authorization form (if applicable).
 - The study site is listed as "approved" in the CTSU RSS.
 - c. Access requirements for OPEN:
 - Site staff will need to be registered with CTEP and have a valid and active CTEP-IAM account. This is the same account (user ID and password) used for the CTSU members' web site.
 - To perform registrations, the site user must have been assigned the 'Registrar' role on the SWOG or CTSU roster:
 1. If you are a SWOG member, to perform registrations on SWOG protocols you must have an equivalent 'Registrar' role on the SWOG roster. Role assignments are handled through SWOG.
 2. If you are not a SWOG member, to perform registrations on SWOG protocols you must have the role of Registrar on the CTSU roster. Site and/or Data Administrators can manage CTSU roster roles via the new Site Roles maintenance feature under RSS on the CTSU members' web site. This will allow them to assign staff the "Registrar" role.
- Note: The OPEN system will provide the site with a printable confirmation of registration and treatment information. Please print this confirmation for your records.
- d. Further instructional information is provided on the OPEN tab of the CTSU members' side of the CTSU website at <https://www.ctsu.org> or at <https://open.ctsu.org>. For any additional questions contact the CTSU Help Desk at 1-888-823-5923 or ctsucontact@westat.com.

- 7.5 Exceptions to SWOG registration policies will not be permitted.
- a. Patients must meet all eligibility requirements.
 - b. Institutions must be identified as approved for registration.
 - c. Registrations may not be cancelled.
 - d. Late registrations will not be accepted.

8.0 DATA SUBMISSION SCHEDULE

8.1 Data Submission Requirements

Data must be submitted according to the protocol requirements for **ALL** patients registered, including patients deemed to be ineligible. Patients for whom documentation is inadequate to determine eligibility will generally be deemed ineligible.

8.2 Master Forms

Master forms can be found on the protocol abstract page on the SWOG website (www.swog.org) and (with the exception of the sample consent form and the Registration Worksheet) must be submitted on-line via the Web; see [Section 8.3](#) for details.

8.3 Data Submission Procedures

- a. SWOG institutions must submit data electronically via the Web using Medidata Rave® at the following url:

<https://login.imedidata.com/selectlogin>

1. If prompted, select the 'CTEP-IAM IdP' link.
2. Enter your valid and active CTEP-IAM userid and password. This is the same account used for the CTSU members' web site and OPEN.

- b. **You may also access Rave® via the SWOG CRA Workbench. Go to the SWOG** web site (<http://swog.org>) and logon to the Members Area using your SWOG Roster ID Number and password. After you have logged on, click on *Workbenches*, then *CRA Workbench* to access the home page for the CRA Workbench and follow the link to Rave® provided in the left-hand navigation panel.

To access the CRA Workbench the following must be done (in order):

1. You are entered into the SWOG Roster and issued a SWOG Roster ID Number,
2. You are associated as an investigator or CRA/RN at the institution where the patient is being treated or followed,
3. Your Web User Administrator has added you as a web user and has given you the appropriate system permissions to view data for that institution.

For assistance with points 1 and 2 call the Operations Office at 210/614-8808. For point 3, contact your local Web User Administrator (refer to the "Who is my Web User Administrator?" function on the swog.org Members logon page).

For difficulties with the CRA Workbench, please email technicalquestion@crab.org.

- c. Institutions participating through the Cancer Trials Support Unit (CTSU) please refer to the CTSU Participation Table on [Page 3](#).

8.4 Patient Data Submission Timeline

- a. AFTER PATIENT CONSENTS TO SPECIMEN BANKING:

Obtain patient blood sample for banking. Samples are to be frozen and may be shipped in batch weekly or monthly based on site preference (see [Section 9.0](#)).

- b. WITHIN 21 DAYS OF REGISTRATION:

Submit the following:

S1204 Viral Risk Survey

S1204 Viral Status Form (**NOTE:** Upload source documentation to support the data submitted on this form.)

S1204 Source Documentation: Baseline Form (upload documentation supporting viral status and the data submitted on the **S1204** Viral Status Form)

S1204 Baseline Laboratory Values Form (if patient is HIV, HBV and/or HCV positive)

- c. WITHIN 60 DAYS OF REGISTRATION:

Submit the following:

S1204 Onstudy Form

- d. AT 6 MONTH POST-REGISTRATION (WITHIN 21 DAYS) (HIV, HBV and/or HCV positive patients only):

Submit the following:

S1204 Six-Month Follow-Up Form (Refer to the patient's medical record to complete this form.)

NOTE: Reasons for unavailability of follow-up data will be captured on this form.

- e. AT YEARS 1, 2, 3, 4 AND 5 POST-REGISTRATION (All patients):

Submit the **S1204** Annual Vital Status Update Form (**NOTE:** Submit this form at any time upon death of a patient, rather than waiting a full year before submitting the form.)

8.5 Site Summary Data Submission Timeline

- a. MONTHLY THROUGH 1 MONTH AFTER STUDY IS CLOSED TO ACCRUAL:

Submit the following for each month to summarize new cancer patients seen at the cancer clinic during the reporting calendar month:

S1204 Monthly Summary of Newly Diagnosed Cancer Patient Visits Form

NOTE: This form is submitted to report summary data on all new cancer patients age 18 years and older presenting at cancer clinic. This form is not submitted for each patient. Refer to the special submission instructions in the **S1204** Rave Form Display document located in the forms packet on the protocol abstract page of the SWOG website (www.swog.org). (See [Section 4.1b](#) for more information).

9.0 SPECIAL INSTRUCTIONS

9.1 Blood Specimens for Banking for Future Research (optional for sites and patients)

a. Consent

Institutions must have patient consent to bank serum and whole blood for future translational medicine studies. With consent, serum and whole blood will be banked at the SWOG Specimen Repository.

b. Specimen collection kits are not being provided for this submission; sites will use institutional supplies.

c. Collection

From all consenting patients (viral status is not a factor): one 10 mL of whole blood will be collected in an EDTA lavender/purple top tube and one 10 mL of serum will be collected in a red top tube for banking.

Collecting Whole Blood

- Use 10mL purple top vacutainer tube with EDTA to collect whole blood.
- Pre-label vacutainer tube(s) according to specimen labeling requirements (treatment protocol number, SWOG patient I.D. number, patient's initials, timepoint, date of specimen collection, specimen number and/or specimen type).
- Use aseptic techniques and draw blood from the patient into the vacutainer tube(s).
- Immediately after the blood is drawn, thoroughly mix the blood with the anticoagulant by gently inverting the vacutainer tube(s) multiple times.
- Immediately freeze vial in a freezing apparatus (ex. Mr. Frosty). If not available, slow freeze vials on dry ice or in a -70°C to -80°C freezer. Store frozen whole-blood vials in a -70°C to -80°C freezer until ready to ship.

Collecting Serum

- Use 10mL red or red/black marble top vacutainer tubes with no anticoagulant to collect whole blood for serum processing.
- Use aseptic techniques and draw blood from the patient.
- Follow the instructions below for serum collection:
- Allow blood to clot for 30-60 minutes at room temperature.
- Centrifuge vacutainer tube (s) at 900 x g for 10-15 minutes at room temperature.
- Pre-label cryovials according to specimen labeling requirements (treatment protocol number, SWOG patient I.D. number, patient's initials, timepoint, date of specimen collection, specimen number and/or specimen type).
- Using a sterile pipette, remove serum (yellow-clear liquid above clot).
- Aliquot the serum into 2mL cryovials at 1 mL each.
- Immediately freeze vials in a freezing apparatus (ex. Mr. Frosty). If not available, slow freeze vials on dry ice or in a -70°C to -80°C freezer. Store frozen serum vials in a -70°C to -80°C freezer until ready to ship.

- d. General specimen collection and submission instructions for whole blood and serum can be accessed on the SWOG Specimen Submission webpage (<https://swog.org/members/clinicaltrials/specimens/STSpecimens.asp>).
- e. If -70°C to -80°C freezer is not available, ship samples to bank using same day/overnight shipping. Refer to url in [Section 9.1d](#).
- f. The provided per-accrual funding is intended, in part, to help offset costs related to specimen collection and shipping. Sites may ship batched specimens weekly or monthly at their convenience.
- g. SHIPPING SAMPLES

1. SWOG Specimen Tracking System (STS)

All specimen submissions for this study must be entered and tracked using the SWOG online Specimen Tracking system. SWOG members may log on the online system via the CRA Workbench. To access the CRA Workbench, go to the SWOG Web site (<http://swog.org>) and logon to the Members Area. After you have logged on using your SWOG roster ID number and password, click on the *CRA Workbench* link to access the home page for CRA Workbench website. First time non- SWOG users must refer to start-up instructions located at <https://gill:crab.org/SpecTrack/>.

A copy of the Shipment Packing List produced by the online Specimen Tracking system should be printed and placed in the pocket of the specimen bag if it has one, or in a separate resealable bag.

ALL SPECIMENS MUST BE LOGGED VIA THIS SYSTEM; THERE ARE NO EXCEPTIONS.

To report technical problems with Specimen Tracking, such as database errors or connectivity issues, please send an email to technicalquestion@crab.org. For procedural help with logging and shipping specimens, there is an introduction to the system on the Specimen Tracking main page

(<http://dnet.crab.org/SpecTrack/Documents/Instructions.pdf>);
or contact the Data Operations Center at 206/652-2267 to be routed to the Data Coordinator for further assistance.

In the online specimen tracking system, the appropriate SWOG laboratory for submission of bone marrow, serum, and peripheral blood samples for SWOG Repository Submission and SNP testing is identified as follows:

Lab #201: SWOG Specimen Repository
Solid Tissue, Myeloma & Lymphoma Div
Nationwide Children's Hospital
700 Children's Dr. WA 1340
Columbus, OH 43205
Contact: SWOG Repository Coordinator
Phone: 614/722-2865
FAX: 614/722-2897
E-mail: bpccbank@nationwidechildrens.org

2. Federal guidelines for the shipment of blood products:
 - a. The tube must be wrapped in an absorbent material.
 - b. The tube must then be placed in an AIRTIGHT container (like a resealable bag).
 - c. Pack the resealable bag and tube in a Styrofoam shipping container.
 - d. Pack the Styrofoam shipping container in a cardboard box.
 - e. Mark the box "Biohazard".

10.0 ETHICAL AND REGULATORY CONSIDERATIONS

The following must be observed to comply with Food and Drug Administration regulations for the conduct and monitoring of clinical investigations; they also represent sound research practice:

Informed Consent

The principles of informed consent are described by Federal Regulatory Guidelines (Federal Register Vol. 46, No. 17, January 27, 1981, part 50) and the Office for Protection from Research Risks Reports: Protection of Human Subjects (Code of Federal Regulations 45 CFR 46). They must be followed to comply with FDA regulations for the conduct and monitoring of clinical investigations.

Institutional Review

This study must be approved by an appropriate institutional review committee as defined by Federal Regulatory Guidelines (Ref. Federal Register Vol. 46, No. 17, January 27, 1981, part 56) and the Office for Protection from Research Risks Reports: Protection of Human Subjects (Code of Federal Regulations 45 CFR 46).

Monitoring

This study will be monitored by the Clinical Data Update System (CDUS) Version 3.0. Cumulative CDUS data will be submitted quarterly to CTEP by electronic means. Reports are due January 31, April 30, July 31 and October 31.

Adverse Experiences

There is no SAE Reporting for this study.

11.0 BIBLIOGRAPHY

1. Simard EP, Engels EA. Cancer as a cause of death among people with AIDS in the United States. *Clin Infect Dis* 51(8):957-62. PMID: 2943990, 2010.
2. Shiels MS, Pfeiffer RM, Gail MH, Hall HI, Li J, Chaturvedi AK, et al. Cancer burden in the HIV-infected population in the United States. *J Natl Cancer Inst* 103(9):753-62. PMID: 3086877, 2011.
3. Centers for Disease Control and Prevention. HIV surveillance--United States, 1981-2008. *MMWR Morb Mortal Wkly Rep* 60(21):689-93, 2011.
4. Centers for Disease Control and Prevention. Diagnoses of HIV infection and AIDS in the United States and Dependent Areas, 2008. [Report] Atlanta, GA; [cited 2011 September 30]; Available from: <http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/index.htm>, 2010.
5. Fairchild AL, Bayer R. HIV surveillance, public health, and clinical medicine--will the walls come tumbling down? *N Engl J Med* 365(8):685-7, 2011.
6. Beckwith CG, Flanigan TP, del Rio C, Bartlett JG. Screening for HIV. *Ann Intern Med* 143(12):916-7, 2005.
7. US Preventive Services Task Force. Screening for HIV: recommendation statement. *Ann Intern Med* 143(1):32-7, 2005.
8. Branson BM, Handsfield HH, Lampe MA, Janssen RS, Taylor AW, Lyss SB, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep* 55(RR-14):1-17, 2006.
9. Qaseem A, Snow V, Shekelle P, Hopkins R, Jr., Owens DK. Screening for HIV in health care settings: a guidance statement from the American College of Physicians and HIV Medicine Association. *Ann Intern Med* 150(2):125-31, 2009.
10. Chou R, Selph S, Dana T, et al. Screening for HIV: systematic review to update the 2005 U.S. Preventive Services Task Force recommendation. *Ann Intern Med* 2012;157:706-718
11. Screening for HIV. Draft recommendation statement. Rockville, MD: Preventive Services Task Force, 2012. (<http://www.uspreventiveservicestaskforce.org/uspstf13/hiv/hivdraftrec.htm>).
12. Chou R, Dana T, Bougatsos C, Blazina I, Khangua J, Zakher B. Screening for hepatitis B virus infection in adolescents and adults: a systematic review to update the U.S. preventive services task force recommendation. *Ann Intern Med* 161(1):31-45. doi:10.7326/M13-2837, 2014.
13. Artz AS, Somerfield MR, Feld JJ, Giusti AF, Kramer BS, Sabichi AL, et al. American Society of Clinical Oncology provisional clinical opinion: chronic hepatitis B virus infection screening in patients receiving cytotoxic chemotherapy for treatment of malignant diseases. *J Clin Oncol* 28(19):3199-202, 2010.
14. Day FL, Karnon J, Rischin D. Cost-effectiveness of universal hepatitis B virus screening in patients beginning chemotherapy for solid tumors. *J Clin Oncol* 29(24):3270-7, 2011.
15. US Preventive Services Task Force. Screening for Hepatitis C in Adults. [Website]: US Preventive Services Task Force [updated 2004 November 2004; cited 2011 September 30]; Available from: <http://www.uspreventiveservicestaskforce.org/uspstf/uspshcpc.htm>, 2004.

16. Owens DK, Sundaram V, Lazzeroni LC, Douglass LR, Sanders GD, Taylor K, et al. Prevalence of HIV infection among inpatients and outpatients in Department of Veterans Affairs health care systems: implications for screening programs for HIV. *Am J Public Health* 97(12):2173-8. PMID: 2089082, 2007.
17. Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. *Ann Intern Med* 144(10):705-14, 2006.
18. Loomba R, Rowley A, Wesley R, Liang TJ, Hoofnagle JH, Pucino F, et al. Systematic review: the effect of preventive lamivudine on hepatitis B reactivation during chemotherapy. *Ann Intern Med* 148(7):519-28. PMID: 2729097, 2008.
19. Persad GC, Little RF, Grady C. Including persons with HIV infection in cancer clinical trials. *J Clin Oncol* 26(7):1027-32, 2008.
20. Little RF, Pittaluga S, Grant N, Steinberg SM, Kavlick MF, Mitsuya H, et al. Highly effective treatment of acquired immunodeficiency syndrome-related lymphoma with dose-adjusted EPOCH: impact of antiretroviral therapy suspension and tumor biology. *Blood* 101(12):4653-9, 2003.
21. Chiao EY, Dezube BJ, Krown SE, Wachsman W, Brock MV, Giordano TP, et al. Time for oncologists to opt in for routine opt-out HIV testing? *JAMA* 304(3):334-9. PMID: 3160789, 2010.
22. St Louis ME, Rauch KJ, Petersen LR, Anderson JE, Schable CA, Dondero TJ. Seroprevalence rates of human immunodeficiency virus infection at sentinel hospitals in the United States. The Sentinel Hospital Surveillance Group. *N Engl J Med* 323(4):213-8, 1990.
23. Marshall DA, Kleinman SH, Wong JB, AuBuchon JP, Grima DT, Kulin NA, et al. Cost-effectiveness of nucleic acid test screening of volunteer blood donations for hepatitis B, hepatitis C and human immunodeficiency virus in the United States. *Vox Sang* 86(1):28-40, 2004.
24. Gold MR, Siegel JE, Russel LB, Weinstein MC. *Cost Effectiveness in Health and Medicine*. New York, NY: Oxford University Press; 1996.

Informed Consent Model for S1204

*NOTES FOR LOCAL INSTITUTION INFORMED CONSENT AUTHORS:

This model informed consent form has been reviewed by the DCTD/NCI and is the official consent document for this study. Local IRB changes to this document are allowed. (Institutions should attempt to use sections of this document that are in bold type in their entirety.) Editorial changes to these sections may be made as long as they do not change information or intent. If the institutional IRB insists on making deletions or more substantive modifications to the risks or alternatives sections, they may be justified in writing by the investigator and approved by the IRB. Under these circumstances, the revised language, justification and a copy of the IRB minutes must be forwarded to the SWOG Operations Office for approval before a patient may be registered to this study.

Please particularly note that the questions related to banking of specimens for future study are in bolded type and may not be changed in any way without prior approval from the SWOG Operations Office.

Readability Statistics:

Flesch Reading Ease	<u>56</u>	(targeted above 55)
Flesch-Kincaid Grade Level	<u>9.6</u>	(targeted below 8.5)

- Instructions and examples for informed consent authors are in *[italics]*.
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- The term "study doctor" has been used throughout the model because the local investigator for a cancer treatment trial is a physician. If this model is used for a trial in which the local investigator is not a physician, another appropriate term should be used instead of "study doctor".
- The dates of protocol updates in the header and in the text of the consent is for reference to this model only and should not be included in the informed consent form given to the prospective research participant.
- The local informed consent must state which parties may inspect the research records. This includes the NCI, the drug manufacturer for investigational studies, any companies or grantors that are providing study support (these will be listed in the protocol's model informed consent form) and SWOG.

"SWOG" must be listed as one of the parties that may inspect the research records in all protocol consent forms for which patient registration is being credited to SWOG. This includes consent forms for studies where all patients are registered directly through the SWOG Data Operations Office, all intergroup studies for

which the registration is being credited to SWOG (whether the registration is through the SWOG Data Operations Office or directly through the other group), as well as consent forms for studies where patients are registered via CTSU and the registration is credited to SWOG.

- When changes to the protocol require revision of the informed consent document, the IRB should have a system that identifies the revised consent document, in order to preclude continued use of the older version and to identify file copies. An appropriate method to identify the current version of the consent is for the IRB to stamp the final copy of the consent document with the approval date. The stamped consent document is then photocopied for use. Other systems of identifying the current version of the consent such as adding a version or approval date are allowed as long as it is possible to determine during an audit that the patient signed the most current version of the consent form.

***NOTES FOR LOCAL INVESTIGATORS:**

- The goal of the informed consent process is to provide people with sufficient information for making informed choices about participating in research. The consent form provides a summary of the study, of the individual's rights as a study participant, and documents their willingness to participate. The consent form is, however, only one piece of an ongoing exchange of information between the investigator and study participant. For more information about informed consent, review the "Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials" prepared by the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials for the National Cancer Institute. The Web site address for this document is <http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/>
- A blank line, “_____”, indicates that the local investigator should provide the appropriate information before submitting to the IRB.

*These notes for investigators are instructional and should not be included in the consent form sent to IRBs.

Consent Form

Study Title for Study Participants:

Viral Infections in Newly Diagnosed Cancer Patients

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

S1204 A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for HIV, Hepatitis B and Hepatitis C Among Newly Diagnosed Cancer Patients

Why is this study being done? *(section updated 9/11/13)*

We want to learn how often people with newly diagnosed cancer also have viral infection and the best and most effective way to find which cancer patients have these viruses.

Even if you don't think you have these viruses, your participation is very important to this study. In fact, for the purposes of this study, it will be very helpful to include those who believe they are at very low risk for having been infected by any of these viruses.

There will be about 3,000 people taking part in this study.

What is the usual approach to use of medical information for research? *(section moved 9/11/13)*

Hospitals usually use a Release of Medical Information form to gather medical information from patients. However, for this study, we are using a consent form to specify what type of information we want to use from your medical records.

What are my other choices if I do not take part in this study? *(section updated 9/11/13)*

Even if you decide not to take part in this research study, you have other choices. For example:

- you can get treatment for your cancer without being on a study
- you may choose to take part in a different study, if one is available
- you can still be screened for viruses without being on this study

How long will I be in this study? *(section moved 9/11/13)*

We will gather most of the information at the time you agree to take part in the study. If you are positive for HIV, HBV, and/or HCV, we will gather information about your cancer and virus treatment at 6 months. We will check your medical records once a year for 5 years to get your survival status. After 5 years we will not ask for any more information from your medical records.

What is involved?

Most of the information gathered for this study will be the same for all study participants. If you agree to take part, the following information will be obtained from your medical records and included as part of the research data:

- Basic information about you and your cancer (height, weight, date of diagnosis, type of cancer)
- Information about your health, habits, and medical history
- Your social security number (however this is optional) (*updated 12/16/13*)
- Whether or not you are infected with HIV, HBV, and/or HCV, and results of your viral testing
- Information about your survival status, to be checked every year for 5 years (*updated 3/26/15*)

If you test positive for any of the viruses, the following additional information will be obtained from your medical records and included as part of the research data:

- Information about your cancer treatment and the treatment for your viral infection
- Results of your blood tests

By signing this consent form, you agree that we may include this information from your medical records in the research study.

After your viral screening, you do not need to come to the clinic to take part in this research study.

What extra tests and procedures will I have if I take part in this study?

Participation in this study does not require extra testing or procedures.

What risks can I expect from taking part in this study?

Risks related to the blood draw for general blood work and/or viral screening will be provided by the cancer center. (*9/11/13*)

You may have some emotional discomfort when you fill out a study survey about risk behaviors or as a result of being interviewed about your health status.

There is also a possible risk that your personal information might be compromised. We have secure programs and procedures in place to protect your personal information and we will do our best to make sure that the personal information used for this study will be kept private.

However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

To help make sure your information is private, your doctor or nurse will go to a secure data submission program sponsored by the National Cancer Institute (NCI) to send us your information. We have programmed all of the questions that we need to have answered about you at each time point, so the doctor/nurse will just enter the information into the system from your records. We can then go to the same secure program and get your information to include it with the information from all of the other patients taking part in the study.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if screening everyone for virus is better than the usual approach so this study may or may not help you. We hope that the information from this study will help doctors learn more about how viruses affect cancer and cancer care. This information could help future cancer patients. (9/11/13)

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ (insert name of center) Institutional Review Board at _____ (insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)

What are the costs of taking part in this study?

We expect your health plan/insurance company will pay for the HIV, HBV and HCV testing as it is considered standard of care at the clinic where you are being seen. If you do not have insurance, or if your health plan/insurance company will not pay for testing, you will be charged. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, SWOG.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- The Fred Hutchinson Cancer Research Center who will analyze the cost-effectiveness of screening all cancer patients for these viruses as part of this study.

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]

Where can I get more information?

You may visit the NCI Web site at <http://cancer.gov/> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.



Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ (*insert name of study doctor[s]*) at _____ (*insert telephone number*).

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say ‘no’ to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

1. Optional Sample Collections for Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part, a sample of your blood will be collected. (12/16/13) The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called “biobanking”. The Biobank is being run by the SWOG Specimen Repository Solid Tissue, Myeloma & Lymphoma Division of Nationwide Children’s Hospital and is supported by the National Cancer Institute.

What is involved?

If you agree to take part, here is what will happen next:

- 1) About 1 tablespoon of blood (two tubes) will be collected from a vein in your arm. (12/16/13) Your sample and some related health information may be stored in the

- Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up.
- 2) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
 - 3) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
 - 4) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

What are the possible risks?

- 1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
- 2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- 3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
- 4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

If your confidential genetic information is discovered, you may suffer from genetic discrimination. Genetic discrimination occurs if people are treated unfairly because of differences in their genes that increase their chances of getting a certain disease. In the past, this could have resulted in the loss of health insurance or employment. Because of this, The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This act was signed into federal law on May 21, 2008, and went into effect May 2009. This law does not cover life insurance, disability insurance and long-term care insurance.

While this study has safeguards in place to protect your confidential genetic information and to make it extremely unlikely that your identity would be connected with any special studies that are performed on your tissue, it is possible that this information could be discovered by someone who is unauthorized to have access to it.

How will information about me be kept private?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

- 1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
- 2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
- 3) Researchers to whom SWOG sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- 4) Information that identifies you will not be given to anyone, unless required by law.
- 5) If research results are published, your name and other personal information will not be used.

What are the possible benefits?

You will not benefit from taking part.

Your samples may be helpful to research whether you do or do not have HIV, HBV and/or HCV. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

What if I change my mind?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, (*insert name of study doctor for main trial*) at _____ (*insert telephone number of study doctor for main trial*) who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

What if I have more questions?

If you have questions about the use of your samples for research, contact the study doctor, _____, (*insert name of study doctor for main trial*), at _____ (*insert telephone number of study doctor for main trial*).

Please circle your answer to show whether or not you would like to take part:

SAMPLES FOR FUTURE RESEARCH STUDIES:

My blood samples and related information may be kept in a Biobank for use in future health research.

YES NO

Future Contact

Occasionally, researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact participants in a particular study. You can agree or not agree to future contact by circling “yes or no”

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the *main study* and any additional studies where I circled ‘yes’.

Participant’s (or legally authorized representative’s) signature _____

Date of signature _____

Signature of researcher obtaining consent _____ (added 9/11/13)

Date of signature _____ (added 9/11/13)

Information deleted 3/26/15

Consent Appendix: *(Appendix added 9/11/13)*

This purpose of this appendix is to provide sites with additional language options for specific areas of the consent when the local IRB is requesting more information be provided to participants. The decision to use the abbreviated language of the current consent or the comprehensive text is up to the local IRB.

Options for:

Why is this study being done?

“This is not a treatment study for cancer. The purpose of this study is to find out how common human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV) infections are among new cancer patients.

Screening newly diagnosed cancer patients for HIV, HBV and/or HCV infections is very important. If a doctor treats a cancer patient without knowing that the patient has one of these viruses, it could cause severe problems or even death. The Center for Disease Control (CDC) and the American College of Physicians and US Preventive Services Task Force (USPTF) recommend HIV screening in the general population. The USPTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965. The CDC recommends Hepatitis B screening for all patients undergoing treatment with certain types of drugs that can affect the immune system (like some of the drugs used to treat cancer). Despite these recommendations, cancer centers do not always routinely screen for these viruses.

We are asking you to take part in this voluntary study so that we can find cost-effective ways for cancer centers to test patients for HIV, HBV, and HCV. We want to learn the best way to find and treat cancer patients who have these viruses.

Even if you don't think you have these viruses, your participation is very important to this study. This cancer center screens all new cancer patients for HIV and Hepatitis. By agreeing to be on this study, you agree to allow us to know your viral status (positive or negative) along with other medical information to be used to answer questions for this research study.

There will be 3,000 people taking part in this study.