Supplementary Appendix

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

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

Supplementary Appendix

Supplement to Schoen RE, et al. Incidence and Mortality from Colorectal cancer in the PLCO Flexible Sigmoidoscopy Screening Trial

Contents

Figure S1: Consort Diagram

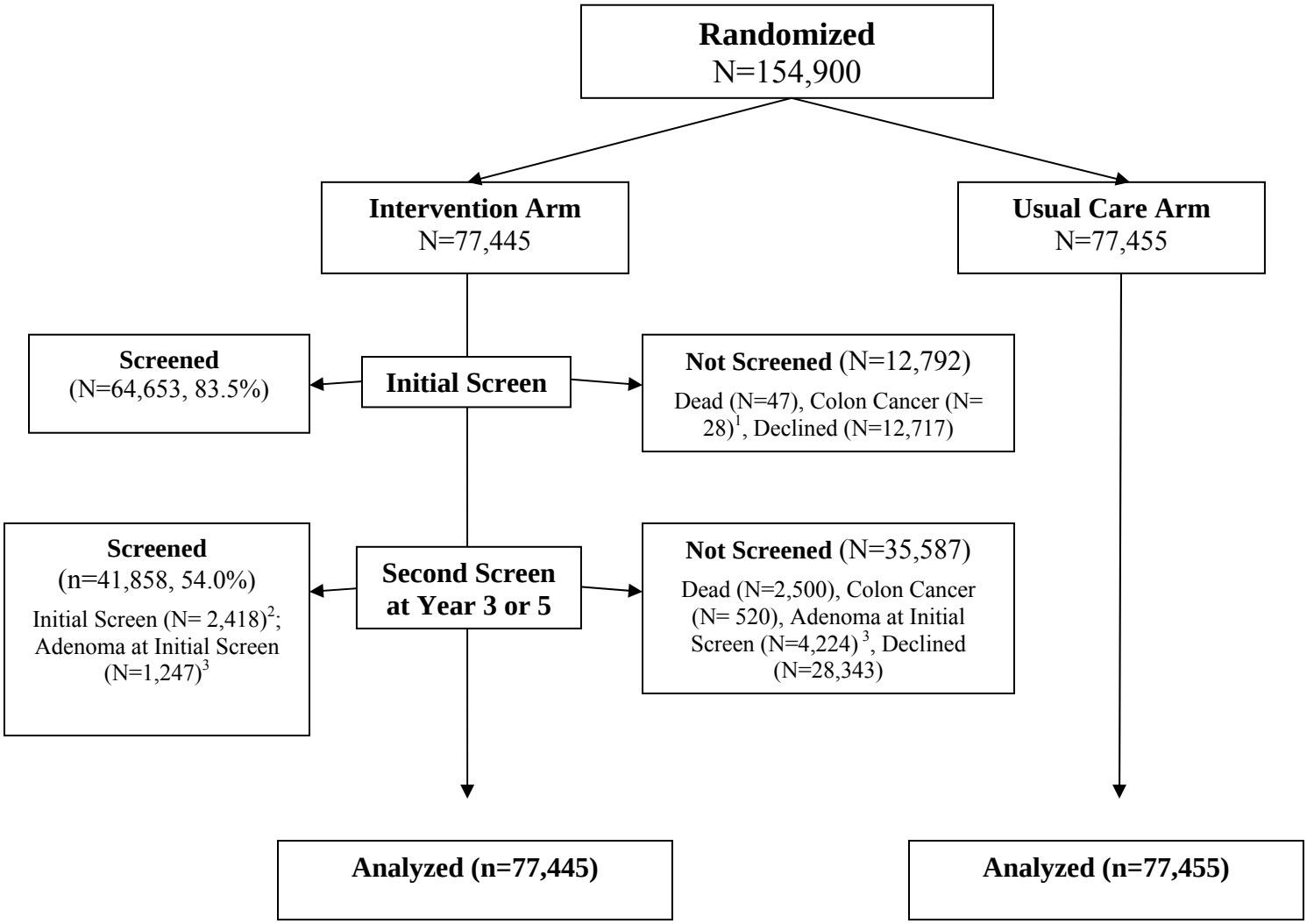

Figure S1 legend:

1. These patients were found after enrollment to have had preexisting diagnosis of colon cancer.
2. These subjects underwent their initial screening exam at year 3 or at year 5.
3. These subjects had an adenoma detected after an abnormal initial sigmoidoscopy screen. Some subjects with adenomas (1247/5471, 22.8%) returned for repeat screening.

Table S1: Primary Treatment by Stage in Intervention and Usual Care Arms

		Resection Alone		Resection and Chemotherapy and/or Radiation		Chemotherapy and/or Radiation without Resection		Total
		N	%	N	%	N	%	N
Stage								
Stage I	Intervention	297	90	27	8	6	2	330
	Usual Care	365	90	32	8	7	2	404
Stage II	Intervention	157	66	79	33	2	1	238
	Usual Care	193	63	109	36	5	2	307
Stage III	Intervention	29	12	211	88	1	0	241
	Usual Care	45	14	278	86	2	1	325
Stage IV	Intervention	22	17	85	66	21	16	128
	Usual Care	25	13	125	67	37	20	187
Total [1]		1133	52	946	44	81	4	2160

[1] There are 75 participants in the Intervention and 64 participants in the Usual Care arms for whom colorectal cancer stage and/or primary treatment information is not available.

Table S2: Location of Cancers in the PLCO Trial

	Intervention	Usual Care
Distal Colon	479	669
Rectum	190	240
Recto-Sigmoid	28	57
Sigmoid	195	292
Descending Colon	38	50
Splenic Flexure	28	30
Proximal Colon	512	595
Transverse Colon	82	83
Hepatic Flexure	50	81
Ascending Colon	176	202
Cecum	204	229
Unknown	21	23
Total		

Table S3: Death Certificate Cause of Death, Excluding Prostate, Lung, Colorectal and Ovarian Cancer Deaths, by Study Arm

	Intervention (N=77,445)	Usual Care (N=(77,455)
	N (%)	N (%)
Non-PLCO Cancers [1]	2266 (24.8)	2227 (24.2)
Ischemic heart disease	1623 (17.8)	1592 (17.1)
Cerebrovascular accident	545 (6.0)	546 (5.9)
Other circulatory disease[2]	1332 (14.6)	1411 (15.2)
Respiratory disease	1006 (11.0)	1012 (10.9)
Digestive disease	322 (3.5)	306 (3.3)
Infectious disease	205 (2.2)	190 (2.0)
Endocrine, nutritional and metabolic diseases and immunity disorders	362 (4.0)	381 (4.1)
Diseases of nervous system	356 (3.9)	375 (4.0)
Accident	470 (5.1)	480 (5.2)
Other	651 (7.1)	746 (8.0)
Total	9138	9286[3]

1.Excluding deaths from Prostate, Lung, Colorectal, and Ovarian cancer
2. Includes cardiovascular, arterial, and cardiopulmonary disease
3. Deaths from non PLCO cancers were similar in the two arms (RR 0.98, 95%CI 0.96-1.01, p=0.28)

Statistical Methods for Interim Monitoring of PLCO Colorectal Component

Differences in mortality rates were assessed using a weighted log-rank (WLR) test, incorporating increasing weights proportional to the pooled colorectal cancer mortality (1). A weighted statistic was chosen because of the presumed delayed effect of screening upon colorectal cancer mortality. Interim analyses were performed at least annually beginning in 2002 and were presented to the trial DSMB. The interim analysis plan, adopted by the DSMB, stipulated monitoring the WLR statistic for efficacy and futility. A one-sided efficacy boundary was constructed via the Lan-Demets procedure using an O'Brien-Fleming spending function and a total probability of type I error of 5% (2). Total weighted information was derived by projecting the time required to obtain 3796 events as stipulated in the design, which was determined to be roughly 21 years after the initial randomization using the method outlined in expression 8.9 of (3). Beginning with the 10th interim analysis, increments to the information fraction were modified to reflect linear growth in information with study termination at a maximum follow-up time of 13 years. In order to allow for early stopping due to lack of effectiveness or harm, the monitoring design also stipulated a non-binding futility boundary, constructed via the stochastic curtailment procedure (4).

At each interim analysis, we first calculated the weighted information fraction as the ratio of the current WLR statistic variance to the projected variance of the WLR statistic at the scheduled trial conclusion, $\tau = 13$ years. This end of trial variance was projected using the method outlined following expression 8.7 of [3]. We then calculated the one sided efficacy boundary point, b_k , according to the Lan-Demets procedure as indicated above. Next, a futility boundary point, a_k , was derived according to the stochastic curtailment procedure in the following way. The stochastic curtailment procedure for futility is based upon the conditional

$$\mathbb{P}_{\mathrm{H}_A}\{Z_\tau < b_{\mathrm{end}} | Z_{t_k}\} = \Phi\left(\frac{(b_{\mathrm{end}} - \mu(\tau)) - (\sqrt{f_k} Z_{t_k} - \mu(t_k))}{\sqrt{1 - f_k}}\right) \qquad (1)$$

probability under the design alternative hypothesis, $\boldsymbol{H}_A$, that the

end of trial WLR statistic will not reject the null given the current value of the WLR statistic at analysis k : for designs having a positive alternative hypothesis with slight modifications for

designs in which the alternative hypothesis is negative. In the above, Z_{t_k} ,is the current value of the WLR statistic, f_k , is the weighted information fraction, and $\mu(t_k)$ and $\mu(\tau)$ are values of the drift function at the current analysis and at the scheduled end of the trial, This conditional probability is compared to a threshold value, p_c, with values in excess being considered futility boundary crossings. The stochastic curtailment procedure is equivalent to a sequence of futility boundary points on the standard normal scale according to the following expression:

$$a_k = \frac{b_{\text{end}} - (\mu(\tau) - \mu(t_k)) - \sqrt{1 - f_k}\Phi^{-1}(p_c)}{\sqrt{f_k}}. \qquad (2)$$

We used the threshold value $p_c = 0.90$. The end of trial drift was projected using the design alternative logged relative risk log(0.90), under the constant shape assumption according corollary 4.3 of [3].

The sequential one sided p-value of the test statistic was derived using stage-wise ordering according expression 5.4 of [3]. The primary aim was summarized in the following way. Without unequal weighting of events, the test statistic and its sequential 95% confidence interval correspond via a scale change to the logged relative risk, β, and its sequential 95% confidence interval, CI. When unequal weighting is used, as in the present situation, such a relationship exists, but the prediction interval is now based upon a weighted average logged relative risk , β*, and its sequential 95% confidence interval, CI*. We report the usual logged relative risk, β, together with a confidence interval, centered about it, obtained from the sequential design. This choice, made a-priori, is based upon the greater conservatism, in this particular case, of the usual logged relative risk, β, as compared with the weighted average logged relative risk, β*.

Results

Interim Analyses

Values of the weighted information fraction, WLR statistic, and efficacy and futility boundary points are listed in table 2. The sign is consistent with a negative value of the alternative hypothesis, log(0.90)

Table 2: WLR statistic, weighted information fraction and efficacy and futility boundary points on the standard normal scale.

Analysis	*Wtd information fraction*	*WLR statistic*	*Efficacy Boundary*	*Futility Boundary*
1	0.0011	-0.067	-8.210	19.954
2	0.0019	0.325	-8.210	14.938
3	0.0031	0.317	-8.210	11.617
4	0.0069	0.023	-8.210	7.584
5	0.0090	-0.842	-8.210	6.534
6	0.0118	-1.421	-8.210	5.602
7	0.0182	-0.186	-8.210	4.318
8	0.0295	-1.454	-8.210	3.135
9	0.0444	-2.073	-8.210	2.279
10	0.3176	-4.077	-3.288	1.978

Test Statistic, P-value and Prediction Interval

The test statistic, -4.077, had a one-sided 95% sequential p-value of 2.15×10^{-5}. The logged crude relative risk and its two-sided 95% sequential confidence interval were determined to be –0.303 (-0.466 to -0.140). The weighted average logged relative risk and its two-sided 95% sequential confidence interval were determined to be -0.415 (-0.506 to -0.323). These results correspond to the second line of the algorithm summarized in table 1 which yielded –0.303 (-0.466 to -0.140).

Reference List

(1) Proschan MA, Lan KKG, Wittes JT. Statistical Monitoring of Clinical Trials: A Unified Approach. New York: Springer-Verlag; 2006.

(2) Demets DL, Lan G. The alpha spending function approach to interim data analyses. [Review] [84 refs]. Cancer Treatment & Research 1995;75:1-27.

(3) Izmirlian G. Estimation of the relative risk following group sequential procedure based upon the weighted log-rank statistic. ArXiv 2011 February. Available from: URL: http://arxiv.org/abs/1102.5088I

(4) Lin DY, Yao Q, Ying ZL. A general theory on stochastic curtailment for censored survival data. Journal of the American Statistical Association 1999;94(446):510-21.

PLCO Trial Investigators (*denotes former employee)

National Cancer Institute Staff and Consultants (Bethesda, Maryland)

Project Officer
Chief, Early Detection Research Group, DCP
Christine D. Berg, MD
John K. Gohagan, PhD, FACE*

Associate Project Officer and Senior Statistician
Chief, Biometry Research Group, DCP
Philip C. Prorok, PhD

PLCO Etiology and Early Markers Principal Investigator
Ann W. Hsing, PhD
James V. Lacey, Jr., PhD*
Mark Purdue, PhD
Richard B. Hayes, PhD*

Staff Scientist
Amanda Black, PhD, MPH
Wen-Yi Huang, PhD

Assistant Project Officer for Minority Issues
Nancy K. Simpson, ScM*

Assistant Project Officer
Richard Cumberlin, MD*
Susan Rossi, PhD, MPH*
Kelly Yu, PhD

Biorepository Manager
Claire Zhu, PhD

Biomedical Engineer
Guillermo Marquez, PhD

Coordinator and Assistant Project Officer
Joyce E.H. Browne*

Contracts Officer, RCB
Susan Hoffman

Contracts Specialist
Deborah Baca
Dorothy M. Coleman*
Charles Jackson*
Erin Lange*
Mary Loesch
Dorothy McMillan*
Evantha Papadopoulos*
Desiree Sylver-Foust*
Rachel Weiszer

Director of Communications
Dorothy Sullivan

Economist
Martin Brown, PhD

Program Specialist
Jennifer Gaegler
Linda Gray*
Amanda Hansborough

Director, DCP
Peter Greenwald, MD, DrPH

Director, DCEG
Joseph F. Fraumeni, JR., MD

Statisticians
Richard M. Fagerstrom, PhD
Ping Hu, PhD
Grant Izmirlian, PhD
David L. Levin, MD, MS*
Paul Pinsky, PhD
Jian-Lun Xu, PhD.

Epidemiologists
Aimee Kreimer, PhD*
Pamela M. Marcus, PhD, MS

Research Nutritionist
Amy F. Subar, PhD, MPH, RD*

Director, Division of Cancer Prevention
Peter Greenwald, MD, DrPH*
Barnett S. Kramer, MD, MPH

Senior Investigators
Patricia Hartge, ScD
Robert N. Hoover, MD, ScD
Regina G. Ziegler, PhD, MPH

Consultant
Richard Costlow, PhD*
Andrew F. Laine, DSc*
Anthony B. Miller, MB
Dinah Pearson, MHA*
John R. van Nagell, MD*

Collaborators, Centers for Disease Control and Prevention

Fred L. Stallings, MD, MPH*
Daniel S. Miller, MD*

Central Laboratory (LAB): University of California at Los Angeles (Los Angeles, California)

Principal Investigator
David Chia, PhD
Sarah Dry, MD
David Seligson, MD
Paul Terasaki, PhD*

Coordinator
Jean Reiss, MT
Sheila Tze

Laboratory Technician
Andrew Acalinovich*
Stefan Besada
Henry Chan, MS
Gardenia Cheung-Lau
Shaun Corbett*
Patty Durongwong
Mervi Eeva
Labo Folayan
Bianca Gruebel
Omar Habeeb
Kiet Huynh*
Cindy Kanegai*
Helen Kim*
Sarang Kim
Ara Ko
Sean Kohlmeier*
Cassandra Lamb
Marianne Lu, MT*
June Martin, MT*
Scott Maynard*
Fred Noravian*
Osvaldo Schirrippa
Gabriel Padilla*
Alexis Rumbin
Linda Shevlin
Rica Ty*
Qun Wang
Joanne Wong*
Shuang Xu
Hong Yu

Biorepository and Biorepository Processing Lab (Frederick, Maryland)

Coordinator
Janis Koci, BS

Laboratory Coordinator
William Kopp, PhD

Laboratory Supervisor
Helen Rager

Laboratory Research Technician
Craig Smith
Dave Roser

Coordinating Center (CC): Westat, Inc. (Rockville, Maryland)

Corporate Officer
Jack Cahill, MA

Project Director
Barbara O'Brien, MPH
Susan Gardner, PhD*

Deputy Project Director
Danielle Carrick, PhD
Susan Yurgalevitch, MS, MPH
Marsha Dunn, MPH*

Study Manager
Cheryl Bailey, MPH*
Yancy Bodenstein, MPH*
Peggy Burr, MPH, PA-C*
Jacqueline Cutrin*
Joseph Eisen, MPH*
Amena Frias, MPH*
Sara Glashofer, MPH*
Kathy Hurt-Mullen, MPH*
Katie Kavounis, MPH
Polly Ke
Fauzia Khanani*
Benjamin Laimon, MBA*
Leah Mechanic, PhD, MPH*
Mary Mesnard
Leah Nichaman*
Shama Novey, MBA*
Cindy Palace, MPH*
Steve Peace*
Karen Pettit
Stuart Pratt, MPH*
Lawrence Ragard, MD
Jennifer Rosenbaum, MPH*
Demaris Sanchez, MPH*
Shari Schuman*
Mark Stewart, MPH*
Mary Beth Waterman, MPH*

Systems Manager
Keith Umbel
Donna Ferrantello, MPA*
Bobbie Havel, MS*

Systems Director
Marsha A. Hasson, MS

Data Manager
Beth Bridgeman
Ellen Martinusen
Mary Sabastianelli*

Coordinator
Amy Miller, MPH
Fay Menacker, PhD*
Mollie Miedzinski, MPH*

Research Assistant
Shaima Chowdry
Lindsay Miesko
Cathy Lease*
Melinda Rinehart*

Systems Staff
Maks Agamir*
Kamla Awatramani*
John Barbee*
William Christopher Barlow*
Donna Beach*
Barbara Bradley
Karen Brenner
Lois Butler*
Joel Bristor, MS*
Clifford Caughman, MS*
Ramachandra Chanapatna
Linda Cranson*
Jerry Desir, MA*
Katheryn Donegan, JD*
John Fleming*
Michael Florczyk
Jeff Galyon*
Christopher Gordon, MS*
Cheol Han, MS*
Aubrey Hendricks*
Donna Hickman*
Maggie Ho
Elizabeth Jackson, MA*
Dalia C. Kahane, PhD
Asia Khan, MPH
Mei Laio
Annabelle Lee, MLS*
Ben Lott
Donna Lucas-Mudd, MS*
Diane Moore*
Alan Morgan
Gabriel Neagu
Peter Ohan*
Margarita Revzin, MS *
Joseph Rychlec
Reza Samiel*

Erin Siford
Desiree Simons, MSc
Matthew Smith *
Liyun Swei
Elias Theodorou*
Aleksandr Vakhlis
Judith H. Walsh*
Blaine Wenzel, MS

Marianne Whitlock, MBA, MA *
Steve Williamson*
Maureen Wu, MS*
Cheng-Lan Yang*
Sekou Yoda
Maureen Wu, MS

NOVA Research Company (Bethesda, Maryland)

Project Manager, Biostatistician
Max H. Myers, PhD*

Deputy Project Director
Paul A. Young, MBA, MPH*

Project Manager/Senior Analyst
Denise A.R. Lewis*
Robert W. Francis Jr, PhD*

Project Coordinator/Statistical Analyst
Lori A. Saunders, MA*
Carmita Signes*

Systems Analyst/Programmer
Susan Scheck, MSLS*

Information Management Systems, Inc. (Rockville, Maryland)

Corporate Officer
William Lake, Jr., BA

Project Manager
Thomas Riley, BS

Senior Systems Analyst
Joe Austin, BS
Diane E. Erwin, MA
Doug Flynn
Jerome E. Mabie, BS

System Analyst
Jonathan D. Clapp, BS*
Matthew R. Moore, BS
FangFang Xu, MIS

Senior Programmer/Analyst
Gordon C. Jones, MS
Joshua M. Rathmell
Craig R. Williams
Michael Young, BS

Programmer/Analyst
Andrew Goodman, BS
Thomas P. Hickey

Senior Programmer
John M. Commins
Patrick Wright

Programmer
Sally K. Shaul

University of Colorado Denver (Denver, Colorado)

Principal Investigator
E. David Crawford, MD

Project Coordinator
Sheryl L. Ogden, RN

Coordinator Hispanic Recruitment/Retention
Sally Tenorio, RN

Nurse Screener
Peggy Fyles, RN
Diane Golz, RN*
Stacy Hommel, RN*
Deborah McCormick, RN*
Gale Pashleigh, RN*
Nancy Slimak, RN*
Nancy Turner, RN*

Data Coordinator
Nicole Green Ayodeji*
Denise Josse*
Julie McAfee*
Eric Meskimen*
Jenny Pennington*
Wendy Suchey*

Data Manager
Mashal Ali-Ahmadi*
Amy Wheeler Barnett*
Jennifer Brothers*
Nicole Davis Chronister*
Danielle Cipolla*
Ryan Crawford*
Sung Chun*
Karina Gebhart*
Jhenny Hernandez
Helen Hunter*
Kanak Patel
Wendy Poage*
Meegan Pozzetta*
Shayna Simms*
Jeff Swingler*
Cory Taylor*
Marie Turner*
Ariana Wallack*

Nosologist
Kathleen Curtis
Darlene Pierce

Medical Record Abstractor
Patricia Vallejos Borrego

Recruiter
Chris Rundus*

Eloise Bonde*

Recruitment/Retention Coordinator
Eduard Gamito* (deceased)

Retention Coordinator
Shannon Pretzel

Administrative Assistant
Joanne Dahmer*
Terri Deines*
Monica Geske*
Marcia Holladay*
Helen Jackson*
Tammy Jordan*
Eda Ordonez*

Student Assistant
Tia Beechum*
Marc Crawford*
Kristi Dittmer*
Alicia Donohue*
Felicia Garcia*
Scott Giese*
Amy Klenfield
Melissa Kleinman*
Wendy Moss*
Kayo Motomiya*
Roger Murken*
Dana Neel*
Javan Quintela
Carrington Razook*
Ali Shoaga*
Andrew Thompson*
Stephanie Vargas*

Radiologist
David Lynch, MD
Martin O'Driscoll, MD*
Ron Townsend, MD*
Elizabeth Stamm, MD*

Sonographer
Julia Drose, RDMS, RDCS*

Gynecologist/Oncologist
Susan Davidson, MD

Gastroenterologist
Dennis Ahnen, MD*

Joel Levine, MD*
William Murchison, MD*
Steve Steinberg, MD*

Georgetown University (Washington, DC)

Principal Investigator
Edward P. Gelmann, MD*
Claudine Isaacs, MD

Study Coordinator
Colleen McGuire, RN, MSN
Nina Trocky, RN, MSN, CAN*

Recruitment Coordinator
Christopher Bourdeau

Nurse Examiner
Polly Ke, RN

Data Manager
Laura Martino, BS
Ipatia Apostolides*
Constance Elbon-Copp, M.Ed.*
Kimberly Klemm *
Catherine Lippman*

Medical Secretary
Carol Klotz
Tanita McLaurin*

Project Assitant
Tanja Williams
Johnsonette Ginyard

Medical Record Abstractor
Sara Cantrell, CTR*
Gigi Marsh, ART, CTR*
Amy Tran, BS*
Chrispina Wray, CTR
Baigalmaa Yondonsambu, CTR

Medical Technologist
Ciro Taddeo

Recruitment Coordinator
Kathleen Bennett*
Tracy Bowen*
Kathryn English*
Kimberly Seaton*

Retention and Operations Coordinator
Tiffanie Hammond, BS
Morgan Ford, MS*
Kate Newman, MA*

Nurse Examiner
Meg Kren, RN*
Nancy English, RN*
Dianne McKenzie, RN*

Pacific Health Research Institute (Honolulu, Hawaii)

Principal Investigator
Lance A. Yokochi, MD, MPH
Fred Gilbert, MD* (deceased)

Investigators
David Curb, MD, MPH*
James Davis, PhD
Bruce Kessel, MD
James Navin, MD
Helen Petrovich, MD
Vicki Shambaugh, MA, MPH
Frank Tabrah, MD
Beth Waitzfelder, PhD
Bradley Willcox, MD

Project Coordinator
Victoria Jenkins, BSN, MEd
Rachelle Chasnoff*
Joanne Vander Does*
Jamaal Martin, MPH*
Barbara Ideta*

Examiner
Kim Stryker, RN*
Elsie Batangan*
Liz Dolan*
Kristin Horton*
Karen Taylor*
Ted Tokumine, RN*

Recruitment
Rebecca Troyer*
Sarah Barrow*
Susan Hayashida*
Shirley Commander*
June Morfit
Joy Tani
Kathy Banggo*
Amy Brunst*
Wendy Francis*
Leslie Grove*
Brooke Holderbaum*
Kim Kinney*
Melanie Ogino
Teresa O'Sullivan*

Medical Research Associate
Peggy Rowan-Lau, RN*

Abstractor
Kathleen Bow, RN, CTR
Helene Shiratori, RN
Jean Tsukamoto, RN
Helene Hodges, CTR*
Shirleen Hyun*
Julia Kuiee, CTR*
Lori Lucente, CTR*
Pat Oshiro, CTR*
Kathy Shota*

Data Manager
Louisa Turner

Data Assistant
Gladys Hino
Esther Nakano
Myrle Johnson
Lilian Villaruz
Anne Chung*
William Huynh*
Nika Hickey*

Research Assistant
Marilyn Calulot
Victoria Chun
Cheryl Lewis

Henry Ford Health System (Detroit, Michigan)

Principal Investigator
Paul A. Kvale, MD
Raymond Demers, MD*
Ronald Fogel, MD*
Wilmer Rutt, MD*

Co-principal Investigator
Christine Cole Johnson, PhD, MPH
Lois Lamerato, PhD, MS
Robert S. Bresalier, MD*

Coordinator
Karen Broski

Investigator
Sharon Hensley-Alford, PhD
Marvella E. Ford, PhD*
Jennifer Elston LaFata, PhD*
Bruce McCarthy, MD*
Richard Ward, MD*

Data Manager
Tara Andrews
Margie Day*
Lynn M. Flickinger, MA*
Teresa Hantz
Dorothea Talley*
Diana Wilson*

Epidemiologist
Angela Blount, MPH*
C. Martin Tammemagi, PhD, DVM

Abstractor
Nimisha Goswami
Wendy Haykus
Angela Piasecki
Claudia Barr*
Timothy Hall*
Sherrie Stanifer*
Patricia Baker*
Rita Montague*

Clerical Staff
Charlotte Day*
Anna Nanovski*
Cynthia Hill*
Teresa Boles*
Audrey Witherspoon*
Gina Banks*
Karen Green*
Kathy Bernardin*
Paul Kozlowski*
Jan Wells*
Holly Salisbury*
Anne Shepard*
Jackie McKeeman*
Tonya Jeffery*
Cherice Castor*
Markieta Boswell*

Data Management Support Staff
Claire Hooker
Lisa Ingram
Dojna Mototolea
Nora Szabo
Mylitta Gardner
Claire Hooker
Noel Maddy*
Juanita Morris*
Judith Berlicz*
Tavia Bonds*
Shelley Fountain*
Millie Williams*
Boban Djuric*
Mylitta Gardner*

Screening Center Staff
Christine Cross*
Deborah Emmer, BSN*
Fran Jagger, RN*
Amena Johnson*
Linda McCarver, RN*
Melissa Scharbonneau*
Virginia Thomas*
Marquetta Norwood*
Madeline Mobley, MSN*
SueAnn Kokko, MSN*
Darlene Doute, MSN*
Karen Ciccoretti, RN*
Karen Wilkinson Wright, RN*
Pamela Shabazz, RN*
Anna Leyson-Fiel, RN*
Kathy Pratt, RN*
Mary Bailey*

University of Minnesota (Minneapolis, Minnesota)

Principal Investigator
Timothy R. Church, PhD
Jack Mandel, PhD, MPH*

Co-principal Investigator
Martin M. Oken, MD

Study Coordinator
Deb Engelhard, MA

Clinic Coordinator
Jill Cordes, RN

Clerical Staff
Peggy Bradley
Carol Hansen*
Joshua Kokubu
Ryan Lee
Gabrielle Meyer
Heather McLaughlin*
Krista Palmquist
Nissa Sandley
Brad Sigal
Tanya Barnes, BA*
Michelle Fleishhacker, BA*
Jason Grengs, BA*
Shannon Hebner*
Michael Lewis, MLS*
AnaMaria Mendez*
Deanna Miller*
Jennifer Nielsen, AS
Lori Theis*

Computer Staff
Ann Bangerter*
Donna DesMarais
Natalya Portnov
Greg Silverman
Frank Strahan
Simone Vuong
Gavin Watt, BA
Aaron Zirbes
Ann Fredrickson, BA*
Richard Hoffbeck, BA*
Robert Murzyn*
Joseph Woodside, MA, PhD*

Clinic Nurse
Patricia Beckmann, RN
Mark Boldt, RN
Linda Jurjans, RN
Susan Swenson, RN
Shirley Terrien, RN

Fiscal Coordinator
Jim Fisher

Research Fellow/Assistant
Mindy Geisser
Steve Mongin
Christina Oancea
Ricky Jansen

Phoning Staff
Sophie Breer
Susan Collins
Janet Manuel
LeAnn Matous
Lois Miller*
Candace Muller
Phyllis Olsson
Susan Peterson
Mary Lynn Steele
Susan Tonnell
Jennifer Halverson, BS*
Margaret Hanna*
Jan Hathaway-Ott*
Betty Harper*
Helen Hunter, BA*
Judy Lindall-Hawkins, MA*
Cathy Longen, BA*
Shirlyn Nickelson*
Doris Overby*
MaryAnn Rodier*
Barbara Smith*
Virginia Weiner*

Medical Record Abstractor
Mary Clement*
Cheri Haselhuhn
Darlene Heath
Elaine Julin
Nita Michels*
Linda Naslund
Surekha Pagidipala*
DeeAnn Swavely, RN
Carla Syktta*
Deborah Warren

Clinic Clerical Staff
Jann Sitarz
Carol Steinberg
JoAnn Thomas

Laboratory Technologist

Jeff Burrell
Linda Sandell

Equipment Processor
Scott Helevik
Mark Hoard

Washington University School of Medicine (St. Louis, Missouri)

Principal Investigator
Gerald L. Andriole, MD

Coordinator
Adelheid A. Lowery, RN, MS*
Elaine Freesmeier

Study Coordinator
Elaine Charlton, RN*
Ann Desai, RN*
Vivien Gardner, RN, BSN*

Data Manager
Debbie Stanczak*
Kathy Taylor*

Clinical Coordinator
Karen Civitelli, RN*
Katherine Ehrhard, RN*
Patricia Nieters, RN*

Recruiter
Cindy Hilke, BA*
Kate Phillips*
Wanda Robinson, BA
Michelle Wehde*

Part-Time Recruitment Staff
Carol Branam*
Kristin Freesmeier*
Candy Kane*
Sharon Murphey*
Dave Royal*
Joann Scire*

Data Entry Staff
Kelly Bickford*
Elizabeth Fleming
Julie Goforth*
Deborah Graham*
Jane Montani*
Kate Naughton*
Becky Palumbo*
Jayne Sicard-Su*

Examiner
Rita Blanke, RN
Pat Cashel, LPN*
Kelly DeFord, MA*
Kourtney Liddy, RN*
Angela Lieberoff, RN, BSN*
Karen Nelson, MA*
Lisa Reismeyer, RN*
Barb Ritter, RN*
Shelly Robertson, RN*
Shelly Standbrook, RN*
Darlene Stilts, RN*

Lead Medical Record Abstractor
Janise Webb, RHIT, CTR

Medical Record Abstractor
Kathy Carrett, RHIT
Sydney Laster, CTR
Celia Stolin*

University of Pittsburgh Cancer Institute (Pittsburgh, Pennsylvania)

Principal Investigator
Joel L. Weissfeld, MD, MPH

Co-principal Investigator
Robert E. Schoen, MD, MPH

Co-investigator
Lyndon Hill, MD*
Thomas Hakala, MD*
Richard Guido, MD*
Carl Fuhrman, MD*
Wylie Overly, MD*
Julian W. Proctor, MD*
Matthew Sulecki, MD*
Mark Trombetta, MD*

Coordinator
Betsy Gahagan, BSN, CTR

Recruiter
Janet Bonk, RN, MPH*
Mary Yagjian*
Roni Gitchel, BS* (deceased)

Data Manager
Pam Sufka
Kathleen McDonough

Clinic Staff
Kathleen Carl *
Janet Gongloff*
Terry Karl, BSN*
Carol Lucas, RN*
Lynn Lytle, RN*
Marcia Sibbet*
Judy Weinstein*

Data Coordinator
Betty Coopie*
Lucinda Dyjak
Lettie Johnson
Jan Kielty*
Ginny Landis*
Sue Misko
Peggy Oleson*
Mary Ritman

Medical Record Abstractor
Lisa Clement, CRNP
Ann Danvers, CRNP*
Mary Alyce Riley, CRNP*

University of Utah Health Sciences Center (Salt Lake City, Utah)

Principal Investigator
Saundra S. Buys, MD

Coordinator
Lisa H. Gren, MSPH

Recruitment Staff
Jeffery Childs
Adriane Andersen*
Jennifer Bacon*
Marie Bossi*
Laura Briscoe*
Mark Broschinsky*
Bill Callahan*
Thomas Conner*
Jenni Ernst*
Rachel Fischer, MSPH*
Jeremy Gregersen*
Nickolas Hamatake*
Chris Hamatake*
Amity Henrichsen*
Nikole lhler*
Lesli Jensen*
Kara Jones*
Lindsay Killian*
Mindy Liddle*

Mary Lochner*
Alie Monaco*
Robert Morreal*
Amy Nate*
Kimberly Nolan*
Cassie Olson*
Andee Park*
Shannon Ricks*
Scott Sheltra*
Alina Stewart*
Lisa Sturges*
Julie Sullenger*
Kristi Taylor*
Chris Toyn*
Eduard Van Stam*

Data Entry Staff
Neil Argyle*
Jeff Christensen
Sue Bennett*
Jeremy Biggs*
Donna Branson*
Melanie Bryson*
Brandon Childs*
Cherie Dalton
Brian Doi
Jenifer Doi*
Susan Foss*
Paulina Gudgell*
Linda Hicks*
Polly Hsu*
Devon LaMay*
Chani Montalbo*
Linda Newman*
Anne Randall
Judy Thompson*
Karen Schliep*
Kasey Stanfield*
Darcy Watson*
Linda Newman*

Marcia Reese*
Brianne Whittaker*
Nathan Whittaker*
Eddy Wicklander
Jake Wolf*

Medical Record Abstracting Staff
Julie Varner, CTR, CPC
Niela Bennett, CTR*
Michele Bonoacci, CTR, RHIT*
Angela Harper, RHIT*
Sandra Reay, CTR*

Clinical Staff
Kathleen McFadden, BSN*
Karen O'Toole, RN
Toni Butcher*
Darrelle Walker, BSN*
Johathan Richardson, MA*
Howard Hong, BSN*
Barbara Lund, RN*
Jennifer Rowley*
Jon Tlachac*
John VanRy*
Crystal Walker, RN*

Examiner Training and Quality Assurance
Blake Hamilton, MD*
Richard Labasky, MD*
Stewart Landau, MD*
Richard Middleton, MD*
Robert Stephenson, MD*

University of Utah Satellite, St. Luke's Mountain States Tumor Institute (Boise, Idaho)

Satellite Principal Investigator
Thomas M. Beck, MD

Coordinator
Lisa Sturges, MSPH*
Bonita Wohlers, MS, RN

Data Entry
Kathy Berreth*

Pamela Roberts*

Clinical Staff
Patricia Carter, RN*
Dawn Goodman*
Gena Hagerman, MA*
Tiffany Hon, RN*
Janette Marshock, RN*
Rolanda Martin, BSN*

Transvaginal Ultrasonographers
Carole Jamieson, RDMS, RVT*
Andrea Arnone, RDMS*
Dalene Davis, RT, RDMS*
Kathleen Dennis, RDMS*
Deanna Hanson, RDMS*
Jan Hyder, TR*
Doug McCraney, RDMS*
Kevin Michel, RDMS*
Farzaneh Shahriari, RT*
Lisa Sirianni, RT*

Radiologists
Todd Bruce Burt, MD*
Charles R. Carrasco, MD*
Elaine N. Daniel, MD*
Richard H. Lane, MD*
Peter A Langhus, MD*
Craig E. Leymaster, MD*
James R. Maxwell, MD*
Ray M. Thorpe, MD*
Brent D. Nelson, MD*
Steven V. Marx, MD*
Bruce Hubler, MD*
John S. Waltz, MD*
Quinn A DeMordaunt, MD*
Michael T. Fisher, MD*

Examiner Training and Quality Assurance
Paul Battershall, NP*
Louis Burke, PA-C*
Lorranine Fortunati, NP*
John M Werdel, MD*

Marshfield Medical Research and Education Foundation (Marshfield, Wisconsin)

Principal Investigator
Douglas Reding, MD, MPH, FACP

Co-investigator
Robert Greenlee, PhD
William Hocking, MD

Study Coordinator
Karen Lappe, BSN

Clinical Research Manager
Deborah Multerer

Health Educator/Recruiter
Virginia Fischer, MS*

Systems Support Specialist
Juline C. Heiting*
Cathy Mueller*

Certified Medical Assistant
Kay Mathiesen-Viergutz, CMA

Adminstrative Secretary
Kari Bohman*
Laurel Carey*

Nurse Clinician/Medical Abstractors
Amy Vieth, BSN
Kelly Aue, BSN*
Denise Kriescher, RN*
Claudia Miller, BSN*
Norma Thums, BSN*
Sheila Wein, BSN*

Licensed Practical Nurse
Karen Kofka, LPN*

Certified Tumor Registrar
Karen Luttropp

Cancer Control Clerk
Camille Mueller*

Appointment Coordinator
Brenda Dix*
Lin Mueller*
Kathy Swensen*
Shirley Wachholz*

Data Entry Clerk
Ranae Kramer
Becky Bright*
Sue Zahradka*

University of Alabama at Birmingham (Birmingham, Alabama)

Principal Investigator
Mona Fouad, MD, MPH
Albert Oberman, MD, MPH*

Co-investigator
Edward Partridge, MD (Ob/Gyn)
Donald Urban, MD (Urology)
Catarina Kiefe, MD, PhD
James Shikany, DrPH

Project Manager
Darlene Higgins

Recruitment Coordinator
Joanice Thompson

Retention Coordinator
Mel Johnson

Clinic Coordinator, Flex Sigmoidoscope Examiner
Alisha Moore, CRNP*
Beverly Powell, CRNP*

Data Manager
Billy McCoy*
Christie Oden

Medical Record Abstractor, Transvaginal Ultrasound Examiner
Rekha Khatri, CTR

Clinic Coordinator
Margaret Pike, RN

Cancer Institute of Brooklyn at Maimonides Medical Center (Brooklyn, New York)

Principal Investigator
Sameer Rafla, MD, PhD*

Coordinator
Annette Angelone, RN*

Recruitment Manager
Vivienne DeStefano*

Data Manager
Jerry Varkey*

Project Coordinator Sandra Watson*

Director, Cancer Control
Josephine M. DiVernieri*