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# The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status

John K. Gohagan, PhD, FACE, Philip C. Prorok, PhD,  
Richard B. Hayes, PhD, and Barnett S. Kramer, MD, MPH  
for the PLCO Project Team\*

*Division of Cancer Prevention (J.K.G., P.C.P., B.S.K.) and Division of Cancer Epidemiology and Genetics (R.B.H.), National Cancer Institute, Bethesda, Maryland*

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**ABSTRACT:** The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is enrolling 148,000 men and women ages 55–74 at ten screening centers nationwide with balanced randomization to intervention and control arms. For prostate cancer, men receive a digital rectal examination and a blood test for prostate-specific antigen. For lung cancer, men and women receive a posteroanterior view chest X-ray. For colorectal cancer, men and women undergo a 60-cm flexible sigmoidoscopy. For ovarian cancer, women receive a blood test for the CA125 tumor marker and transvaginal ultrasound. Members of the control arm continue with their usual care. Follow-up in both groups will continue for at least 13 years from randomization to assess health status and cause of death. The primary endpoint is mortality from the four PLCO cancers, which accounts for about 53% of all cancer deaths in men and 41% of cancer deaths in women in the United States each year. Blood specimens are collected from screened participants, buccal cell DNA from controls, and histology slides from cases; these are maintained in a biorepository. Participants complete a baseline questionnaire (covering health status and risk factors) and a dietary questionnaire. More than 12,000 participants were enrolled in the pilot phase (concluded in September 1994). Changes in the eligibility criteria followed. As of April 2000, enrollment exceeded 144,500. Data are scanned into designated on-site computers for uploading by participant identification number to the coordinating center for quality checks, archival storage, and preparation of analysis datasets for use by the National Cancer Institute (NCI). Scientific direction is provided by NCI scientists, trial investigators, external consultants, and an independent data safety and monitoring board. Performance and data quality are monitored via data edits, site visits, random record audits, and teleconferences. The PLCO trial is formally endorsed by the American Cancer Society and has been ranked by the American Urological Association

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\* See appendix for a roster of the project team.

Address reprint requests to: Dorothy Sullivan, Early Detection Research Group, Division of Cancer Prevention, National Cancer Institute, EPN 330, 6130 Executive Blvd., Bethesda, MD 20892-7346 (E-mail: ds255j@nih.gov).

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as one of the most important prostate cancer studies being conducted. Special efforts to enroll black participants are cosponsored by the U.S. Centers for Disease Control and Prevention. *Control Clin Trials* 2000;21:251S–272S © Elsevier Science Inc. 2000

**KEY WORDS:** *Randomized trial, screening, prostate cancer, colorectal cancer, lung cancer, ovarian cancer, minorities, etiology, biomarkers*

## HISTORY

In the 1980s, transrectal ultrasound was advertised by clinics as an effective method to detect early prostate cancer, with the implication or assumption that the chance of cure would be increased by early detection. The essential elements of one such ad are included in Figure 1. Dr. Gerald Chodak, a University of Chicago urologist, approached Dr. David P. Byar (deceased), urologist and chief of the National Cancer Institute (NCI), Division of Cancer Prevention and Control (DCPC) Biometry Branch, with concerns that the data available did not support the claims being made in the ads. He argued that the NCI had an obligation to determine through scientific investigation both the effectiveness and risks of such early detection practices, whether by transrectal ultrasound or other technologies.

Thus began an arduous 2-year period of inquiry, data analysis, and deliberations that evolved through intensive internal and external critique into a clinical trial designed to answer the fundamental question posed by Dr. Chodak. The design of the trial evolved from the single focus of assessing the effect of prostate (P) cancer early detection technologies in a necessarily large population of older men to include lung (L) and colon (C) cancer early detection technologies in the same population of men (the PLC Cancer Screening Trial).

The design concept for the PLC trial began in September 1989 at the NCI in the DCPC Biometry and Early Detection Branches [since renamed the Biometry and Early Detection Research Groups of the Division of Cancer Prevention (DCP)]. Through the summer of 1989, discussions were held with the DCPC Board of Scientific Counselors (BSC) and experts in prostate, lung, and colorectal cancers and screening trials. Data on approximately 1800 men who had had digital rectal examination (DRE), prostate-specific antigen (PSA) determinations, and transrectal ultrasound were analyzed, resulting in a decision to delete ultrasound as a primary screening modality because it contributed very little to cancer detection beyond PSA and DRE. The DCPC BSC approved the PLC trial concept on October 12, 1989 [1,2].

Procedures to award contracts to perform the trial were initiated, and a request for proposals for the data management and coordinating center was issued in May 1990. However, in August 1990 the NCI Executive Committee stopped the PLC trial until women were added or a parallel trial for women was developed because lung and colorectal cancers affect women as well as men. Redesign efforts were initiated immediately over a wide range of options, including separate trials for men and women for single or multiple cancer sites. Because ovarian (O) cancer, though rare, is the most life-threatening urogenital cancer in women, commonly being fatal by the time it is clinically evident, the option of including ovarian screening in the trial was also considered. A workshop of gynecologists convened to deliberate the issue of screening for ovarian cancer initially recommended a pretrial investigation to better determine the detection properties of ovarian cancer screening modalities before

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**Figure 1** Prostate ultrasound ad.

launching a screening trial, but further investigation determined that a study population nearly as large as that needed for a screening trial would be required for the pretrial investigation. The recommended pretrial investigation could be conducted more efficiently within a full-scale screening trial. Consequently, ovarian cancer screening was added to the PLC trial concept to create the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, which was approved by the DCPC BSC in January 1991 [3, 4]. Contracts were awarded competitively for ten screening centers (SCs), a central laboratory (LAB), and a coordinating center (CC) in 1992, and the protocol development phase of the trial began in October 1992. The concept for a PLCO biorepository to accumulate blood products for early detection biomarker and etiology research was approved in October 1992 by the DCPC BSC and integrated into the trial [5].

The multiyear effort outlined above entailed extensive deliberations regarding a variety of issues pertinent to the design of the PLCO, including the disease burden of the cancers involved, the state of development of the proposed screening tests, whether the trial should involve a single or multiple cancer sites, compatibility with other proposed trials (including efforts outside the United States), and the window of opportunity during which it would still be possible to undertake a trial in the face of increasing clinical utilization of the unproven cancer screening technologies being evaluated in the PLCO. Also considered were the value of negative as well as positive results, implementation of the results of the trial should one or more of the tests prove to be of benefit, costs of the trial, and costs of the screening process to the medical care system.

## **TRIAL RATIONALE**

In various forms (see, for example, Kramer et al. [6]), the following qualitative criteria are widely appreciated as necessary conditions for engaging in cancer screening in asymptomatic individuals:

1. The disease should be a substantial public health burden.

2. An asymptomatic, nonmetastatic phase of disease should be recognizable.
3. An acceptable screening procedure with adequate accuracy must be available.
4. The treatment of screen-detected disease must reduce disease-specific mortality.

All but the fourth criterion were satisfied, as discussed below, for the four cancers under consideration. The PLCO was designed to determine whether disease-specific mortality would be reduced by screening for these cancers using the most promising screening tests available. Secondary analyses include stage, screening test operating characteristics, survival, costs, risks, etiology, and disease natural history.

Lung and colorectal cancers are among the most common cancers in American males and females. Together they account for about 41% of cancer deaths in males and 36% of cancer deaths in females. In males, the prostate is the second most common cancer site, accounting for approximately another 11% of cancer deaths. In females, ovarian cancer accounts for an additional 5% of cancer deaths. It has been estimated that 28,500 deaths in women and 27,800 in men from colorectal cancer will occur in 2000 and, respectively, 67,600 and 89,300 deaths from lung cancer. About 14,000 women will die from ovarian cancer and 31,900 men from prostate cancer [7].

Death rates for prostate and colorectal cancers remained relatively constant for many years, while the death rate for lung cancer continued to rise rapidly in both sexes, more so in women [7]. The rise in prostate cancer mortality, on the tail of the rapid rise in incidence consequent to widespread introduction of PSA screening in the 1990s, and its subsequent decline to (or slightly below) its prior temporal trend have been extensively investigated, but the pattern cannot adequately be explained, nor can its future trajectory be predicted from existing data sources [8–11]. Lung cancer death rates among white American men had begun to decline in the 1990s, presumably due to cigarette smoking cessation, but concurrent increased initiation of smoking among teenagers could in time reestablish the upward trend. The death rate for ovarian cancer continues to rise, though slowly. Because over 67% of ovarian cancers present as advanced disease with poor prognosis and some reports indicate that early disease may have as much as a 90% cure rate [12], successful screening programs for these cancers could possibly have a major impact on cancer mortality.

Uncertainty regarding the relative harms and benefits of screening for these cancers has resulted in conflicting positions in the medical community and confusion in populations at risk. The PLCO randomized, controlled trial was designed to resolve the uncertainties by determining the effects of screening on disease-specific mortality and the balance of benefits against diagnostic and treatment-related morbidities and costs [13–18].

## ORGANIZATION AND MANAGEMENT

The organization of the PLCO is shown in Figure 2. Overall management of the trial is provided by NCI project officers. The principal investigators (PIs) of each of the ten SCs direct their respective operations and, with NCI project officers, constitute a steering committee for the trial. The senior NCI project

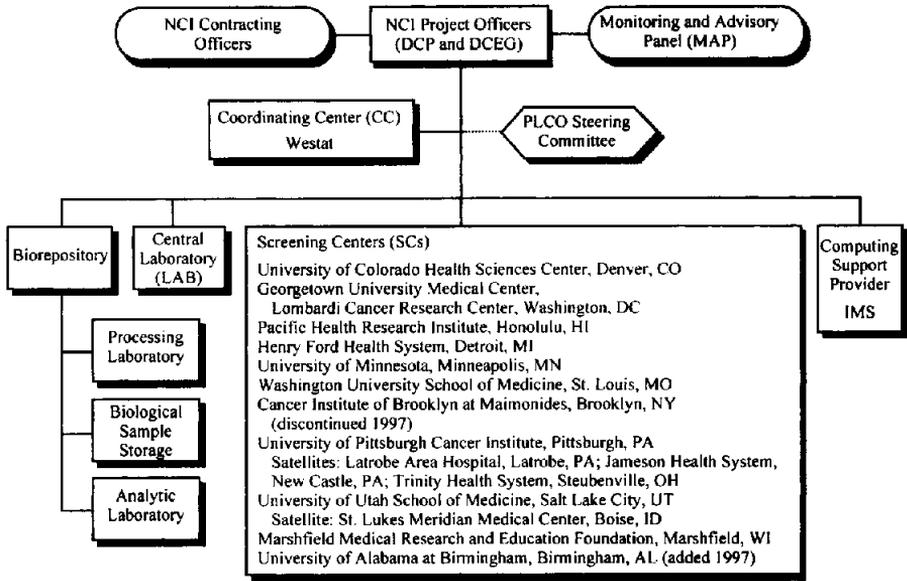


Figure 2 PLCO organization.

officer chairs the steering committee. SC PIs chair all working groups and subcommittees. The NCI contracting officers have legal authority for the trial and work closely with the project officers. A data safety and monitoring board of independent organ site experts, statisticians expert in clinical trial design and conduct, and consumers provide external oversight. This board is called the Monitoring and Advisory Panel (MAP). Data management, quality assurance, operations oversight, systems management, and coordination are provided by the CC [19]. All reported deaths are reviewed by an independent team of experts to establish cause [20].

The NCI and the CC routinely monitor all trial activities including recruitment, screening, diagnostic evaluation, cancer diagnosis, and annual health status information by on-site observation and auditing of participant files, as well as through computerized data quality assurance analyses. The PLCO steering committee meets at least annually to review data and discuss the progress of the trial and outstanding protocol issues. The MAP convenes once a year to review data and make recommendations regarding conduct and continuation of the trial. Subcommittee meetings and working group sessions are conducted at steering committee meetings and throughout the year via teleconference as issues need to be addressed. The PIs and NCI staff meet twice each year, once at the steering committee meeting and once separately, to review data and plan scientific manuscripts. A list of key personnel involved in the PLCO is given in the appendix.

**DESIGN**

The PLCO is a 23-year, two-armed randomized trial in which 37,000 men will be screened for lung, colorectal, and prostate cancers and 37,000 women

**Table 1** Design of the PLCO

Randomization	Intervention Arm	Control Arm
148,000	37,000 men PSA: annual T0-T5 DRE: annual T0-T3 XRY: annual T0-T3 FSG: T0 plus T3 or T5	37,000 men Usual care
	37,000 women CA125: annual T0-T5 TVU: annual T0-T3 OVR: annual T0-T3 XRY: annual T0-T3 FSG: T0 plus T3 or T5	37,000 women Usual care

T0 = the initial baseline screening examination; T3, T5 = the third and fifth annual screening re-examinations; PSA = prostate-specific antigen (Hybritech Tandem R); DRE = digital rectal examination; XRY = posteroanterior chest X-ray (T3 exam discontinued April 1999 for all who "never smoked"); FSG = 60-cm flexible sigmoidoscopy (changed from T3 to T5 in April 1999); CA125 = cancer antigen 125 modified (Centocor CA125 II); TVU = transvaginal ultrasound; OVR = palpation of the ovaries (discontinued in April 1999).

will be screened for lung, colorectal, and ovarian cancers. The design is summarized in Table 1. An equal number of men and women participating as controls will continue their usual medical care practices. The eligible age range at entry is 55-74 years. Both screened and control participants are to be followed for at least 13 years from randomization for cancer and death ascertainment to determine if screening results in reduced disease-specific mortality.

Screening modalities being investigated include PSA and DRE (for prostate), chest X-ray (for lung), 60-cm flexible sigmoidoscopy (for colon), and CA125 blood test and transvaginal ultrasound (for ovary). Intervention participants are screened for all appropriate cancers at one visit of approximately 2-hours duration annually. All aspects of the trial are documented in the PLCO manual of operations and procedures (MOOP).

Baseline information on demographic characteristics, known risk factors for the cancers under study, and screening history are collected from all participants. Blood samples collected at each screening visit are processed into multiple products and stored for future molecular analyses, as are buccal cell DNA collections from control participants. Participants in both the intervention and control arms complete a dietary questionnaire. All participants also provide annual health status information. Further details of the protocol are provided elsewhere in this supplement [5, 19, 21, 22].

Statistically, the trial has approximately 90% power to detect a 20% reduction in mortality from prostate cancer and a 10% reduction in lung cancer mortality. Power is estimated at 99% to detect a 20% reduction in colorectal cancer mortality. For ovarian cancer, which is much less common than the others, power is estimated at 88% to detect a 35% mortality reduction. Power calculations included adjustments for expected contamination by participants not adhering to the protocol.

As part of the pilot phase (September 30, 1992 to September 29, 1994), enrollment began on November 16, 1993. Observations of these "vanguard"

participants and subsequent monitoring of main-phase (September 30, 1994 to present) participants by the NCI and the MAP led to several modifications of protocols. Major changes include the following:

1. Most data collection forms were changed to an optical-mark format to facilitate data entry and thus improve the quality of the data collected.
2. Following the evaluation of the pilot phase, eligibility criteria were changed to exclude all men with more than one PSA test in the past 3 years and all men and women with any endoscopic or radiologic colorectal examination in the past 3 years, resulting in a successful reduction in contamination from these sources.
3. A change in the eligible age range was made in January 1996 on the advice of the MAP, which felt that men (and women) in the 55–59 age range would be likely to receive treatment for prostate (and ovarian) cancer and had the potential for a substantial gain in life years and, therefore, should be included along with the original participants ages 60–74.
4. Questions related to routine screening were eliminated from the Periodic Survey of Health Questionnaire to decrease the risk of encouraging contamination in the control arm.
5. A Health Status Questionnaire was developed for annual administration to a random sample of 1000 men and women to assess contamination in the control arm.
6. In response to a recommendation from the MAP, women without ovaries were made eligible for the trial effective October 1996 to assure that PLCO goals are met for lung and colorectal cancers, which have a high mortality and incidence in American women. Prior to this change, women were disproportionately found to be ineligible for participation due to prior oophorectomy.
7. In December 1998, ovarian palpation was discontinued, the interval for flexible sigmoidoscopy was modified from baseline (T0) and third annual re-examination (T3) to T0 and fifth annual re-examination (T5), T3 X-ray was discontinued for participants who never smoked, PSA and CA125 were continued through T5, biorepository blood collections were continued through T5, and follow-up was extended for 3 additional years.

## DATA MANAGEMENT

The PLCO data entry and editing system (DEES) and study management system (SMS) networks were designed and installed by the CC. Initially conceived as a small, three-computer system for trial management and keyed data entry, the concept was revised during the protocol development phase to accommodate remote data entry from machine-readable standard forms with accompanying edits, reports, uploads to the central data repository on a specified schedule, and remote upgrades and maintenance incorporating five to seven computers, multiple printers, and a scanning unit at each SC. Interfacing systems are maintained at the central LAB and the biorepository. The details of the DEES and the SMS are provided elsewhere in this supplement [22].

**Table 2** PLCO Analysis Plan

Analyses	Project Years
Population characteristics	2-10
Coverage and compliance	3-15
Screening yield	3-15
Contamination	3-15
Diagnostic follow-up	4-23
Etiology	4-23
Incidence and prevalence	6-23
Screen test characteristics	6-20
Cancer characteristics	6-23
Stage of disease	6-23
Case survival	7-23
Lead time	8-20
Advanced stage rate	7-23
Mortality rates	7-23

Uploaded data receive quality assurance checks at the CC and are subjected to correction by each contributing SC before being forwarded to the central computer. The individual SCs also archive their data. All clinical data are maintained only at the SCs in hard copy, and participant identifying information is collected and maintained in secure areas occupied exclusively by PLCO staff at the SC to ensure privacy and to facilitate clinical follow-up. SCs ship blood serum to the LAB (and blood products to the biorepository) weekly and, on a designated day weekly, interrogate their password-protected files on the LAB's PLCO server to read out the PSA and CA125 assay results. Reports of screening results for all exams are computer generated at the SCs and edited as necessary before mailing to participants and their physicians within 4 weeks after screening. Annual surveys of health status are computer generated for mailing to all participants. Annual on-site record audits are conducted by the NCI with the CC and consultants using a standardized process. Results are recorded and reviewed with investigators to ensure quality. Cases are selected randomly beforehand and revealed to the SC only upon request to pull the file for the site visitors. Medical record abstracting of diagnostic and treatment follow-up of positive screens and cases diagnosed in the control arm is standardized and under the direction of certified personnel at the SCs.

The CC, under the direction of the NCI's senior PLCO statistician, prepares summary tables on a periodic basis for monitoring trial progress and quality of data archived. A computing support provider under contract to the NCI furnishes additional statistical and analytic support. A staged analysis plan (Table 2), which tracks with the anticipated accumulation of trial data, guides the analytical effort. Quality control measures are taken at many steps in the data process. These are described in more detail elsewhere in this supplement [23].

## SPECIAL STUDIES

Important scientific investigations ancillary to the PLCO, but ideally suited to the context and enrichment of the screening trial and its associated biorepository, are conducted under contract modifications or in some cases with PLCO

PI collaboration under grant support. Mechanisms and committees to review ideas ensure that only suitable and scientifically relevant projects that will not negatively impact on the operations and mission of the trial are advanced. Special projects approved include a collaboration with a manufacturer regarding a free PSA assay, SC collaborations on cost-effectiveness and quality of life assessments, a comparison of virtual colonoscopy with endoscopy, analysis of minority recruitment, and studies of molecular markers.

## RECRUITMENT STATUS

The PLCO trial began project year eight on September 30, 1999. As of April, 2000, about 144,500 of the targeted 148,000 participants had been randomized with one and a half years of scheduled recruitment remaining. The SCs are continuing expansion of their direct mail operations, the most effective recruitment strategy, and there is coordination of local promotion with national promotion efforts conducted by the NCI's Office of Cancer Communications as described in the accompanying recruitment paper [24]. The trial is endorsed by the American Cancer Society, and the Prostate Disease Clinical Trials Subcommittee of the American Urological Association has ranked it the second most clinically and scientifically important ongoing prostate cancer trial in the country, second to the randomized Prostatectomy Intervention Versus Observation Trial (PIVOT) sponsored by the Veterans Administration. The Centers for Disease Control and Prevention, as described elsewhere in this supplement [25], is sponsoring projects to enhance minority recruiting and is cofunding with the NCI the PLCO minority-focused SC at the University of Alabama at Birmingham [24]. Recruitment is enhanced because of these positive relations, though the numerical impact is impossible to assess.

## INTERNATIONAL COLLABORATIONS

Clinical trials to determine the effect of periodic screening for prostate, colorectal, and ovarian cancers have been launched separately in Europe. The European and American teams are formally collaborating in prostate cancer trials and have formed the International Prostate Studies Evaluation Group (IPSTEG). Investigators conducting prostate trials in the United States, the Netherlands, Belgium, Sweden, Finland, Portugal, Italy, and Spain, along with scientific representatives from the United Kingdom and Canada who serve on IPSTEG committees, meet annually to review data and commission publications [26,27]. The formation of a similar collaboration with investigators in the United Kingdom conducting ovarian cancer screening trials is anticipated. These collaborations offer many advantages as discussed in a recent paper by Miller for IPSTEG [28]. A similar incipient collaboration exists between the PLCO and investigators conducting an ovarian cancer screening trial in the United Kingdom.

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**APPENDIX PLCO TRIAL INVESTIGATORS**

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**National Cancer Institute Staff and Consultants (Bethesda, Maryland)**

Project Officer Chief, Early Detection Research Group, DCP John K. Gohagan, PhD, FACE	Program Specialist Jennifer Gaegler
Associate Project Officer and Senior Statistician Chief, Biometry Research Group, DCP Philip C. Prorok, PhD	Program Assistant Linda Gray
Associate Project Officer for Etiology and Early Markers Environmental Epidemiology Branch, DCEG Richard B. Hayes, PhD	Director, DCP Peter Greenwald, MD, DrPH
Assistant Project Officer for Minority Issues Nancy K. Simpson, ScM	Deputy Director, DCP Barnett S. Kramer, MD, MPH
Assistant Project Officer Susan Rossi, PhD, MPH*	Statistician Richard M. Fagerstrom, PhD David L. Levin, MD, MS Paul Pinsky, PhD
Coordinator and Assistant Project Officer Joyce E.H. Browne	Epidemiologist Pamela M. Marcus, PhD, MS
Contracts Officer, RCB Susan Hoffman	Research Nutritionist Amy F. Subar, PhD, MPH, RD
Contracts Specialist Dorothy M. Coleman Erin Lange Dorothy McMillan Desiree Sylver-Foust*	Senior Investigator Regina G. Ziegler, PhD, MPH
Information Officer Dorothy Sullivan, BS	Consultant Richard Costlow, PhD Andrew F. Laine, DSc Anthony B. Miller, MB Dinah Pearson, MHA John R. van Nagell, MD
Economist Martin Brown, PhD	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 Paul Terasaki, PhD*	Laboratory Technician Andrew Acalinovich Henry Chan, MS Kiet Huynh* Helen Kim* June Martin, MT Scott Maynard* Fred Noravian Gabriel Padilla Joanne Wong*
Coordinator Jean Reiss, MT	

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*(continued)*

**APPENDIX** *Continued***Biorepository and Biorepository Processing Lab (Frederick, Maryland)**

Coordinator Janis Koci, BS	Laboratory Supervisor Helen Rager
Laboratory Coordinator William Kopp, PhD	Laboratory Research Technician Craig Smith Dave Roser

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

Corporate Officer Jack Cahill, MA	Systems Staff William Christopher Barlow Lois Butler Donna Beach Joel Bristor, MS Clifford Caughman, MS Linda Cranson Jerry Desir, MA Katheryn Donegan, JD John Fleming Annabelle Lee, MLS Ben Lott Jeff Galyon Kamla Awatramani Erin Siford Christopher Gordon, MS Cheol Han, MS Bobbie Havel, MS Aubrey Hendricks Donna Hickman Elizabeth Jackson, MA Dalia C. Kahane, PhD Asia Khan, MPH Donna Lucas-Mudd, MS Diane Moore Alan Morgan Margarita Revzin, MS Joseph Rychlec Marianne Shitlock, MBA, MA Matthew Smith Elias Theodorou Judith H. Walsh Blaine Wenzel, MS Steve Williamson Maureen Wu, MS
Project Director Barbara O'Brien, MPH Susan Gardner, PhD*	
Deputy Project Director Marsha Dunn, MPH	
Study Manager Cheryl Bailey, MPH* Peggy Burr, MPH, PA-C Sara Glashofer, MPH* Kathy Hurtmullen, MPH* Katie Kavounis, MPH Leah Nichaman* Cindy Palace, MPH Karen Turk Susan Yurgalevitch, MS, MPH	
Systems Manager Donna Ferrantello, MPA	
Systems Director Marsha A. Hasson, MS	
Data Manager Beth Bridgeman	
Coordinator Fay Menacker, PhD* Mollie Miedzinski, MPH	
Research Assistant Cathy Lease* Melinda Rinehart* Jennifer Rosenbaum	

*(continued)*

**APPENDIX** *Continued***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)**

Project Manager  
William Lake, Jr.

Senior Systems Analyst  
Thomas Riley

Programmer/Analyst  
Joe Austin  
David DeFrancesco\*  
Dianne Depuy

Programmer  
Sean Brennan  
James Edgington\*  
Ariel Kaplan  
Jeannine Prothero

**PLCO Death Review Committee**

Anthony B. Miller, MB (Chair)  
Division of Clinical Epidemiology  
Deutsches Krebsforschungszentrum

Peter Albertson, MD  
Associate Professor and Chief of Urology  
University of Connecticut

Mario Eisenberger, MD  
Johns Hopkins Oncology Center

Eli Gladstein, MD  
Professor, Vice Chairman and Clinical  
Director  
Department of Radiation Oncology  
University of Pennsylvania Medical  
Center

**University of Colorado Health Sciences Center (Denver, Colorado)**

Principal Investigator  
E. David Crawford, MD

Project Coordinator  
Sheryl L. Ogden, RN

Coordinator Hispanic Recruitment  
Sally Tenorio, RN

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

*(continued)*

**APPENDIX** *Continued*


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<b>Data Coordinator</b> Nicole Green Denise Josse Julie McAfee Eric Meskimen Jenny Pennington Shannon Lewis Pretzel Wendy Suchey	<b>Administrative Assistant</b> Joanne Dahmer Terri Deines Monica Geske Marcia Holladay Eda Ordonez
<b>Data Manager</b> Mashal Ali-Ahmadi Jennifer Brothers Danielle Cipolla Ryan Crawford Karina Gebhart Wendy Poage Meegan Pozzetta Jeff Swingler Cory Taylor	<b>Student Assistant</b> Felicia Garcia Carrington Razook Stephanie Vargas Kristi Dittmer Roger Murken Ali Shoaga
<b>Nosologist</b> Kathleen Curtis Darlene Pierce	<b>Data Entry</b> Tammy Jordan
<b>Medical Records Abstractor</b> Patricia Bargas Chris Rundus	<b>Radiologist</b> David Lynch, MD Martin O'Driscoll, MD Ron Townsend, MD
<b>Recruiter</b> Eloise Bonde Eduard Gamito	<b>Sonographer</b> Julie Drose, RDMS, RDCS
	<b>Gynecologist/Oncologist</b> Susan Davidson, MD
	<b>Gastroenterologist</b> Joel Levine, MD Steve Steinberg, MD
 <b>Georgetown University (Washington, DC)</b>	
<b>Principal Investigator</b> Edward P. Gelmann, MD	<b>Data Manager</b> Laura Martino, BS Ipatia Apostolides* Constance Elbon-Copp, MEd* Kimberly Klemm* Catherine Lippman*
<b>Study Coordinator</b> Colleen McGuire, RN, MSN	
<b>Recruitment Coordinator</b> Christopher Bourdeau	<b>Medical Secretary</b> Carol Klotz Tanja Williams
<b>Nurse Examiner</b> Polly Ke, RN	

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*(continued)*

**APPENDIX** *Continued*

Medical Record Abstractor  
Gigi Marsh, ART

Medical Technologist  
Ciro Taddeo

Study Coordinator  
Nina Trocky, RN, MSN, CAN\*

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

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)

Associate Principal Investigator  
David Curb, MD, MPH

Assistant Principal Investigator, Quality Assurance  
Michael Kusaka, MD, MPH

Coinvestigator, Radiology Quality Assurance and  
Interpretation  
Virgil Jobe, Jr., MD  
Robert May, MD

Coinvestigator, Transvaginal Ultrasound Quality  
Assurance  
Roy Nakayama, MD

Coinvestigator, Recruitment  
Helen Petrovich, MD

Coinvestigator, Recruitment, Veterans Administration  
Robert Whang, MD

Coinvestigator, Recruitment, Tripler Army Medical  
Center\*  
Jeffrey Berenberg, MD  
Harrison Hassell, MD

Coinvestigator, GI/Flexible Sigmoidoscopy, Training  
William Hartman, MD

Coinvestigator, Prostate, Training  
Walter Strode, MD  
Stephen Chinn, MD

Coinvestigator, Cancer Abstracting  
Reginald Ho, MD  
Reuben Guerrero, MD

Coinvestigator, Epidemiology  
Loic Le Marchand, MD, PhD  
Robert Worth, MD, PhD

Research Director  
Vicki Shambaugh

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

Examiner  
Kim Stryker, RN  
Ted Tokumine, RN  
Elsie Batangan  
Heidi Estrada\*  
Kristin Horton\*  
Karen Tayler

Recruitment Research Coordinator  
Rebecca Troyer  
Sarah Barrow\*

Recruiter  
Susan Hayashida\*  
Shirley Commander\*

Recruitment Assistant  
Kathy Banggo\*  
Kim Kinney\*

Data Manager  
Louisa Turner

Data Assistant  
Gladys Hino  
Esther Nakano  
Nika Hickey\*

Research Assistant  
Arlene McCafferty\*  
Danni Kim\*  
Brooke Holderbaum\*

*(continued)*

**APPENDIX** *Continued*

Medical Research Associate  
Peggy Rowan

Abstractor  
Helene Hodges  
Lori Lucente

**Henry Ford Health System (Detroit, Michigan)**

Principal Investigator  
Raymond Demers, MD  
Ronald Fogel, MD\*  
Wilmer Rutt, MD\*

Coprincipal Investigator  
Robert S. Bresalier, MD  
Christine Cole Johnson, PhD, MPH

Coordinator  
Karen Broski

Investigator  
Marvella E. Ford, PhD  
Bruce McCarthy, MD  
Jennifer Elston LaFata, PhD  
Richard Ward, MD\*

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

Epidemiologist  
Lois Lamerato, MS  
Angela Blount, MPH  
C. Martin Tammemagi, PhD, DVM

Abstractor  
Timothy Hall\*  
Claudia Barr  
Sherrie Stanifer

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

Data Support Staff  
Noel Maddy  
Judith Berlicz\*  
Tavia Bonds  
Shelley Fountain  
Millie Williams  
Boban Djuric

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

*(continued)*

**APPENDIX** *Continued***University of Minnesota (Minneapolis, Minnesota)**

Principal Investigator Timothy R. Church, PhD Jack Mandel, PhD, MPH*	Phoning Staff Darcie Baxter Jennifer Halverson, BS Margaret Hanna Jan Hathaway-Ott Betty Harper Helen Hunter, BA Judy Lindall-Hawkins, MA Cathy Longen, BA Janet Manual Shirlyn Nickelson Phyllis Olsson Doris Overby MaryAnn Rodier Betty Sanders Barbara Smith Virginia Weiner
Coprincipal Investigator Martin M. Oken, MD	Medical Record Abstractor Mary Clement, RN Nita Michels, RN Cheri Reinhold, AS DeeAnn Swavely, RN
Study Coordinator Deb Engelhard, MA	Clinic Clerical Staff Jann Sitarz JoAnn Thomas
Clinic Coordinator Jill Cordes, RN	Laboratory Technologist Jeff Burrell Linda Sandell
Clerical Staff Tanya Barnes, BA Michelle Fleishhacker, BA Jason Grengs, BA Shannon Hebner Michael Lewis, MLS AnaMaria Mendez Deanna Miller Jennifer Nielsen, AS Lori Theis	Equipment Processor Scott Helevik
Computer Staff Donna DesMarais Ann Fredrickson, BA Mindy Geisser, MS Richard Hoffbeck, BA Robert Murzyn Gavin Watt, BA Joseph Woodside, MA, PhD	
Clinic Nurse Patricia Beckmann, RN Mark Boldt, RN Linda Jurjans, RN Susan Swenson, RN Shirley Terrien, RN	

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

Principal Investigator Gerald L. Andriole, MD	DataManager Debbie Stanczak* Kathy Taylor
Coordinator Adelheid A. Lowery, RN, MS	Clinical Coordinator Katherine Ehrhard, RN Karen Civitelli, RN*
Study Coordinator Elaine Charlton, RN* Ann Desai, RN*	

*(continued)*

**APPENDIX** *Continued***Recruiter**

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

**Data Entry Staff**

Kate Naughton  
 Julie Goforth  
 Elaine Freesmeier  
 Jayne Sicard-Su

**Examiner**

Angela Lieberoff  
 Shelly Robertson  
 Patty Nieters  
 Karen Nelson

**Medical Record Abstractor**

Janise Webb  
 Celia Stolin

**University of Pittsburgh Cancer Institute (Pittsburgh, Pennsylvania)****Principal Investigator**

Joel L. Weissfeld, MD, MPH

**Coinvestigator**

Lyndon Hill, MD  
 Thomas Hakala, MD  
 Richard Guido, MD  
 Carl Fuhrman, MD  
 Wylie Overly, MD  
 Julian W. Proctor, MD  
 Robert E. (Rocky) Schoen, MD, MPH  
 Matthew Sulecki, MD  
 Mark Trombetta, MD

**Coordinator**

Betsy Gahagan, RN, BSN

**Recruiter**

Janet Bonk, RN, MPH  
 Mary Yagjian

**Data Manager**

Pam Sufka

**Nosologist**

Sharon Winters, MS, RRA, CTR

**Abstractor**

Lisa Clement, CRNP  
 Mary Alyce Riley, RN  
 Kathy Carl, MA  
 Betty Coopie  
 Ann Danvers, CRNP  
 Lucinda Dyjak  
 Roni Gitchel  
 Janet Gongloff, MA  
 Terry Karl, RN  
 Jan Kielty  
 Ginny Landis  
 Carol Lucas, RN  
 Lynn Lytle, RN  
 Kathy McDonough  
 Sue Misko  
 Peggy Oleson  
 Marcia Sibbet

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

Sandra S. Buys, MD

**Coordinator**

Lisa H. Gren, MSPH

**Clinical Staff**

Kathleen McFadden, BSN  
 Karen O'Toole, RN  
 Jonathan Richardson, MA  
 John VanRy  
 Howard Hong, BSN\*  
 Barbara Lund, RN\*

**Recruitment Staff**

Jeffery Childs  
 Thomas Conner  
 Nikole Ihler  
 Marc Morgan  
 Bill Callahan\*  
 Rachel Fischer, MSPH\*  
 Nicolas Hamatake  
 Jill Stephenson\*  
 Eduard Van Stam\*  
 Kara Jones\*

*(continued)*

**APPENDIX** *Continued***Data Entry Staff**

Niela Bennett, CTR  
 Celeste Bennett  
 Michele Bonacci, CTR, ART  
 Cherie Dalton  
 Brian Doi  
 Jennifer Doi  
 Susan Foss  
 Paulina Gudgell  
 Anne Randall  
 Judy Thompson  
 Julie Varner  
 Darcy Watson  
 Donna Bell, CTR, ART\*  
 Donna Branson\*  
 Darrelle Green\*  
 Angela Harper, CCS\*  
 Polly Hsu\*  
 Mary Ann Lochner\*  
 Amy Nate\*  
 Linda Newman\*  
 Marcia Reese\*  
 Bonnie Schreck, CCS\*

**Examiner Training and Quality**

Assurance  
 Catherine Babcock, MD  
 Randall Burt, MD  
 Mark Dodson, MD  
 Maryellyn Gilfeather, MD  
 Marc Gosselin, MD  
 Harry Hatasaka, MD  
 Anne Kennedy, MD  
 Richard Labasky, MD  
 Stewart Landau, MD  
 Valerie Logsdon, MD  
 Richard Middleton, MD  
 Kathleen Murray, MD  
 Peggy Norton, MD  
 Keith Tolman, MD  
 Paula Woodward, MD  
 David Bragg, MD\*  
 Anthony Doyle, MD\*  
 Nathan Markowitz, MD  
 Shari McGuire, RN\*  
 David Smotkin, MD\*  
 Roya Sohaey, MD\*

**Examiner**

Hector Ahumada, RT  
 Randy Bate, RT  
 Lynn Batty, RN  
 Adaire Blair, RN  
 Carol Bowcutt, RN  
 Kathy Colosimo, RT  
 Dale Clukey, RT  
 Naomi Cummings, RT, RDMS  
 Lynn Dolan, RT, RDMS  
 Kathleen Donner, RT, RDMS  
 Dianne Engleby, RT, RDMS  
 Andrew Hypio, RT  
 Sally Kopesec, RT  
 Janine Maurice, RT  
 Robert Medema, RT  
 Lezlie Morrison, RT, RDMS  
 Jillyn Myers, RT, RDMS  
 Alexis Nieves, RT  
 John Parsons, RT  
 Camille Phillips  
 Kathleen Pruden, RN  
 Nicole Sacco, RT  
 Ellen Sandberg, RT  
 Dave Scholl, RT  
 Johanna Simon, RT, RDMS  
 Bradley Sorenson, RT  
 Patrick Spaulding, RT  
 Catherine Townsend, RT, RDMS  
 Marcie Walters, RT  
 Becky Weintraub, RT, RDMS  
 Ida Williams, RT, RDMS  
 Ruth Zollinger, RT, RDMS  
 Ross Anderson, RT\*  
 Cathy Familo, RT\*  
 Chrisanne Foster, RT\*  
 Sherian Garrett, RT\*  
 Eric Glaus, RT\*  
 James Glinka, RT\*  
 Katrina Harris, RT\*  
 Julie Hebert, RT\*  
 Rob Jones, RT student\*  
 Trent Larsen, RT\*  
 Becky MacKay, RT\*  
 Jerry McPhie, RT\*  
 Blake Neeley, RT\*  
 Frank Pate, RT\*  
 John Pugmire, RT\*  
 Bridget Quintana, RT\*  
 Brad Ruffing, RT\*  
 Steve Sawyer, RT\*  
 Steven Vliestra, RT\*  
 Kathleen Warlick, RT\*

*(continued)*

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

## Satellite Principal Investigator

Thomas M. Beck, MD

## Coordinator

Lisa Sturges, MPH

## Data Entry

Pamela Roberts

## Clinical Staff

Patricia Carter, RN

Tiffany Hon, RN\*

Janette Marshock, RN\*

Rolanda Martin, BSN

## Examiner Training and Quality Assurance

Paul Battershell, RN

Todd B. Burt, MD

Charles R. Carrasco, MD

Elaine N. Daniel, MD

Lorraine Fortunati, LPN

Richard H. Lane, MD

Peter A. Langhus, MD

Craig E. Leymaster, MD

James R. Maxwell, MD

Avery L. Seifert, MD, FACS

Patrick Schow, MD

Ray Thorpe, MD

Donald Walker, MD

John Werdel, MD

## Examiner

Andrea Carole Arnone, RDMS

Jennifer M. Bassura, RT

Lori E. Blakely, RT

Barry R. Clot, RT

Troy Cook, RT

Kathleen Dennis, RDMS

Carol Jamieson, RDMS, RVT

Arthur J. Kerbein, RT

Cindy I. Lewis, RT

Dalene Lewis, RT

Doug J. McCraney, RDMS

Ray May, RT

Candace Prestwich, RT

Cheryl L. Whistler, RT

**Marshfield Medical Research and Education Foundation (Marshfield, Wisconsin)**

## Principal Investigator

Douglas Reding, MD, MPH, FACP

## Coinvestigator

Paul Gunderson, PhD

## Study Coordinator

Karen Lappe, BSN

## Supervising Physician of Health Screen Unit

Terry Wahls, MD

## Radiologist—Transvaginal Ultrasound Subcommittee

Gerald Mulligan, MD

## Administrative Services Coordinator

Deborah Multerer

## Health Educator/Recruiter

Virginia Fischer, MS

## Systems Support Specialist

Juline C. Haralson

## Nurse Clinician

Norma Thums, BSN

Amy Stendel, BSN

Claudia Miller, BSN

## Licensed Practical Nurse

Karen Kofka

## Administrative Secretary

Cathy Mueller

## Cancer Control Clerk

Kay Janssen

Camille Mueller

## Appointment Coordinator

Shirley Wachholz

Brenda Dix

Christina Bores

## Data Entry Clerk

Sue Zahradka

Becky Bright

*(continued)*

**APPENDIX** *Continued***University of Alabama at Birmingham (Birmingham, Alabama)**

Principal Investigator  
Albert Oberman, MD, MPH

Coprincipal Investigator  
Mona Fouad, MD, MPH

Coinvestigator  
Edward Partridge, MD (Ob/Gyn)  
Donald Urban, MD (Urology)  
Katarina Kiefe, MD, PhD

Project Manager  
Darlene Higgins

Recruitment Coordinator  
Joanice Thompson

Clinic Coordinator, Flexible  
Sigmoidoscope Examiner  
Alisha Moore, CRNP

Data Manager  
Billy McCoy

Medical Record Abstractor,  
Transvaginal Ultrasound Examiner  
Rekha Khatri, MD

Clinic Coordinator  
Lisa Amaro, 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\*

\* denotes former employee.