**Attachment 9: Assurances of Compliance: Certification of IRB Review**

Westat | An Employee-Owned Research Corporation

# Memo

**Date:** March 28, 2011

**To:** Barbara O'Brien, Project Director

**From:** Kerry Levin, Chair Westat IRB Kerry Levin

**Subject:** **Initial Approval of PLCO CDCC, Project 8906**
**FWA 05551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **PLCO CDCC, Project 8906.** The Westat IRB reviews all studies involving research on human subjects. This project is sponsored by National Cancer Institute. This study received full review and approval by the NCI SSIRB on November 16, 2009.

Westat will serve as the Central Data Collection Center (CDCC) for the 18 year old Prostate, Lung, Colorectal, and Ovarian (PLCO) cancer screening trial. Their responsibilities will include all active data collections with participants, physicians, and medical records and pathology departments for those PLCO participants who agree to be followed by Westat for five additional years.

All previously enrolled PLCO participants who agree to continued follow-up by the CDCC will participate in the study. As part of the planned phase-out of the ten PLCO screening centers (SCs), and following their own IRB's review and approval, SCs will notify or re-consent their PLCO study participants to allow for their data to be transferred to Westat for continued active follow-up.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before March 28, 2012.
- In the interim, notify the IRB Office as soon as possible if there are any injuries to subjects as well as problems or changes with the study that relate to human subjects.

cc: Institutional Review Board
Nancy Weinfield

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
uchsc.edu/comirb [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

# Protocol Amendment Approval

19-Apr-2011

| | |
|---|---|
| **Investigator:** | E Crawford |
| **Sponsor(s):** | National Cancer Institute/NIH/DHHS~ |
| **Subject:** | COMIRB Protocol 93-377 Amendment |
| **Effective Date:** | 15-Apr-2011 |
| **Title:** | NATIONAL CANCER INSTITUTE PROSTATE, LUNG, COLORECTAL AND OVARIAN (PLCO) CANCER SCREENING TRIAL |

## Amendment Description:

PAM007-2
1. Notification letter was revised to be one page with an additional page for participants to note their choice of follow-up option.
2. The plan for follow-up of Spanish-speaking participants was revised to include mailing a letter to participants notifying them of the change to the study and giving them 2 options: (1) passive follow-up by UCD PLCO or (2) withdrawal from the study.
3. waiver of consent is not required, so attachment M is not included.
4. The Protocol Summary was amended to add a statement regarding participants who will be followed passively by default. Because adequate consent has been obtained for continued long-term follow-up, no waiver of consent is required.

Attachments:
1. COMIRB Feedback letter
2. Change Form (as originally submitted)
3. revised letter to participants
4. Letter to Spanish-speaking participants
5. Revised Protocol Summary

## Review Comments:

PAM007-2
Minor modifications completed and requested PAM007 is approved.
Note: The Spanish consent can now be translated from English to Spanish. Please submit this on a change form along with the translator's credentials prior to use.

Sincerely,
UCD Panel A

MedStar Health
Research Institute

**MedStar Health Research Institute-Georgetown University Oncology**
**Institutional Review Board**

Date: May 10, 2011

To: Claudine Isaacs, MD
Hematology/Oncology
Washington, DC 20057

From: Diana Armanca
Project Coordinator
Institutional Review Board

Title: Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial

IRB#: 1993-276

Annual Approval Date: February 23, 2011

Expiration Date: February 22, 2012

Action: Expedited Amendment/Modification
PLCO Screening Center Closeout and Centralized Administration of Follow-up of Participants
Letter from the Department of Health & Human Services dated April 11, 2011 re: screening center closeout and centralized administration of follow-up of participants in the PLCO trial.
Attachment A: NCI SSIRB Approval for centralized administration of follow-up of PLCO Participants letter dated December 30, 2009.
Attachedment B: Rationale for continued follow-up of PLCO participants
Attachment C: CDCC Data Security Procedures
Attachment D: PLCO Centralized Follow-up Participant Cover letter
Attachment E: PLCO Centralized Follow-up Participant Notfication Form
Attachment F: Notification Procedures
Memo dated March 28, 2011 re: initial approval of PLCO CDCC, Project 8906

The revisions as referenced above to your protocol were recommended for approval through expedited review by Dr. Jimmy Hwang, the Chair of the Institutional Review Board or the designee, on May 6, 2011.

This is to inform you that you may continue your project.

Please remember to:

1. Seek and obtain prior approval for any modifications to the approved protocol.
2. Promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the Institutional Review Board within 7 calendar days. This includes information obtained from sources outside MedStar Health Research Institute and Georgetown University that reveals previously unknown risks from the procedures, drugs or devices used in this study.

32342
CC: Levy, Sharon

EA 32342

RECEIVED

APR 28 2011

INSTITUTIONAL REVIEW BOARD

NATIONAL CANCER INSTITUTE
PLCO
Prostate, Lung, Colorectal, & Ovarian CANCER SCREENING TRIAL

Lombardi
COMPREHENSIVE CANCER CENTER

PLCO Cancer Screening Trial
Georgetown University
Box 571470
Washington, DC 20057-1470

Phone: (202) 687-7324
Toll Free: (866) 505-2260
Fax: (202) 687-0440
E-mail: plco@georgetown.edu

**MEMORANDUM**

DATE: April 28, 2011

TO: Medstar Research Institute-Georgetown University
Oncology Institutional Review Board

FROM: Claudine Isaacs, MD
PLCO Principal Investigator
Lombardi Comprehensive Cancer Center

Colleen McGuire RN, MSN
PLCO Study Coordinator Colleen McGuire
Lombardi Comprehensive Cancer Center

SUBJECT: **PLCO Cancer Screening Trial: IRB # 1993-276**

Screening Center Closeout and Centralized Administration of Follow-up of Participants

The Georgetown University PLCO contract will expire on September 29, 2011. Westat was awarded a new contract on March 1, 2011 to establish and maintain a Centralized Data Collection Center (CDCC). Their responsibilities will include all active data collections with participants, physicians, and medical records and pathology departments for those PLCO participants who agree to be followed by Westat for five additional years. Westat has served as the Coordinating Center for PLCO from the beginning of the Trial and will continue in this role for another five years. They have extensive knowledge of the Trial and are familiar with data security and confidentiality requirements for Personal Identifiable Information (PII) and Personal Health Information (PHI).

All previously enrolled PLCO participants who agree to continued follow up by the CDCC will participant in the study. The Georgetown University PLCO Screening Center staff will notify PLCO participants that they will be followed by the CDCC if they are willing to participate in continued active follow-up. Participants will have the option to decline centralized active follow-up in favor of being followed up passively by the Georgetown University Screening Center through linkage to state cancer registries and NDI, or to withdraw completely from the study. Participants have previously signed consent forms regarding participation in the PLCO Trial and the use of their collected biologic specimens for research.

NATIONAL CANCER INSTITUTE COMPREHENSIVE CANCER CENTER NCI CCC

GEORGETOWN UNIVERSITY 1789

The Georgetown University PLCO Screening Center will continue to perform the following tasks as part of the continued follow-up effort, supported through a subcontract administered by Westat: IRB preparation and submissions, provide support as needed for the collection of medical records, pathology tissue and transmission of data to the CDCC and coordinate passive follow-up activities for participants who have declined centralized follow-up. These follow up activities will include state tumor registry searches and annual NDI searches

Enclosed please find the following documents for review and approval:

1. Memo from Christine D. Berg, MD, NCI PLCO Project Officer
2. ATTACHMENT A: NCI SSIRB Approval for Centralized Administration of Follow-up of PLCO Participants
3. ATTACHMENT B: Rationale for Continued Follow-up of PLCO Participants
4. ATTACHMENT C: CDCC Data Security Procedures
5. ATTACHMENT D: PLCO Centralized Follow-up Participant Cover Letter
6. ATTACHMENT E: PLCO Centralized Follow-up Participant Notification Form
7. ATTACHMENT F: Notification Procedures
8. Memo from Westat Chair IRB for Initial Approval of PLCO CDCC

☐ Noted
☒ Approved
☐ Approved
☐ Approved
☐ Approved

DATE: 5/6/11
w/modifications:
Exempt
Expedited

☐ Disapproved

Chair, Institutional Review Board

cc: PLCO File

**DEPARTMENT OF VETERANS AFFAIRS**
**VA Pacific Islands Health Care Systems**
**Spark M. Matsunaga Medical Center**
**459 Patterson Road**
**Honolulu, Hawaii 96819-1522**

April 26, 2011

In Reply Refer To: 151/RCC

Lance A. Yokochi, MD.
National Center for PTSD
3375 Koapaka Street, Suite I-540
Honolulu, HI 96819

SUBJ: Project Number: 2010-03/LY/PROMISE/0001
Project Title: Prostate, Lung, Colorectal & Ovarian Cancer Screening Trial

Dear Dr. Yokochi:

I am pleased to inform you that on April 26, 2011 the Institutional Review Board approved your amendment request to make the following changes:

Additional Documents Added:

Protocol Addendum

Continued Follow-up Notification to Participants

Participant Cover Letter

The amendment was approved through the expedited review process of the IRB and is effective immediately.

If you have any questions or concerns, please contact Douglas Miller, Research Committee Coordinator, R&D Office, at 433-0127, or Douglas.miller@va.gov.

Sincerely,

Daryl Fujii, Ph.D.
Chairperson, Institutional Review Board

Encl: Protocol Addendum
Continued Follow-up Notification to Participants
Participant Cover Letter

# REQUEST FOR PLANNED CHANGE(S)

Changes **may not** be implemented until IRB written approval is received.
*Investigators are responsible for utilizing the most current versions of IRB forms and the IRB has the authority to refuse out of date forms.*

**This form can now be submitted electronically! See general directions at end of form!**

Principal Investigator (PI): **Paul A. Kvale, MD**

Department (select from the drop downs): **BRE** Division:

Entire Project Title (no acronyms): **Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO Study)**

IRB #.: **112** Current IRB Approval Period: **4/21/2010** – **4/20/2011** Location to send correspondence (required): OFP 3C75
Contact Person: **Karen Broski** Contact phone #: **874-7053** Contact e-mail: **kbroski1@hfhs.org**

Reason for IRB review (check all that apply):
1. ☒ Protocol Amendment:**NCI transition of PLCO Study from HFH to a central data coordinating center CDCC**
2. ☐ Investigator Brochure Update/Package insert:
3. ☐ Response to IRB Concerns from:
   - ☐ Initial Submission
   - ☐ Previous Planned Change Form
   - ☐ Adverse Event Form
   - ☐ Continuation/final report un-approved
   - ☐ Other:
4. ☐ Revised Consent Form:
5. ☐ Advertisement
6. ☐ PI Change (will require revised consent form)
7. ☐ Title Change (will require revised consent form)
8. ☐ Database Declaration
9. ☐ DSMB Reports (attach report)
10. ☐ Protocol Deviation:
11. ☐ Request to Re-open a closed study
12. ☐ Study closed to accrual:
13. ☐ Other:

## THE REST OF THIS PAGE IS FOR IRB USE ONLY

Type of IRB Review:
☒ Expedited ☐ Full Board (reviewed at a Full Board Meeting on: )

Risk to subjects increased: ☐ Yes ☒ No
Consent form satisfactorily revised: ☐ Yes ☐ No ☒ N/A

*If yes, does this require re-consenting **currently active** subjects in treatment phase:* ☐ Yes ☐ No
*If yes, does this require re-consenting **all** subjects:* ☐ Yes ☐ No

Result of IRB Review:
☒ Approve
☐ Withheld pending response (☐ Member review ☐ Administrative review)
☐ Approval denied (requires full board review)
☐ IRB notified: Approval not required

| APPROVAL STAMP |
| --- |
| APPROVED |
| Mar 24, 2011 |
| INSTITUTIONAL REVIEW BOARD |

The HFHS IRB has read & reviewed this protocol & finds that this research is appropriate in design and meets the requirements of the Federal Guidelines, 45 CFR Part 46 and 21 CFR Part 50. The signature below denotes IRB approval of this study.

Timothy Reeves PhD

_____ Date: **3-24-11**
Chairperson or designee - Henry Ford Health System IRB

Comments from Chairperson or designee:
Action required:

**COMPLETE THE FOLLOWING QUESTIONS AS DIRECTED**
**(if your item number is not noted, you only need to complete numbers 1-5 on this page)**

1. Provide a description/explanation of this submission. ("See attached" format is not acceptable) **The National Cancer Institute (NCI) plans to continue the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO Study) beyond the end of our contract which expires in September 29, 2011 at several centers (doc 1- Letter of Direction and Notification from Dr Berg and doc 2- NCI SSIRB approval of Centralized Follow up). The continuation plan will follow up these study participants through a contract with one central administration rather than the current multi-site administration (doc 3 Rational for Continued Follow up of PLCO participants). The new contract for continued follow up was awarded to establish and maintain a centralized data collection center (CDCC). This CDCC contract was awarded to Westat Inc. on March 1, 2011. Westat has served as the coordinating center for the PLCO Study from the beginning of the trial and will continue to serve in this role for an additional 5 years. Westat has extensive knowledge of the PLCO Trial and is familiar with the data security and confidentiality requirements for PHI (doc 4- Data Security Procedures). In addition to continuing to administer the Annual Study Update (ASU) mailings, the CDCC (WESTAT) will perform other tasks formerly carried out by the Screening Centers. The continuing tasks include: the administration of the Health Status Questionnaire (HSQ), a brief risk factor questionnaire, participant retention and tracing activities, the collection of medical records to confirm reported cancers and cause of death, periodic linkages to the National Death Index (NDI), collection of pathology tumor tissue specimens, periodic linkages to state cancer registries. Once IRB Approval is obtained at the original screening centers (SC), the SC's will send a letter to inform study participants that the study will continue and they will be followed by a centralized data coordinating center (WESTAT) if they are willing to participate in continued active follow up (doc 5- Draft Centralized Follow Up Cover Letter and doc 6- Draft Continued Follow Up Notice). Participants will have the option to decline active follow up in favor of being followed up passively by the screening centers through linkages to the state cancer registries and National Death Index search. Participants will also have the option to withdraw completely (doc 7- Notification Procedures) Participants have previously signed consent forms regarding participation in the PLCO Study and the use of their biological specimens for research. It is anticipated that the screening centers will continue to perform a limited number of tasks as part of the continued follow up effort. This continued participation would be supported through a subcontract with Westat Inc. (CDCC). These tasks would include: organized submissions to the local IRB, assisting with data submissions to the NDI and state cancer registries, liason with the local medical community as needed to facilitate collection of medical records. Each screening center will continue to have a Principal Investigator who will remain scientifically involved in the continued follow up of this trial and will attend an Annual Steering Committee Meeting.**

2. Does this change increase the risk significantly? ☒ **No** ☐ **Yes** (consent changes may be required)

3. How many HFHS subjects are currently enrolled? **24,676** Is the study still enrolling subjects at HFHS?
   - ☒ **No**
     - Are there subjects still in the active treatment phase of the study? ☒ No ☐ Yes
     - Are there subjects still in the long term follow-up phase of the study? ☐ No ☒ Yes
   - ☐ Yes

4. Does the benefit still outweigh the risk for this study? ☐ **No** ☒ **Yes**

5. Does the new information require a revised informed consent?
   - ☒ **No**
     - o If no, why not?
     - o Was consent for this study waived originally? ☐ **No** ☐ **Yes**
   - ☐ **Yes** - submit 2 copies of the consent form with one yellow highlighted to show the changes

6. If you checked numbers **1 - 2** on page one, answer the following. If not, proceed to the next question.
   - Is the study sponsored? ☐ **No** ☒**Yes** Name of Sponsor (if applicable): **National Cancer Institute (NCI)**

     If yes, check the appropriate box and provide the information requested:
     - ☒ A copy of the sponsor's amendment, if sponsor initiated the change.
     - ☐ A copy of your notice to the sponsor, if you initiated the change.
     - ☐ Other:

7. If you checked number **3** on page one, attach the copy of the IRB letter you received, your response, and the revised consent form (attach 2 copies of the revised consent, all consent changes must be marked with a yellow highlighting on one copy) if applicable. If not, proceed to the next question.

8. If you checked number **5** on page one, complete the following. If not, proceed to the next question.
   - Advertisements must be submitted for review before being published. Please include the reasons for the advertisement, and where it will be placed.
   - If you are submitting an advertisement for television or radio, please attach a copy of the script along with a video or audiotape if available.
   - If you are submitting an advertisement for the HFHS external Internet, please complete the following and attach the sponsor's approval of the text of the advertisement as a supporting document.
     - Date you want trial on web site:
     - Date you want trial off web site:
     - Choose your clinical area: If 'other', please specify:
     - In lay terms, please indicate the eligibility criteria for subjects:
     - How do you want patients to contact you to get into the trial (ie. name & phone #)?
     - In lay terms, describe the purpose of the study (you can use the sentence from your consent form:
     - If the study is sponsored, please indicate the sponsor name:
     - If you know the grant number, please provide:

9. If you checked number **6** on page one, attach letter from the new PI indicating they will assume the responsibility for the study and the signatures of both the current & new investigator. You must also change the PI in the consent form (if applicable), and submit. If not, proceed to the next question.

10. If you checked number **7** on page one, type the old & new title in the title section of page 1, & highlight the new title, you must also change the title on the consent form (if applicable), & submit it for review. If not, proceed to the next question.

11. If you checked number **10** on page one, submit only significant deviations as deemed by the investigator. If not, proceed to the next question.

12. If you checked number **11** on page one, please indicate the reason below. If not, proceed to the next question.
    - ☐ Audit Site Visit
    - ☐ Query for data clarification/data existing at the time of study closure
    - ☐ Query for new data related to events occurring since study closure
    - ☐ To Notify Subjects of their Randomization and the Study Results (attach the letter)
    - ☐ Protocol lapsed and was administratively closed (provide reason for lapse, any study-related unanticipated problems that occurred since the study closed, and plan to prevent a lapse from occurring in the future).

## General Information for completing this form

1. This form must be typed with all blank shaded spaces completed. You can tab through the form, entering your information in the spaces provided. Please use attachment pages when requested, providing all the required and necessary information.
2. You may submit this request either paper or electronically (but not a combination of both). If you submit electronically, all supporting documents must also be submitted electronically and be saved in word or adobe.

| To submit by paper | To submit Electronically |
|---|---|
| Submit this original signed form and any attachments, along with *1 extra* copy (of this form and any attachments) to the Research Administration (IRB) Office (CFP Basement room 46). Please copy the packet either all front side only or all both sides (not a combination). | E-mail this completed form **and** supporting documents to: research_admin@hfhs.org You must follow these directions:<br>• The e-mail subject line must be in the following format (with underscore):<br>a. Indicate 'IRB PCF'<br>b. PI last name<br>c. HFHS IRB #<br>d. ***Example:*** 'IRB PCF_Jones_123'<br>• Attach the *Planned Change Form* saved with a title of: PCF and PI last name and IRB number (i.e. 'PCF_jones_123'). Note use an underscore between the items.<br>• *If applicable:* attach supporting documents saved with PCF, PI last name, IRB number and 'supportingdoc' as the title. If there is more than one supporting document, differentiate them by number (supportingdoc_1, supportingdoc *2,* ICF_3, etc.). *example:* |

| | |
|---|---|
| | PCF_Jones_123_supportingdoc_1<br><br>Your forms will be returned to you by e-mail. You may print them for your records as you will **not** be receiving copies through interdepartmental mail. As always, should you need a copy, the IRB maintains paper files for every study. |

***All IRB forms are available through the Research Administration website (http://henry.hfhs.org/body.cfm?id=166).***

-------- Original Message --------
**Subject:**9302M06411 - PI Church - IRB - APVD Continuing Review
**Date:**Thu, 29 Jul 2010 23:19:40 -0500 (CDT)
**From:**irb@umn.edu
**To:**engel006@umn.edu
TO : okenx001@umn.edu, trc@umn.edu, engel006@umn.edu, ccprc@umn.edu, fishe061@umn.edu, ccprc@umn.edu,

The IRB: Human Subjects Committee renewed its approval of the referenced study listed below:

Study Number: 9302M06411

Principal Investigator: Timothy Church

Expiration Date: 07/27/2011

Approval Date: 07/28/2010

Title(s):
Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial - Screening Centers

---

This e-mail confirmation is your official University of Minnesota HRPP notification of continuing review approval. You will not receive a hard copy or letter. This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

You may go to the View Completed section of http://eresearch.umn.edu/ to view or print your continuing review submission.

For grant certification purposes you will need this date and the Assurance of Compliance number, which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Childrens Specialty Healthcare FWA00004003). Approval will expire one year from that date. You will receive a report form two months before the expiration date.

In the event that you submitted a consent document with the continuing review form, it has also been reviewed and approved. If you provided a summary of subjects' experience to include non-UPIRTSO events, these are hereby acknowledged.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems and adverse events should be reported to the IRB as they occur. Research projects are subject to continuing review.

If you have any questions, please call the IRB office at (612) 626-5654.

The IRB wishes you continuing success with your research.

# Washington University in St.Louis

**Human Research Protection Office**

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

**IRB ID #:** 201104130

**To:** Gerald Andriole

**From:** The Washington University in St. Louis Institutional Review Board,
WUSTL DHHS Federalwide Assurance #FWA00002284
BJH DHHS Federalwide Assurance #FWA00002281
SLCH DHHS Federalwide Assurance #FWA00002282

**Re:** Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

---

**Approval Date:** 04/15/11

---

**Next IRB Approval Due Before:** 04/13/12

**Type of Application:**

- ☐ New Project
- ☒ Continuing Review
- ☐ Modification

**Type of Application Review:**

- ☐ Full Board:
  Meeting Date:
- ☒ Expedited
- ☐ Exempt
- ☐ Facilitated

**Approved for Populations:**

- ☐ Children
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, Neonates
- ☐ Wards of State
- ☐ Decisionally Impaired

Source of Support: DHHS, National Institutes of Health

06-Wash U

# Washington University in St. Louis

**Human Research Protection Office**

Barnes-Jewish Hospital
St. Louis Children's Hospital
Washington University

Gerald Andriole, MD
Surgery/Urologic Surgery
Box 8242

June 26, 2010

HRPO Number: 93-0495
Title: Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial
Funding Source: National Cancer Institute (NCI)

This project was reviewed and approved by the Washington University Human Research Protection Office (HRPO) according to the terms and conditions described below:

| | | | |
|---|---|---|---|
| - IRB Approval Date: | 6/26/2010 | - Reviewing Committee | Biomedical Committee |
| - Expiration Date: | 6/25/2011 | - Type of Review: | Minimal Risk Cont. Review (Expedited 5, 7) |
| - Research Risk Level: | Minimal | - HIPAA Compliance: | Compliant with Authorization |

Released for follow-up/data analysis only.

HRPO complies with Federal regulations 45 CFR 46, 45 CFR 164, 21 CFR 50, and 21 CFR 56, which allow the use of an expedited review procedure for research which presents no more than minimal risk to human participants and meets the criteria for one or more of the categories of research published in the Federal Register. All actions and recommendations approved under expedited review are reported to a Full Committee.

You are expected to comply with the requirements outlined in the WU HRPO Assurance of Commitment and Policies Procedures (https://hrpo.wustl.edu). This includes reporting any unanticipated problems involving risk to research participants or others.

Changes in the conduct of the study, including the consent process or materials, require submission of an amendment application which must be approved by HRPO *prior* to implementation of the changes.

According to Federal regulations, this project requires IRB continuing review. As such, prior to the project expiration date above, you must submit either a Renewal or the Final Report. If you have questions or require additional information, please contact HRPO at (314) 633-7400 or eIRB@msnotes.wustl.edu.

Sincerely,

Philip A. Ludbrook, M.D.
Executive Chair and Associate Dean

# University of Pittsburgh
***Institutional Review Board***

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)


MEMORANDUM

TO: Joel L. Weissfeld, MD, MPH

FROM: Christopher Ryan, PhD, Vice Chair

DATE: March 31, 2011

SUBJECT: IRB # 9602115: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (UPCI 93-03)

The Institutional Review Board reviewed the recent modifications to your protocol and consent form(s) and find them acceptable for expedited review. These changes, noted in your submission of March 28, 2011, are approved.

Please include the following information in the upper right-hand corner of all pages of the consent form(s), if modifications were made to the consent form(s):

Modification Approval Date: March 30, 2011
Renewal Date: August 2, 2011
University of Pittsburgh
Institutional Review Board
IRB # 9602115

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

If this research study is subject to FDA regulation, please forward to the IRB all correspondence from the FDA regarding the conduct of this study.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:kh

INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

**IRB_00004389**

**Principal Investigator: Saundra Buys**

**Title: Prostate, Lung, Colorectal, & Ovarian Cancer Screening Trial - Screening Centers**

This Amendment Application (CDCC notification) has been reviewed and approved by a University of Utah IRB convened board. The convened board approved your amendment request for this study on 5/11/2011. The approval of this amendment request does NOT change the expiration date of this research study as noted below.

**Your study will expire on** 10/5/2011 11:59 PM**.**
Any future changes to this study must be submitted to the IRB prior to initiation via an amendment form.

**APPROVED DOCUMENTS**

**Other Documents**
PLCO Centralized Follow-up Cover Letter_FINAL.doc
PLCO Centralized Follow-up Notification_FINAL.doc
Rationale for Continued Follow-up
CDCC Data Security Procedures
NCI IRB Approval for CDCC
Westat IRB Approval for CDCC

Click AM_00009958 to view the application and access the approved documents.

Please take a moment to complete our customer service survey. We appreciate your opinions and feedback.

Marshfield Clinic
Research Foundation

1000 North Oak Avenue
Marshfield, WI 54449-5790

715-387-5241
1-800-782-8581
Fax 715-389-3131

# MCRF INSTITUTIONAL REVIEW BOARD

FWA # (FWA00000873)

Date: April 18, 2011
PI: DOUGLAS J REDING, MD - 3A1
SP Code: RED10393+PLCO-C Protocol #:
Title: Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial--Screening Centers

The Institutional Review Board has reviewed the request for additional five-years of annual active follow-up of PLCO participants (as outlined in Amendment Submission form dated March 27, 2011) using a Centralized Data Collection Center (CDCC), the collection of additional data to update key exposure data including medication use and medical conditions that are common among older adults, the collection of additional clinical data and tumor tissue for colorectal and ovarian cancer, and the participant cover letter for the above-named study using Expedited Review, under 45 CFR 46.110(b)(2), on April 18, 2011. The item, as described, has been Approved/Accepted.

Attached is a copy of the approved combined consent/HIPAA authorization document dated April 18, 2011 to be used to re-consent PLCO participants as outlined in your IRB submission materials.

The IRB has approved the sharing of data with PLCO Centralized Data collection Center as outlined in your IRB application. If your research involves the sharing of individual level data or specimens with any external party, an appropriate transfer agreement must be in place. To initiate an agreement, complete and submit a "Request to Transfer Data or Materials" form, which is available in the Marshfield Clinic Policy and Forms Library. Contact Melissa Ostrowski with any questions.

Jonathan Reeser, M.D., Ph.D., Chairperson
Institutional Review Board

c: STUART GUENTHER - 3B1
KAREN A LAPPE - ML3

OMB No. 0990-0263
Approved for use through 1/31/2012

# Protection of Human Subjects
## Assurance Identification/IRB Certification/Declaration of Exemption
### (Common Rule)

*Policy*: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

| 1. Request Type | 2. Type of Mechanism | 3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. |
|---|---|---|
| [ ] ORIGINAL<br>[X] CONTINUATION<br>[ ] EXEMPTION | [ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP<br>[ ] COOPERATIVE AGREEMENT<br>[ ] OTHER:_____ | |

| 4. Title of Application or Activity | 5. Name of Principal Investigator, Program Director, Fellow, or Other |
|---|---|
| Prostate, Lung, Colo-Rectal and Ovarian (PLCO) Cancer Screening Trial Expansion for Minority Enrollment (Supplement Medical Records Abstraction) | FOUAD, MONA N |

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00005960; the expiration date 10/26/2010 IRB Registration No. IRB00000196

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [X] Full IRB Review on (date of IRB meeting) 7/21/2010 or [ ] Expedited Review on (date) _____
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

| 8. Comments | Title F970626001 |
|---|---|
| Protocol subject to Annual continuing review. | Prostate, Lung, Colo-Rectal and Ovarian (PLCO) Cancer Screening Trial Expansion for Minority Enrollment (Supplement Medical Records Abstraction) |

IRB Approval Issued: 7-22-10

| 9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided. | 10. Name and Address of Institution |
|---|---|
| 11. Phone No. *(with area code)* (205) 934-3789<br>12. Fax No. *(with area code)* (205) 934-1301<br>13. Email: smoore@uab.edu | University of Alabama at Birmingham<br>701 20th Street South<br>Birmingham, AL 35294 |
| 14. Name of Official<br>Albert Oberman, M.D., MPH | 15. Title<br>Vice Chair, IRB |
| 16. Signature Albert Oberman, MD, MPH /RC | 17. Date 7-22-10 |

Authorized for local Reproduction

Sponsored by HHS