## Attachment 8: Institutional Review Boards (IRB's) Certifications

**Department of Health & Human Services**

**Public Health Service**

**National Institutes of Health**
**National Cancer Institute**
**Bethesda, Maryland 20892**

iRIS Reference Number 336566

IRB Number: OH97CN041
Study Status: Open - No Longer Recruiting - Follow-up Only
Expiration Date: 06/02/2015

05/27/2014

***TO:*** Robert Hoover

***FROM:*** Chairperson, Special Studies Institutional Review Board, NCI

***SUBJECT:*** Action on Clinical Research Protocol

Your Continuing Review of, "Etiologic and Early Marker Studies in the PLCO Trial," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by expedited review and approved on 05/27/2014.

The SSIRB has taken the following action:

| | |
|---|---|
| X | Approved. Forwarded for administrative processing by OPS, Clinical Center. |
| | Approved with stipulations pending re-review by SSIRB Chair. See review. |
| | Deferred pending response to stipulations and re-review by the full SSIRB. See review. |
| | Disapproved. See review. |

**Department of Health & Human Services**

**Public Health Service**

**National Institutes of Health**
**National Cancer Institute**
**Bethesda, Maryland 20892**

iRIS Reference Number 336764

IRB Number: 13-C-N010
Study Status: Open to Accrual
Expiration Date: 07/07/2015

06/20/2014

***TO:*** Paul Pinsky

***FROM:*** Chairperson, Special Studies Institutional Review Board, NCI

***SUBJECT:*** Action on Clinical Research Protocol

Your Continuing Review of, "National Lung Screening Trial - Data and Image Access System," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by expedited review and approved on 06/20/2014.

The SSIRB has taken the following action:

| | |
|---|---|
| X | Approved. Forwarded for administrative processing by OPS, Clinical Center. |
| | Approved with stipulations pending re-review by SSIRB Chair. See review. |
| | Deferred pending response to stipulations and re-review by the full SSIRB. See review. |
| | Disapproved. See review. |

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An Employee-Owned
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1600 Research Boulevard
Rockville, MD 20850-3129
tel: 301-251-1500
fax: 301-294-2040
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# AMENDMENT REVIEW FORM

(TO ADD OR CHANGE PREVIOUSLY APPROVED RESEARCH)

**All changes or new activities for previously approved studies require submission, review, and approval of an Amendment Review Form.** Please complete and submit this form to irb@westat.com and attach all necessary materials to be reviewed. Once the request has been reviewed, you will be contacted. If this change or new activity requires a full Board review, those meetings occur on the second Tuesday of every month. To check the date of meetings, please see the meeting schedule under IRB in WesInfo. Thank you for your cooperation.

| | | |
|---|---|---|
| 1. **Today's Date:** | 04 / 22 / 2014 | |
| **Date of Original Approval:** | 03 / 28 / 2011 | |
| **Project Name:** | PLCO CDCC | |
| **Westat Project Number:** | 8906.00.00 | |
| **Agency Grant or Contract Number:** | HHSN261201100008C | |
| **Project Director:** | Sunitha M. Mathew | **Ext.** 4472 |
| **Unit Ops Number/Study Area:** | 1121.74 | |
| **Area IRB Representative:** | Nancy Weinfield | **Ext.** 2480 |

2. **Indicate the type of addition or change being requested to a previously approved study.**
***(SELECT ALL THAT APPLY.)***

- ☐ Name(s) of investigators
- ☐ Project number
- ☐ Introduction of a new IRB or request for Westat to serve as the IRB
- ☒ Study design, survey questionnaire, or procedure(s)
- ☐ Informed consent process, consent form(s), parent permission(s), or assent form(s)
- ☐ Recruitment materials or strategies
- ☐ Incentives
- ☐ Survey instruments
- ☐ Number or type of populations studied
- ☐ Review of final instrument such as interview questions or data collection sites for a previously approved study
- ☐ Mode of administration of instruments in your study (e.g., from mail or telephone to web or Internet access)
- ☐ Data access rights
- ☐ Any other change in protocol that affects treatment of human subjects:
***(PLEASE SPECIFY)***

**3. Please provide a brief summary of your change or addition to previously approved research.**

We are adding approximately 54,000 people to the Continued Follow-up of PLCO participants cohort for the purpose of passive follow-up only. These people were participants in the National Lung Screening Trial (NLST), a sister study of the PLCO Cancer Screening Trial, designed to determine the effectiveness of screening with chest X-ray as compared to screening with low dose CT scans on lung cancer mortality. Approximately 35,000 participants were recruited from the same screening

**4. How does each change or addition affect the risks to participants in your study? *(SELECT ONLY ONE.)***

a. ☒ **No change**

b. ☐ N/A – no risks

c. ☐ Decreases the risk *(SPECIFY):*

d. ☐ Increases the risk *(SPECIFY):*

e. ☐ Adds a new risk *(SPECIFY):*

**FOR HARD-COPY SUBMISSION, PLEASE SIGN HERE:**

**A signature is not required when you return this form electronically; however, please fill in the date of completion.**

**The information provided in this request form is complete and correct.**

**Project Director/ Principal Investigator:** **Date:** 04 / 22/ 2014

**Please attach:**

- One document that clearly identifies (through track changes, highlights, or italics) the revision in the previously approved submission.
- Another document labeled "corrected version."

If you have any questions, feel free to contact Sharon Zack, the IRB Administrator, at x8828.

**IRB Administration Use Only**

Expedited review and approval for the modification(s) on this form:

Kerry Levin

5/5/2014

IRB Chair / Associate Chair / Designee

**IRB Office Only**

☒ **APPROVED** – NEXT CONTINUING REVIEW DATE: 03 / 28/ 2015

☐ **CONDITIONAL APPROVAL** (PLEASE SEE ATTACHED LETTER)

☐ **DID NOT QUALIFY FOR EXPEDITED REVIEW**

University of Colorado Anschutz Medical Campus

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]
COMIRB Home Page [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

**Certificate of Approval**

17-Oct-2014

**Not Approved to Enroll Subjects! Recruiting of new subjects will require new COMIRB approval**

| | |
|---|---|
| **Investigator:** | E Crawford |
| **Sponsor(s):** | National Cancer Institute/NIH/DHHS~ |
| **Subject:** | COMIRB Protocol 93-377 Continuing Review |
| **Effective Date:** | 14-Oct-2014 |
| **Expiration Date:** | 13-Oct-2015 |
| **Expedited Category:** | 8 |
| **Title:** | NATIONAL CANCER INSTITUTE PROSTATE, LUNG, COLORECTAL AND OVARIAN (PLCO) CANCER SCREENING TRIAL |

Submission ID: CRV016-2
Description:

CRV016-1: Enrollment complete; research activities limited to Long-term Follow-up.

CRV016-2: Response to Minor Modifications.

All COMIRB Approved Investigators must comply with the following:

- For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before implementation of the changes.
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed. Consent and/or assent forms must include the name and telephone number of the investigator.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- The investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted/high risk protocol, specific details will be outlined
  in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder **75 days prior** to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1055 or UCHSC Box F-490.

**Review Comments:**

APPROVED: Approved with recent clarification of subject numbers and corrected tables.

MedStar Health
GEORGETOWN UNIVERSITY Research Institute

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

Date: 8/18/2014

To: Claudine Isaacs

From: Harley Gould
Institutional Review Board

IRB# 1993-276

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

Annual Approval Date: 7/23/2014

Expiration Date: 7/22/2015

Action Continuing Review - Expedited

Your above referenced continuing review was approved through expedited review by Dr. George K. Philips, IRB Chair or designee, 8/18/2014.

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

Please note that this approval is granted until 7/22/2015. The IRB requires that you submit an application for annual renewal at the end of the approval period and/or at study completion. Please note that this office will automatically terminate the project on the date stated above, unless reviewed and re-approved by the IRB. ***It is the PI's responsibility to submit the application for annual renewal and the appropriate IRB forms at least one month before the expiration date.***

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.

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

September 5, 2014

**In Reply Refer To:** 151/RCC

Lance Yokochi, MD
PHREI
3375 Koapaka Street, Suite I-540
Honolulu, HI 96819

SUBJ: Project Number: 2010-03/LY/PROMISE 0001
Project Title: Prostate, Lung, Colorectal and Ovarian Cancer (PLCO)

Dear Dr. Yokochi:

I am pleased to inform you that at on September 5, 2014, the Institutional Review Board (IRB) approved your request to continue human subject use for the above proposal through the expedited review process. Your Human Use Approval will expire September 4, 2015. If the project is to continue after that date, a new request for continuation must be filed with the Research and Development (R&D) Office at least 1-month prior to the August 2015 meeting. You may continue your human use research based upon this notification.

In accordance with VHA Handbook 1200.01, you will also receive a confirmation letter from the Associate Chief of Staff for Research.

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

The IRB wishes you continued success with this research project.

Sincerely,

Brian Tsuzaki, MD
Institutional Review Board Member Designee

# HENRY FORD HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD
# Continuation/Final report form

The IRB is responsible for the continuing review of research to ensure that the rights and welfare of human participants are being protected. This application for renewal of approval or final report must be submitted to the Research Administration (IRB) Office by the published deadline date at least one month prior to the expiration date to guard against lapse in IRB approval.

**EXPIRED RESEARCH:** ***If you have not responded in time to renew the protocol before it lapses, the protocol is considered expired. Any research activity conducted under an expired protocol is in violation of federal regulations, and could jeopardize the Health System's privilege to conduct human research. The federal regulations allow no "window" after the expiration of the approval period. It is important that your protocol be renewed on time. If your approval expires and you wish to continue your research, the protocol may have to undergo IRB review again as a new protocol. Timely renewal avoids approval lapses.***

The IRB must determine from the information provided on this form whether or not this study should be approved to continue. *Per Federal regulations, "continuing review of research must be substantive and meaningful."* Insufficient information may result in a delay in approving continuation of your project. If this study is part of a multi-center project, provide data on HFHS subjects separately from national data but include both when available.

## DIRECTIONS FOR FORM COMPLETION:

1. Use this form for **all** continuation or final reports. Tab through the form, entering your information in the spaces provided.

2. E-mail this completed form **and** consent form/s (if still recruiting subjects) to: research_admin@hfhs.org
   You must follow these directions:

   - The e-mail subject line must be in the following format (with underscore):
     a. Indicate 'IRB continuation' or 'IRB final'
     b. PI last name
     c. HFHS IRB #
     d. Indicate 'expedited' or 'full'
     e. ***Example:*** 'IRB continuation_Jones_123_full' or 'IRB final _Jones_123_expedited'
   - Attach the *continuation/final report form* saved with a title of: PI last name and IRB number (i.e. 'jones_123'). Note use an underscore between the items.
   - *If applicable:* attach the *consent* saved with PI last name, IRB number and 'ICF' (i.e. *'jones_123_ICF*) as the title. If there is more than one consent form, differentiate them by number (ICF_1, ICF_2, ICF_3, etc.) or other obvious way (ICF_main study, ICF_genetic_substudy) (use an underscore between the items).

3. 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 on our website (http://henry.hfhs.org/body.cfm?id=7764 ).***

# Continuation/Final Report

All submissions must be sent electronically to: research_admin@hfhs.org
*Investigators are responsible for utilizing the most current versions of IRB forms and the IRB has the authority to refuse out of date forms.*

Institutional Review Board

**Please Indicate:** ☒ Continuation ☐ Final Report

## SECTION 1 INVESTIGATOR INFORMATION

Principal Investigator (PI): **Lois Lamerato, PhD**

Department (select from the drop downs): **Public Health Sciences** Division:

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

IRB #.: **112** Current IRB Approval Period: **1/7/2014** – **1/5/2015**

Location to send correspondence (required): **OFP 3E97**

Contact Person: **Karen Broski** Contact phone #: **874-7053** Contact e-mail: **kbroski1@hfhs.org**

Current source of funding: **none** Is this study currently NIH funded? ☒ No ☐ Yes (grant # )

If yes, was it originally submitted as such? ☐ No (if no, submit copy of grant) ☒ Yes

Current budget period (if federally funded): – Title of NIH grant (if different):

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

Type of IRB Review:

☐ Full Board
☒ Expedited *(all expedited continuation & final reports are reviewed as informational items at fully convened IRB meetings)*

Result of IRB Review:

☒ Continuation Approved
☐ Approval Withheld (see reason below)
☐ Final Report Approved (Closure # )

| APPROVAL STAMP |
| --- |
| APPROVAL PERIOD |
| Nov 26, 2014 – Nov 25, 2015 |
| INSTITUTIONAL REVIEW BOARD |

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

Chairperson or designee - Henry Ford Health System IRB

Date: **11/26/2014**

Abstentions:
Comments:
Action required:

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

**Study Number:** 9302M06411

**Principal Investigator:** Timothy Church

**Expiration Date:** 03/25/2015

**Approval Date:** 03/26/2014

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

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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. Results of inspections by any external regulatory agency (i.e. FDA) must be reported immediately to the IRB. 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 #:** 201412078

**To:** David Gierada

**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:** Central Data Collection Center (CDCC) – Continued Follow-up of PLCO Participants

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**Approval Date:** 12/23/14
**Next IRB Approval Due Before:** 12/22/15

**Type of Application:**

- ☒ New Project
- ☐ Continuing Review
- ☐ Modification

**Type of Application Review:**

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

**Approved for Populations:**

- ☐ Children
  - ☐ Signature from one parent
  - ☐ Signature from two parents
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, Neonates
- ☐ Wards of State
- ☐ Decisionally Impaired

Criteria for approval are met per 45 CFR 46.111 and/or 21 CFR 56.111 as applicable.
Project determined to be minimal risk per 45 CFR 46.102(i) and/or 21 CFR 56.102(i) as applicable.

**Source of Support:**
DHHS, National Institutes of Health
Central Data Collection Center (CDCC) – Continued Follow-up of PLCO Participants

# University of Pittsburgh
*Institutional Review Board*

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


**MEMORANDUM**

TO: Joel Weissfeld, MD, MPH

FROM: Christopher R. Ryan, PhD

DATE: June 26, 2014

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

The renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board under 45 CFR 46.110 (8). **This protocol is closed to accrual and all protocol interventions are complete.**

**Approval Date:** **June 26, 2014**

**Renewal Date:** **June 26, 2015**

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Event Coordinator at 412-383-1144

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).

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

CR:kh

## Kristen Keating

**From:** Amy Miller
**Sent:** Tuesday, July 15, 2014 11:41 AM
**To:** Kristen Keating
**Subject:** FW: IRB Notification: Continuing Review Outcome

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**From:** Anne Randall [mailto:anne.randall@hsc.utah.edu]
**Sent:** Tuesday, July 15, 2014 11:32 AM
**To:** Amy Miller
**Subject:** FW: IRB Notification: Continuing Review Outcome

FYI

Anne Randall

---

**From:** irb@hsc.utah.edu [mailto:irb@hsc.utah.edu]
**Sent:** Friday, July 11, 2014 9:46 AM
**To:** Saundra Buys
**Cc:** Jeff Childs; Lisa Gren; Anne Randall
**Subject:** IRB Notification: Continuing Review Outcome

**IRB_00004389**

**PI: Saundra Buys**

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

This Continuing Review Application has been reviewed and approved by a University of Utah IRB convened board. The convened board approved your study on 7/9/2014 . The approval is effective as of 7/11/2014. Federal regulations and University of Utah IRB policy require this research protocol to be re-reviewed and re-approved prior to the expiration date, as determined by the convened board.

**Your study will expire on** 7/8/2015 11:59 PM **.**
Any changes to this study must be submitted to the IRB prior to initiation via an amendment form.

**APPROVED DOCUMENTS**

Click CR_00016408 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: | June 02, 2014 |
| PI: | ROBERT T GREENLEE, PHD - ML2 |
| SP Code: | RED10393+PLCO-C Protocol #: |
| Title: | Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial--Screening Centers |

The continuing review report for the above named study was reviewed by the Institutional Review Board on May 29, 2014 using Expedited Review. Your project is APPROVED for continuation for one year. This report fulfills the continuing review requirements as set forth in 45 CFR 46.

IRB approval expires on May 28, 2015. You will be sent a notice requesting a continuing review report prior to this expiration date. If the project is terminated or completed during the next twelve months the IRB should be so advised.

As principal investigator, you are ultimately responsible for all aspects of this research project. A list of such responsibilities is attached to this letter.

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

c: CONNIE FOLZ - 3B1
DEBORAH S MULTERER - ML2

OMB No. 0990-0263
Approved for use through 3/31/2015

# 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 | [X] GRANT [ ] CONTRACT [ ] FELLOWSHIP<br>[ ] COOPERATIVE AGREEMENT<br>[ ] OTHER:_____ | |
| 4. Title of Application or Activity<br>Prostate, Lung, Colo-Rectal and Ovarian (PLCO) Cancer Screening Trial Expansion for Minority Enrollment (Supplement Medical Records Abstraction) | | 5. Name of Principal Investigator, Program Director, Fellow, or Other<br>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 01/24/2017 IRB Registration No. IRB00000726

[ ] 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: [ ] Full IRB Review on (date of IRB meeting) _____ or [X] Expedited Review on (date) 4/30/14
[ ] 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 X970626001 |
|---|---|
| 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: 5-1-14 | IRB Approval No Longer Valid On: 4/30/15 |

| 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<br>University of Alabama at Birmingham<br>701 20th Street South<br>Birmingham, AL 35294 |
|---|---|
| 11. Phone No. *(with area code)* (205) 934-3789<br>12. Fax No. *(with area code)* (205) 934-1301<br>13. Email: irb@uab.edu | |
| 14. Name of Official<br>Leslie Cooper, CIP | 15. Title<br>Associate Director, IRB |
| 16. Signature Leslie Cooper, CIP | 17. Date 4/30/14 |

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