Attachment 10: 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 ***319990***

Amendment Letter: B
IRB Number: OH97CN041
Version Date: 03/23/2012

4/9/2012

TO: Robert Hoover

FROM: Chairperson, Special Studies Institutional Review Board, NCI

SUBJECT: Action on Clinical Research Protocol Amendment

Your amendment to protocol, "Early Marker and Etiologic Studies in the PLCO Trial," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by expedited review.

The SSIRB has taken the following action:

X	Approved as written. Forwarded to the CC OPS for administrative processing.
	Approved with stipulations pending re-review by SSIRB Chair. See review comments.
	Deferred pending response to stipulations and re-review by a subcommittee of the Board. See review comments.
	Tabled pending response to stipulations and re-review by the full SSIRB. See review comments.

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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 / 16 / 2012	
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:	Barbara O'Brien	**Ext.** 3965
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 plan to collect additional exposure data from PLCO participants that may affect cancer risk. We plan to mail a Risk Factor Questionnaire (attached) to all active participants. Our focus is on collecting additional information on medications that are particularly common among older adults including those that have not been assessed in PLCO previously. We are also requesting consent from participants to link to other health databases like Medicare and Medicaid

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 / 16/ 2012

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:

Sharon Zack
Sharon Zack
2012.04.25 01:58 PM
I have reviewed and approve this document

IRB Chair / Associate Chair / Designee

IRB Office Only

☐ **APPROVED** – NEXT CONTINUING REVIEW DATE: 03 / 00/ 2013

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

☐ **DID NOT QUALIFY FOR EXPEDITED REVIEW**