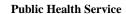
Attachment 10: Institutional Review Boards (IRB's) Certifications







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.							

1600 Research Boulevard Rockville, MD 20850-3129 tel: 301-251-1500

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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 C	DCC					
	Westat Project Number:	8906.00.	.00					
	Agency Grant or Contract Number:	HHSN26	51201100008C					
	Project Director:	Barbara	O'Brien	Ext. 3965				
	Unit Ops Number/Study Area:	1121.74						
	Area IRB Representative:	Nancy W	/einfield	Ext. 2480				
2.	Indicate the type of addition or chang (SELECT ALL THAT APPLY.) Name(s) of investigators Project number Introduction of a new IRB or request Westat to serve as the IRB Study design, survey questionnaire, or procedure(s) Informed consent process, consent a parent permission(s), or assent form Recruitment materials or strategies Incentives Survey instruments Number or type of populations study	st for or form(s), (s)	Review of final instrument surquestions or data collection s previously approved study Mode of administration of in study (e.g., from mail or telep Internet access) Data access rights Any other change in protocol treatment of human subjects: (PLEASE SPECIFY)	ach as interview ites for a struments in your whone to web or				

3.	Please provide a	brief summar	y of your	change of	r addition to	previously	approved	research.
			J - J			I J		

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.	Ho	How does each change or addition affect the risks to participants in your study? (SELECT ONLY ONE.)										
	a.	\boxtimes No	change									
	b.	_ N/										
	c.	De	Decreases the risk (SPECIFY):									
	d.	Inc	creases the	e risl	sk <i>(specif</i>	r):						
	e.	e. Adds a new risk (SPECIFY):										
					-	EASE SIGN						
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Project Director/ Principal Investigator: Date: 04 / 16/					04 / 16/ 20)12						
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• One document that clearly identifies (through track changes, highlights, or italics) the revision in the previously approved submission.									i iii tiit			
	•	Anothe	er documer	ent la	labeled "co	orrected ve	ersion."					
If y	ou h	ave any	questions,	s, fee	eel free to	contact Sha	aron Zack	, the IRB Admi	inistratoı	;, at x882	28.	
IRB Administration Use Only												
	Expedited review and approval for the modification(s) on this form:											
	Maron Jack											
			Sharon Zack 2012-04-25-01-58 PM Thave reviewed and app	u	- 0							
			- marcine away and sig		watering E							
			IRB Cha	nair /	· / Associa	ate Chair	/ Design	ee				

APPROVED – NEXT CONTINUING REVIEW DATE: 03 / 00/ 2013
CONDITIONAL APPROVAL (PLEASE SEE ATTACHED LETTER)

DID NOT QUALIFY FOR EXPEDITED REVIEW

IRB Office Only