

Attachment 15
IRB Approval Memo

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:	05 / 08 / 2015	
Date of Original Approval:	07 / 19 / 2012	
Project Name:	Population Assessment of Tobacco and Health (PATH)	
Westat Project Number:	8954.00.00	
Agency Grant or Contract Number:	HHSN271201100027C, Ref # NO1DA-11-5568	
Project Director:	Michelle Kiser/Scott (for Dave Maklan)	Ext. 2128
Unit Ops Number/Study Area:	1121.56	
Area IRB Representative:	Katie Gasque	Ext. 3694

2. Indicate the type of addition or change being requested to a previously approved study.

(SELECT ALL THAT APPLY.)

- | | |
|---|---|
| <input type="checkbox"/> Name(s) of investigators
<input type="checkbox"/> Project number
<input type="checkbox"/> Introduction of a new IRB or request for Westat to serve as the IRB
<input checked="" type="checkbox"/> Study design, survey questionnaire, or procedure(s)
<input checked="" type="checkbox"/> Informed consent process, consent form(s), parent permission(s), or assent form(s)
<input type="checkbox"/> Recruitment materials or strategies
<input type="checkbox"/> Incentives
<input type="checkbox"/> Survey instruments
<input type="checkbox"/> Number or type of populations studied | <input checked="" type="checkbox"/> Review of final instrument such as interview questions or data collection sites for a previously approved study
<input type="checkbox"/> Mode of administration of instruments in your study (e.g., from mail or telephone to web or Internet access)
<input type="checkbox"/> Data access rights
<input type="checkbox"/> Any other change in protocol that affects treatment of human subjects:
<i>(PLEASE SPECIFY)</i>
<div style="border: 1px solid black; height: 60px; width: 100%; margin-top: 5px;"></div> |
|---|---|

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

This request is for IRB review and approval for the Population Assessment of Tobacco and Health (PATH) Study to conduct the Wave 3 (second follow-up) collection of data and biospecimens, scheduled to begin in the fall of 2015. Some PATH Study materials and procedures have been revised and are now being resubmitted to the IRB for approval before the Wave 3 collections start.

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):

[Empty text box for specifying risk decrease]

d. Increases the risk (SPECIFY):

[Empty text box for specifying risk increase]

e. Adds a new risk (SPECIFY):

[Empty text box for specifying new risk]

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:

[Empty signature box]

Date: 05 / 08 / 2015

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:

Kevin Levin

5/20/15

IRB Chair / Associate Chair / Designee

IRB Office Only

- APPROVED** – NEXT CONTINUING REVIEW DATE: 04 / 18 / 2016
- CONDITIONAL APPROVAL** (PLEASE SEE ATTACHED LETTER)
- DID NOT QUALIFY FOR EXPEDITED REVIEW**