Attachment 16

IRB Approval Memo

June 18, 2013

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Memo

Date: July 19, 2012

To: David Maklan, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Full Approval of Population Assessment of Tobacco and Health (PATH), Project Number 8954**
FWA 00005551

On Tuesday, July 10th 2012 the Population Assessment of Tobacco and Health (PATH), **Project Number 8954** was presented to the full Board. Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. This study is sponsored by the National Institute on Drug Abuse (NIDA). The study received initial approval April 18th, 2012 for cognitive testing including the pretesting of advance letters, consent forms, the study household screener and some questions from the youth interview on tobacco use.

David Maklan, Dr. Andrew Hyland (Technical PI from Roswell Cancer Institute), Scott Crosse, Barbara O'Brien, and Gayle Wisdom (IRB Representative) represented the project team. Greg Conrad and Tim Chlebinski (Hooper-Holmes), participated by teleconference.

During the discussion, the following information was presented to the Board:

- American Indian populations have not been excluded(but not oversampled) from the study.
- There may be situations where parents will not be eligible for the PATH study but their child will be.
- The term "polyuse" described in the PATH Adult Questionnaire, Version 5.3.4 (Attachment 2) is defined as two or more tobacco products used in combination to achieve a particular effect.
- The term "Contraband" is used in the PATH study adult and youth interviews to include questions related to illegal activities and tobacco use. For example, in some cases, tobacco products taxed lower in one location may be illegally moved to another location and sold for a profit. Also, contraband can be referred to when discussing counterfeit tobacco products, where counterfeiters hijack the trademark of a popular brand of cigarettes and pawn it off on their tobacco products.

- Incentives will be provided to study participants in the form of debit cards. These cards will incur $3 monthly fees while the card retains a balance. Participants will also be charged $1 for each bank teller cash withdrawal.

Action Requested: This request includes review of the pilot test and national baseline data collection for the main study protocol, consent procedures and forms, study materials, incentives, and instruments.

Action Taken: Per 45 CFR 46, the Westat IRB determined that this research met criteria for classification as minimal risk and assigned it a conditional approval. (For: 7; Against: 0; Abstain: 0).

A waiver of the requirement for documentation of informed consent for the screening stage is also approved per [45 CFR pt. 46. 116 (d) 46.117 (c) (2)] as the research presents no more than minimal risk of harm to subjects and could not practicably be carried out without the waiver.

A waiver of the requirement to obtain a signed consent from both parents of the youth is also approved as long as it does not conflict with local jurisdiction requirements per 45 CFR Part 46, Subpart D as the research presents no more than minimal risk of harm to subjects and could not practicably be carried out without the waiver.

The following is a list of conditions made by the Board as well as responses by the PD approved under expedited authority on July 18th, 2012:

Overall

1. Clarify in writing, with the clients, who owns the data. The Board expressed a strong preference for the clients to "own" the data upon project completion. Consequently, at the conclusion of the project, it is the clients' responsibility to protect the confidentiality of the data by keeping identifying information separate from the results. Westat will provide the data to the client in this format and expects the client to maintain separate files regardless of who the prime contractor is for the study in the future.

   PD Response: The PATH study has obtained a memo signed by NIDA that clarifies NIDA owns the data. This memo also clarifies that, at the conclusion of the study, NIDA will ensure that identifying information is separated from the data for the study after contract expiration.

Study Sponsors

2. Identify study sponsors in all of the project-related materials, including advanced materials, consent forms, etc. It is the Board's preference that the study sponsors include mention of NIDA and FDA. It is our understanding that the study materials include a PATH logo that identifies all the agencies supporting the study. Please confirm that our understanding is correct.

PD Response: Study sponsors have been identified in practically all of the study materials. The only exceptions are very brief materials, including the language identification card (RS1), interviewer ID badge (RS4), and refrigerator magnet (FRT3).

The study logo does not include the names of the study sponsors. The logo has been added to each of the consent documents. In addition, as indicated on the materials, it will also be added to all of the other participant materials.

Informed Consent Process

3. Add language that more accurately describes the types of questions included in the adult survey (page 34).

   PD Response: Text was added to the adult interview consent form to include "substance use and mental health" among the types of questions to be asked.

4. Replace the language described in the project summary and consent forms that refers to forced disclosure of the data with language provided by the Certificate of Confidentiality.

   PD Response: The Certificate of Confidentiality (COC) draft language was clarified regarding forced disclosure of information in all consent forms. Changes are based on guidance for COC applications. Actual language will be provided in the COC when it is granted.

5. Describe the shadow sample procedures to the parent in plain, simple language. Explain instances where the parent may not be eligible but his/her child could become eligible to participate.

   PD Response: In the study summary, additional information on the procedures for the shadow sample has been added. Further, circumstances under which only shadow youth could will be selected from a household for the study is also explained.

6. Clarify to the respondents that the debit card remains active for a specified period of time to ensure that it is used properly and does not expire.

   PD Response: On the incentive receipt (RS10), information is provided to participants on debit card activation, expiration, inactivity fee, and charge for obtaining cash from a bank teller.

Data Security/Data Sharing

7. Develop procedures for data disclosure that are consistent with current statistical standards. Provide documentation of the process that will be used for cleaning the data set, rules that will be implemented for data suppression, and any other statistical procedures that will be performed prior to providing a public use dataset. If the project needs assistance in developing data suppression rules and other procedures to ensure respondent confidentiality, contact Sylvia Dohrmann or Tom Krenzke.

PD Response: First as a clarification, there is no requirement for a public use data set. Only restricted use files (RUF) will be available for use by approved researchers. Although release policies have not been discussed with NIDA (the first dataset is not due until the 4th year of the contract) the following is considered to be true:

- Access to RUFs will be provided through a data use agreement (or license, as preferred by NIDA) with the researcher to protect disclosure or improper use of restricted use data;

- The data use agreement will describe what information is covered; specify who may have access, define limitations on use and disclosure, and specify any administrative requirements (such as publication review, notification of known or suspected breaches of security, detail any other data requirements such as security, maintenance, or sunset). It is also anticipated that it will carry notifications of penalties for confidentiality breaches (e.g. Privacy Act penalties, Confidentiality Information Protection and Statistical Efficiency Act (CIPSEA) penalties);

- Procedures for obtaining a data use agreement will include typical materials such as a formal letter of request, research plan, data requirements and justifications, security plan, and affidavits of non-disclosure. NIDA will establish a procedure for review and approval of requests;

- Working with NIDA, the research team will prepare guidance for researchers regarding security procedures required in the security plan;

- It is recommended that only the data required to meet the specific research plan be released to the researcher, rather than static RUFs;

- Personal identifying information (PII) and personal health information (PHI) will only be provided if needed and will be released in a physically separate, encrypted file with different passwords from related RUFs. Direct identifiers such as PII (name, phone numbers, other identifiers such as medical numbers, etc.) will not be released at any time.

- The research team will explore with the client alternatives to providing full date of birth, zip codes, etc.; and,

- All data will be released in a secure manner, typically including full encryption of the dataset with separate delivery of passwords and documentation. It is anticipated that the Data Delivery Metadata System (DDMS), which is password protected by user, will be used. Alternatively, NIDA mentioned using the Inter-University Consortium for Political and Social Research (ICPSR) for RUF data release. In that case, the research team would use the same procedures, but release the data to ICPSR rather than directly to researchers.

The first RUF is related to the Baseline data, scheduled to complete field data collection in September 2014. Data acquisition from laboratories will continue for several months

following the end of field data collection. During the Baseline year, ongoing data cleaning will be conducted to ensure smooth field operations. In addition to standard edits, data will be compared across systems and sources to ensure the data tell a cohesive story. In general, the standard process will include:

- Development of data cleaning systems. Systems will include the Blaise Editing System for instrument data and SAS programs for cross-system and cross-dataset editing. A requirements team consisting of data management, systems, operations, and statistical staff has developed requirements which are now in specification and will soon be in programming and testing. Data edits will be documented in data decision logs.

- Monitoring reports. Review of monitoring and operational reports will also be a critical part of the data cleaning process. Issues identified in reports will be discussed with data management, systems, and operations staff.

- Coding. Requirements for coding are still in discussion. Care will be taken to ensure that best practices are reflected, review is conducted by appropriate groups (e.g. stat, operations), staff are trained, and QC measures are in place.

Prior to the RUF deliverables, there are other data deliverables that will be used to identify data anomalies or errors that may not be apparent using standard data editing approaches. The research team is required to provide up to 10 analytic reports, data files, and codebooks per period, as defined by NIDA. It is anticipated that these files will also serve as the basis for the RUFs.

A data steward will be assigned who will have responsibility for ensuring the quality of the data and metadata, application of best practices for data handling, and implementation of decision-making and tracking processes throughout the data life cycle. The data steward will be responsible for ensuring that all relevant groups, including statistical disclosure specialists if needed, are included in planning for review of data handling and processing procedures and scheduling of all required activities associated with data release.

8. Revise the sentence under E1. Confidentiality, Data Security, and Destruction Procedures (page 18) "De-identifying genetic data by stripping off direct identifiers (e.g., name, address) has been referred to as anonymzing the data" to correctly state who will be responsible for setting these procedures.

   PD Response: The following sentence has been added, "NIDA will establish procedures for de-identifying DNA sequence data."

9. Revise the first sentence under E3 Data Ownership/ Data Sharing (Page 20) of the project summary where it says "Westat will transfer to NIH the raw data files, analytic files, and restricted used files and documentation. Clarify that any identifiers provided to NIH will be separated from the dataset.

PD Response: In the study summary, revised text will be added to Section E.3, to remove mention of raw data. Also, language from the memo signed by NIDA on the separation of identifiers and data will be added. (See the response to Condition 1.)

Continuing Review Less Than 12 months

10. Return to the Board with an amendment request to approve additions or changes to the protocol and procedures as a result of the field test data collection.

    PD Response: The PATH study agrees to return to the Board with an amendment request for additions or changes to the protocol and procedures as a result of the field test data collection. Before requesting the amendment, the study will brief the Board on the field test results and their implications for procedures, materials, etc.

As the Project Director you are responsible for the following:

- **Submit to the Board, the revised Adult and Youth informed consent forms with required COC language once the certificate has been granted and prior to the pilot study.**
- You are required to submit this study for a continuing review on or before April 18, 2013.
- 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
Gayle Wisdom

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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 / 15 / 2013	
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:	David Maklan	**Ext.** 2805
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.)

- ☐ 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.

The PATH Study requests approval of changes to the informed consent process and forms, recruitment and other materials, incentives, and instruments. A summary of these changes follows.

- Informed consent process and forms—The study proposes to obtain written consent through electronic signatures; this change is intended to prevent the loss of hardcopy consent forms. The consent forms are revised to simplify the language, reflect minor changes in incentives and study procedures, avoid detailed information on study activities other than those covered by the specific consent form, and explain the importance of the study. Also, following the NHANES approach to obtaining consent for medical exams, the biospecimen consent form is split into a pamphlet and a consent signature page.

- Recruitment and other materials—The recruitment materials (advance materials) are revised to simplify the language, reflect minor changes in incentives and study procedures, avoid detailed information on study activities other than the initial ones (e.g., screening), and explain the importance of the study. Similar changes are proposed for the other study materials. Also, additional refusal conversion letters are included, to address specific reasons for refusal; and email messages are added to initiate or maintain contact with (potential) participants.

- Incentives—The study proposes to add an incentive ($10) for each parent interview, to increase the incentive for buccal cell and urine collection to $25 (from up to $20), and to increase the incentive for blood collection to $25 (from $25 for blood and urine collection).

- Instruments—The instruments are revised to improve wording and organization.

These changes are based on the field test results and additional cognitive testing. The project summary has been revised to reflect the proposed changes.

The study consent forms, recruitment and other materials, and instruments are being translated into Spanish. What's communicated is the same in English and Spanish, except for wording that reflects cultural differences.

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:**	11 / 28/ 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:

Kerry Levin 4/23/2013

IRB Chair / Associate Chair / Designee

IRB Office Only

☒ **APPROVED** – NEXT CONTINUING REVIEW DATE: 07 / 00/ 2013

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

☐ **DID NOT QUALIFY FOR EXPEDITED REVIEW**