TO: Office of Management and Budget (OMB)
Through: Reports Clearance Officer, DHHS
Project Clearance Chief, NIH
Project Clearance Liaison, National Institute on Drug Abuse (NIDA)

FROM: Kevin P. Conway, Ph.D.

SUBJECT: Request to Conduct Cognitive Interviews to Support Development of Questionnaire Items under OMB Control Number 0925-0663, Expiration Date 11/30/2015, Generic Clearance for Cognitive Testing of Instrumentation and Materials for the Population Assessment of Tobacco and Health (PATH) Study (NIDA)

The National Institute on Drug Abuse (NIDA) plans to conduct cognitive interviews under OMB Control Number 0925-0663, expiration date 11/30/15, Generic Clearance for Cognitive Testing of Instrumentation and Materials for the Population Assessment of Tobacco and Health (PATH) Study (NIDA). The purpose of these cognitive interviews is to test existing, revised, and new questions to inform the design and development of the questionnaires that will be used in Wave 4 of the PATH Study.

Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (referred to herein by TCA) became law. The TCA authorizes the Food and Drug Administration (FDA), through the Center for Tobacco Products (CTP), to regulate tobacco products, including, for example, tobacco product standards, constituents, labeling, marketing practices, advertising, and promotional activities to appeal to youth. FDA's CTP requires a solid evidence base to inform its regulatory decisions in fulfilling the mandates of the TCA.

Under data collection authorization of Title 42 USC 285o, NIDA is partnering with FDA's CTP to enhance this evidence base by conducting the national longitudinal cohort study known as the PATH Study. The PATH Study uses automated computer-assisted interviews (ACASI) to collect baseline and follow-up information from youth ages 12-17 and adults ages 18 and older on a number of issues, including use of existing and emerging tobacco products; attitudes and perceptions toward use of different tobacco products; knowledge of the contents of tobacco products and of the health consequences of their use; tobacco-use cessation attempts, cessation outcomes, and rates of relapse; uptake of new products, product/brand switching, and dual-and-poly-use of tobacco products; and health conditions, including those potentially related to use of tobacco products, particularly new and emerging products. The PATH Study is also collecting biospecimens from adults to assess biomarkers of tobacco exposure and potential indicators of harm related to tobacco use.

Purpose and Use of the Information Collection

The objective of this request is to test existing, revised, and new questions to inform the design and development of the questionnaires that will be used in Wave 4 of the PATH Study, slated to begin in the fall of 2016. The items that will be tested address topics such as young adult living situations, perceptions of tobacco-related content on social media sites, use of specific tobacco products such as electronic nicotine products and hookah, and disposal of cigarettes and disposable e-cigarettes.

Cognitive interviewing (or cognitive testing) is used to identify potential problems with existing questions, as well as to test participants' understanding of new questions (e.g., on the use of new tobacco products or on emerging tobacco product use patterns). In the cognitive interview, the participant is asked to complete a questionnaire in the presence of a specially-trained interviewer, who probes the participant for additional information. Probes are used to determine if the participant understands specific terms and concepts, whether response categories are appropriate, and whether questions are unambiguous and easily answered by participants. Cognitive interviewing with participants who use different types of tobacco products will help to inform changes and improvements in the PATH Study's Wave 4 instruments.

Sample Selection. This sub-study will include 111 English-language cognitive interviews. Facilities will advertise the sub-study to solicit participation. Facilities will recruit participants using their own internal recruiting database, as well as newspaper ads, fliers, and Craigslist ads. Facilities will adapt recruiting strategies as needed to ensure adequate participation. Interested participants who contact sub-study recruiters will be asked a series of screening questions to determine their eligibility. (See Attachment A for screening questionnaires.) Persons selected to participate will be contacted by the recruiters and scheduled for their interview session. No youth will be screened without permission from a parent or guardian. Individuals will be selected to the extent possible to achieve diversity by age, gender, educational attainment, race, and ethnicity across the interviews.

The interviews will be conducted in three locations (Denver, CO; Chicago, IL; Boston, MA). Conducting interviews at multiple locations across the country facilitates recruitment of diverse participants from different geographic regions where use patterns and terminology may also vary. In addition, these three locations allow the PATH Study to reduce costs by taking advantage of existing facilities.

English-speaking participants will be eligible if they have participated in fewer than two interviews or focus groups in the past year. Local research facilities in each of the three locations will recruit participants for the in-person one-on-one interviews. Facility staff will use their internal databases of volunteer participants as well as local-area advertisements to recruit a total of 72 adults and 39 youth (ages 12-17) for interviews. These numbers were chosen to ensure sufficient representation in each of the key tobacco product use subgroups.

Adult participants will be recruited to ensure a mix of e-cigarette or other electronic nicotine product users, cigarette smokers, hookah smokers, snus or smokeless tobacco users, social media users, and young adults from a variety of living situations. (Use is defined in the recruitment screener. Participants may fit into more than one category.) Youth participants will be recruited to ensure a mix of tobacco users and non-users, as well as social media users. Youth participants

cannot be screened or participate in the interviews without the consent of a parent or guardian. Youth will not be allowed to participate if a parent or guardian is not present at the beginning of the interview. Youth are allowed to participate even if a parent or guardian from the same household is participating, but will not be interviewed together.

Table 1. Number of interviews by participant type and location

Location	Adult	Youth	Total
Denver, CO	24	13	37
Chicago, IL	24	13	37
Boston, MA	24	13	37
Total	72	39	111

Data Collection. Interviews will be conducted by a team of trained and experienced cognitive interviewers. All interviews will take under 60 minutes to complete. No interview will continue beyond an hour. Using a semi-structured protocol and a mix of concurrent and retrospective probes, interviewers will ask participants to complete selected questionnaire modules (i.e., not the full PATH Study questionnaire). The focus will be on identifying questions that are vague or ambiguous, that cannot be answered readily or accurately by the participant, and that may pose comprehension or instrument navigation challenges.

The questionnaire modules are organized around specific topic areas, such as electronic nicotine products, media, cigarette smoking, and risk and harm perceptions. There will be 10 topic-specific protocols. Each participant will be assigned a group of modules depending on his or her characteristics. Please note that while some of the protocols appear lengthy, no interview will last beyond an hour. The length of the protocols is primarily an artifact of converting a programmed instrument to a self-administered format. For example, the Electronic Nicotine Module contains 4 different versions of each question depending upon whether the respondent needs a fill of "e-cigarette", "e-cigar", "e-hookah", or "e-pipe". So while the protocol appears lengthy on paper, the respondent will only receive approximately a fourth of the module. (See Attachment B for the cognitive testing protocols.) No interview will continue beyond an hour.

The cognitive testing activities and materials outlined in this memo were granted Institutional Review Board (IRB) approval on July 6, 2015 by Westat's IRB (Attachment C).

All cognitive interviews will be audio-recorded with the participant's consent and the recordings will be transcribed. The audio recordings will only be accessible to project staff directly working on the project and no names or other personally identifying information (other than the participant's voice itself) will be included on the audio recordings or transcripts.

Informed Consent. Adult participants will review the informed consent document with the aid of the interviewer and will be asked to sign the form before participating. Should an individual refuse informed consent, s/he will be excused from participation and thanked for her/his time. At the time of consent, the interviewer will also ask permission to audio record the interview.

For youth participants, the consent process will take place with the parent/guardian in the room. Parental permission for the interview and informed assent from the youth will be obtained. Youth will be assured that participant confidentiality means that neither parents nor authorities will have access to any information from the interview. After consent/assent is obtained, parents will be excused from the room before the interview begins.

The consent and assent forms can be found in Attachment D.

Incentive Payment. The cognitive testing sub-study will provide $40.00 cash to each adult participant and $25.00 cash to each youth participant at the completion of the interview. This is the Federal government's standard remuneration for cognitive interviewing, offered to thank the participant for his or her time and contribution to the substudy. Participants will receive the incentive at the completion of each interview. The parents and guardians of youth participants will be offered $10.00 in remuneration for travel expenses; note that the parents and guardians will transport their youth to the session, provide written permission for their youth's participation, and wait as their youth participates in the session. They will not participate in the session with the youth or in a different session at the same time as the youth. The $10.00 remuneration offered to parents and guardians of youth is strictly to offset travel expenses incurred for transporting the youth to and from the cognitive testing session.

Data Analysis. Cognitive interviewers will use qualitative methods to analyze the cognitive interview data. The tested questionnaire items and associated probes will provide the framework for written interview summaries. Interviewers will prepare summary findings on each completed interview based on the completed questionnaire modules, notes taken during the interview, associated audio recordings, and transcripts of the interview itself. Summaries will be analyzed using NVIVO qualitative software to help identify common themes organized by overall questionnaire issues, individual questionnaire items and sections, and participants' overall reactions to the questionnaire. These analyses will guide recommendations for the final question wording of questionnaire items to be included or considered for Wave 4 of the PATH Study's data collection.

Use of Information Technology to Reduce Burden

The cognitive testing sub-study will utilize technology to facilitate recruitment and the scheduling process while also reducing participant burden and controlling study costs. Recruitment efforts will use email communications when possible, because participants increasingly prefer to communicate via email so they can respond when it is convenient. Using email for recruitment and scheduling can help to reduce participant burden and save time and money that would otherwise be spent conducting telephone calls, leaving voice messages, and making call-backs.

Efforts to Identify Duplication

Data collected by this cognitive testing sub-study will be specific to the cognitive testing needs of the PATH Study (i.e., to identify and correct problems in existing questions and response options and to inform the development of new questions for Wave 4 of the PATH Study's data collection). In an effort to maximize the utility of data collected, minimize burden on

participants, and comply with HHS standards, the PATH Study collaborates with other tobacco-related data collections supported by the Federal government and reviewed by OMB. NIH and FDA coordinate with the Assistant Secretary for Planning and Evaluation (ASPE) at HHS and with program leads on tobacco-related studies within NIH (e.g., NCI) and at HHS sister agencies (e.g., CDC, SAMHSA) to harmonize questionnaire development activities among tobacco-related data collection efforts. The PATH Study welcomes the feedback of HHS program leads on its cognitive testing plans, and specifically for this sub-study, has sought to incorporate recommended changes, comments, and suggestions by HHS program leads into the final version of this document for OMB review and approval.

Consequences of Collecting the Information Less Frequently

This cognitive testing sub-study is planned for August - September of 2015 to ensure its findings will be available to use in the development of the PATH Study's Wave 4 questionnaires for the fall of 2016. The consequences of not conducting this cognitive testing sub-study as described herein are that its findings would not be available in time to inform measures development of the Wave 4 questionnaires. Ultimately, this could impact the relevancy, timeliness, quality, and utility of the PATH Study data.

Assurance of Confidentiality Provided to Participants

Participation in this cognitive testing sub-study is voluntary. Personally identifiable information (PII), including names and contact information (phone number and/or email address), will be collected by recruiting facilities for the purpose of scheduling eligible participants for interviews. These data will be securely stored in password protected files to which only project staff will have access, and will be destroyed after the study is finished. Names provided by participants on consent and incentive receipt forms will be stored in locked cabinets, separate from data. Participant PII will never be associated with data collected during the interview. PII for individuals not selected for interviews will be destroyed immediately. PII for selected participants will be destroyed per contract requirements.

The data collection materials (Attachments A, B, and D) used in this sub-study have been reviewed and approved by the Westat Institutional Review Board (IRB) to ensure the protection of human subjects. (See Attachment C for Westat's IRB Approval Letter.)

Estimates of Hour Burden Including Annualized Hourly Costs

The average annual hour burden for the proposed study is presented in Table 2 for each activity (screener, consent, and interview).

Table 2. Annualized hour burden estimates

Activity Name	Type of Participant	Number of Participants	Number of Responses per Participant	Average Burden per Response (in hours)	Total Annual Burden Hours
Adult Screening	Adult	378	1	10/60	63
Parent Screening	Parent	216	1	2/60	7
Youth Screening	Youth	216	1	8/60	29
Adult Consent	Adult	72	1	4/60	5
Parent Permission	Parent	39	1	4/60	3
Youth Assent	Youth	39	1	4/60	3
Adult Interviews	Adult	72	1	56/60	67
Youth Interviews	Youth	39	1	56/60	36
Total					213

The estimates for hourly wage of adult participant (Table 3) are based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics' Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates United States. (See http://www.bls.gov/oes/current/oes_nat.htm.) The estimates for hourly wage of youth participant (Table 3) are based on the federal minimum wage established in 2009. See http://www.dol.gov/dol/topic/wages/minimumwage.htm.

Table 3. Annualized cost to participant

Activity Name	Type of Participant	Number of Participants	Number of Responses per Participant	Average Burden per Response	Total Annual Burden Hours	Hourly wage rate	Respondent Cost
Adult Screening	Adult	378	1	10/60	63	$17.09	$1,077
Parent Screening	Parent	216	1	2/60	7	$17.09	$120
Youth Screening	Youth	216	1	8/60	29	$4.45	$129
Adult Consent	Adult	72	1	4/60	5	$17.09	$85
Parent Permission	Parent	39	1	4/60	3	$17.09	$51
Youth Assent	Youth	39	1	4/60	3	$4.45	$13
Adult Interviews	Adult	72	1	56/60	67	$17.09	$1,145

Activity Name	Type of Participant	Number of Participants	Number of Responses per Participant	Average Burden per Response	Total Annual Burden Hours	Hourly wage rate	Respondent Cost
Youth Interviews	Youth	39	1	56/60	36	$4.45	$160
Total							$2,781

List of Attachments

Attachment A. Recruitment Screeners

A-1. Adult Recruitment Screener

A-2. Electronic Nicotine Product (ENDs) Recruitment Screener

A-3. Youth Recruitment Screener

A-4. Young Adult Recruitment Screener

Attachment B. Cognitive Testing Protocols

B-1. Adult Interview Introduction

B-2. ENDs Interview Introduction

B-3. Youth Interview Introduction

B-4. Screening Module

B-5. Screening Module Images

B-6. Adult Cigarettes Module

B-7. Adult Hookah Module

B-8. Adult Smokeless/Snus Module

B-9. Adult Harm Perceptions Module

B-10. Adult Media Module

B-11. Social Media Card Sort Images

B-12. Adult Barcode Scanning Module

B-13. Adult ENDs Module

B-14. Young Adult Cigarettes Module

B-15. Young Adult Hookah Module

B-16. Young Adult Demographics Module

B-17. Youth Cigarettes Module

B-18. Youth Hookah Module

B-19. Youth Social Norms Module

B-20. Youth Harm Perceptions Module

B-21. Youth Media Module

Attachment C. IRB Approval Letter

Attachment D. Consent, Permission and Assent Forms

D-1. Adult Consent Form

D-2. Parental Permission and Youth Assent Forms