

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 develop new items and update current items for the PATH Study's questionnaires.

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. Fulfilling the mandates of the TCA, FDA's CTP requires a solid evidence base that informs their regulatory decisions, their implementation, and subsequent assessments of their effectiveness, as well as their future regulatory decisions and actions.

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 3 of the PATH Study, slated to begin in September 2015, and in subsequent follow-up waves of data collection.

Cognitive interviewing (or cognitive testing) is used to identify potential problems with existing questions, as well as to develop new questions (e.g., on the use of new tobacco products or on emerging tobacco product use patterns). In the cognitive interview, a volunteer participant is asked to complete a questionnaire in the presence of a specially-trained interviewer, who probes the respondent for additional information. Cognitive testing with a large sample (i.e., more than nine individuals) from key tobacco product use subgroups will help to ensure that wording and concepts presented in the questionnaires are unambiguous and meet the measurement objectives. Results from this sub-study will help to inform changes to the PATH Study's Wave 3 instruments.

Sample Selection. This sub-study will include 144 English-language cognitive interviews as well as 40 Spanish-language cognitive interviews. The English and Spanish language cognitive interviews have different sample selection procedures and criteria based on the varying needs of testing for each language. Facilities will advertise the study in order to solicit participation. Interested participants who contact the study recruiters will be asked a series of screening questions to determine their eligibility (see Attachments A and B for screening questionnaires). Persons selected to participate will be contacted by study recruiters and scheduled for their interview session. Individuals will be selected to ensure maximum diversity by age, gender, educational attainment, race, and ethnicity across all interviews.

English Interviews. The English language interviews will be conducted in four locations (Pittsburgh, PA, Tallahassee, FL, St. Louis, MO, and Los Angeles, CA). English-speaking respondents 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 four 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 112 adults and 32 youth (ages 12-17) for interviews. These numbers were chosen to ensure sufficient representation in each of the key tobacco product use subgroups.

Adult respondents will be recruited to ensure a mix of polyusers (users of more than one type of tobacco product), hookah users, e-cigarette or electronic tobacco product users, cigar smokers, smokeless tobacco users, and women under the age of 40 who have been pregnant. Respondents may also fit into more than one category. Youth will be recruited as part of a parent-child dyad. Youth will not be screened individually, but will instead be chosen based on parent or guardian responses during screening. Adult and youth interviews will take place simultaneously but in separate rooms.

Spanish Interviews. The Spanish language interviews will be conducted at Westat's facilities in Rockville, MD. Rockville was selected to minimize costs and because of its proximity to EurekaFacts, a research firm that specializes in Spanish-language testing. EurekaFacts will

recruit Spanish-speaking adult respondents for the in-person, one-on-one interviews, conducted by their staff of trained bilingual interviewers. Recruitment will be through EurekaFacts’ internal database of participants and through advertisements. Participants will be eligible only if they have participated in fewer than two interviews in the past year. Individuals selected for the Spanish interviews will be native Spanish speakers, for whom Spanish is their primary language, with a mix of ethnic backgrounds or countries of origin. Participant selection will seek to ensure a diverse background of demographics (i.e., age, gender, education attainment, race and ethnicity) and tobacco use. A sufficient number of participants will be recruited to yield 40 adult participants selected for interviews, 15 of whom will be young adults, 18-25 years old.

Data Collection. All cognitive interviews will be conducted in person. The English-language interviews will be conducted at research facilities in one of the four previously mentioned locations. Conducting interviews at multiple locations across the country allows us to open up recruitment to a more diverse population and to include participants from different geographic regions. These four locations were chosen in order to maximize geographic diversity while taking advantage of existing facilities and saving money.

The Spanish-language interviews will be conducted at Westat in Rockville, MD. (See Table 1 for a summary of the interviews by location.)

Table 1. Number of interviews by respondent type and location

Location	English Adult	English Youth	Spanish Adult	Total
Pittsburg, PA	28	8	0	36
Tallahassee, FL	28	8	0	36
St. Louis, MO	28	8	0	36
Los Angeles, CA	28	8	0	36
Rockville, MD	0	0	40	40
Total	112	32	40	184

The interviews will be conducted by a trained and experienced cognitive interviewer. All interviews will take under 60 minutes to complete. Using a semi-structured protocol and a mix of concurrent and retrospective probes, interviewers will ask respondents to complete questionnaire modules (i.e., not the full interview). 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. If a respondent asks about tobacco cessation, interviewers will be prepared to direct the respondent to appropriate resources that can provide this information.

The questionnaire modules are organized around specific topic areas, such as hookahs, e-cigarettes, health and demographics. Given the length of the English protocol, a subset of the

modules will be randomly assigned to each respondent. (See Attachments E and F for the cognitive testing protocols.) Respondents may receive up to 7 modules but no respondent will continue beyond an average of 56 minutes. Spanish-language respondents will be asked to complete Spanish versions of the questionnaire modules.

All cognitive interviews will be audio-recorded with the respondent's consent. 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 respondent's voice itself) will be included on the audio recordings.

Informed Consent. The cognitive testing activities and materials outlined in this memo were granted Institutional Review Board (IRB) approval on 5/30/2014 by Westat's IRB (see Attachment G).

Adult respondents 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 respondents, 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 Attachments C and D.

Incentive Payment. The cognitive testing study will provide \$40.00 cash to each adult and \$25 to each youth participant at the completion of the interview. This is the Federal government's standard remuneration for cognitive testing, offered to thank the participant for his or her time and contribution to the study. Participants will receive the incentive at the completion of each interview.

Data Analysis. The cognitive interviewers will use qualitative analysis methods to analyze the cognitive interview data. The tested questionnaire items and associated probes will provide the framework for written interview summaries. The interviewers will prepare summary findings on each completed interview based on the completed questionnaire modules, notes taken during the interview, and associated audio recordings of the interview itself. The summaries will be analyzed using NVIVO qualitative software to help identify common themes organized by overall questionnaire issues, individual questionnaire items and sections, and respondents' 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 3 of PATH data collection.

Use of Information Technology to Reduce Burden

The cognitive testing study will utilize technology to facilitate recruitment and the scheduling process while also reducing respondent burden and controlling study costs. Recruitment efforts will use email communications when possible since participants may 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 in this cognitive testing study will be specific to the cognitive testing needs of the PATH Study (i.e., to identify and correct problems in existing questions and to develop new questions for Wave 3 of the PATH Study's data collection). Testing of existing questions will be to identify potential problems to help revise and improve those questions; all other testing will be of questions that are under development for the Wave 3 instruments.

Consequences of Collecting the Information Less Frequently

This cognitive testing is planned for July - October of 2014 to ensure its findings will be available in time to inform the PATH Study's Wave 3 questionnaires for data collection in September 2015. The consequences of not conducting this cognitive testing as described herein are that its findings would not be available to meet the PATH Study's needs for reliable and valid measures in its Wave 3 questionnaires, and ultimately, for assuring the relevancy, timeliness, quality, and utility of the PATH study data.

Assurance of Confidentiality Provided to Respondents

Participation in this cognitive testing study is voluntary. Participants will be afforded the same protections as in the main PATH Study. 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 cognitive testing is finished. Names provided by participants on consent and incentive receipt forms will be stored in locked cabinets, separate from data. Respondent 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 respondents will be destroyed per contract requirements.

The data collection materials (Attachments A through G) used in this study have been reviewed and approved by the Westat Institutional Review Board (IRB) to ensure the protection of human subjects. (See Attachment G for Westat's IRB approval letter and consent form.)

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

Estimates of Annual Burden Hours							
Data Collection Activity	Type of Respondent	# of English-Language Respondents	# of Spanish-Language Respondents	Total # of Respondents	# of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Screening	Adults	448	160	608	1	10/60	101
Adult Consent	Adult	112	40	152	1	4/60	10
Parental Consent	Parents	32	--	32	1	4/60	2
Youth Assent	Youth	32	--	32	1	4/60	2
Interviews	Adults	112	40	152	1	56/60	142
	Youth	32	--	32	1	56/60	30
Total							287

The estimates for hourly wage of adult respondents (Table 3) are based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics' Occupational Employment Statistics, May 2013 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 respondents (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 respondents

Annualized Cost to Respondents							
Data Collection Activity	Type of Respondent	Total # of Respondents	# of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours	Median Hourly Wage Rate	Respondent Cost
Screening	Adults	608	1	10/60	101	\$16.87	\$1,703.87
Informed Consent	Adults	152	1	4/60	10	\$16.87	\$168.70
	Youth	32	1	4/60	2	\$7.25	\$14.50
Interviews	Adults	152	1	56/60	142	\$16.87	\$2,395.54
	Youth	32	1	56/60	30	\$7.25	\$217.50
Total					285		\$4,500.11

List of Attachments

- A. English Screening Questionnaire
- B. Spanish Screening Questionnaire
- C. Adult Consent Form
- D. Youth Assent and Parental Consent Forms
- E. Spanish Testing Protocol
- F. English Testing Protocol
- G. IRB Approval Letter