

**Supporting Statement A  
for  
Request for Generic Clearance for  
Cognitive Interviews and Focus Groups  
for the Population Assessment of  
Tobacco and Health (PATH) Study (NIDA)**

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## **A. Justification**

### **A.1 Circumstances Making the Collection of Information Necessary**

The National Institutes of Health (NIH), through the National Institute on Drug Abuse (NIDA) and in partnership with the Food and Drug Administration (FDA), requests Office of Management and Budget (OMB) approval of a revision of an existing Generic Clearance (OMB number 0925-0663, expiration date 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study, for the purpose of conducting cognitive interviews (also referred to as cognitive tests) and focus groups. These techniques serve an essential step in the development of instrumentation and materials used by the PATH Study to collect data and biospecimens.

**The PATH Study.** Under data collection authorization of Title 42 USC 285o (Attachment 1), NIDA is partnering with FDA to conduct the PATH Study through a contractor. The PATH Study is collecting behavioral data and biospecimens on tobacco-use patterns; attitudes and beliefs regarding harmful constituents, and new and emerging tobacco products; and tobacco initiation, cessation, and relapse behaviors among the U.S. civilian non-institutionalized population, ages 12 and older. Its longitudinal, population-based data will help to enhance the evidence base that informs FDA's regulatory actions under the Family Smoking Prevention and Tobacco Control Act (TCA), to protect the Nation's public health and reduce its burden of tobacco-related morbidity and mortality.

The first annual data and biospecimen collection for the PATH Study (Wave 1) took place October 2013 - December 2014 with a total sample of 45,971 (32,320 adults and 13,651 youth). Wave 2 began in October 2014, and Wave 3 is scheduled to begin immediately after Wave 2 in October 2015. Pending funding and other considerations, additional follow up waves may occur thereafter.

**Cognitive Interviews and Focus Groups.** Focus group research uses guided, interactional discussions among a small group of individuals to help identify and understand new or complex issues (Powell & Single, 1996). Cognitive interviewing uses in-depth interviewing that assesses how people interpret, process, retrieve, and respond to words, phrases, questions, response options, and product images (Willis, 2015). These qualitative methodologies help the PATH Study improve the accuracy of its instruments, as well as the comprehensibility of its introductory letters to potential participants, consent forms, brochures, and related materials about the Study.

**Generic Clearance Request.** To meet the ongoing needs of the PATH Study to develop and refine its instruments and data collection materials, this is a revision of a currently approved Generic Clearance (OMB number 0925-0663) that will expire on November 30, 2015. This revision request is for three years for the current Generic Clearance for cognitive interviews, with the addition of focus groups. As shown in section A.12, approval is sought to screen 3,600 individuals each year to recruit approximately 1,200 to participate in cognitive interviews and focus groups. Upon approval, NIDA will submit individual or bundled substudies under this Generic Clearance. Only instruments, consent forms, and other materials that have been approved by the prime contractor's Institutional Review Board (IRB) will be included in requests submitted under this Generic Clearance. NIDA requests a 10-working day OMB review period for substudy submission. Approval for use of participant incentives will be requested as necessary on a case-by-case basis.

## **A.2 Purpose and Use of the Information Collection**

The purpose and use of this information collection are to inform the development of measures, questionnaire items, and related data collection materials for use by the PATH Study. Cognitive interviews and focus groups with a large sample (i.e., more than nine individuals) of demographically diverse respondents will help the PATH Study ensure that the wording and concepts presented in its questionnaires and materials are unambiguous,

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comprehensible, and understood by a variety of individuals from different backgrounds and subgroups of interest (e.g., of different ages, race/ethnicities, genders, and geographic regions). Substudies submitted under this Generic Clearance and approved by OMB will help to inform decisions by the PATH Study on whether to change or retain questionnaire items in the instrument from one wave of data collection to the next. Such changes could be incremental, as in substituting an outdated term for a product with a new one that is now widely recognized and accepted; or substantive, as in response to a recent tobacco product regulation promulgated by FDA. They could also reflect a change in data collection mode, such as the use of a web-based format for use by participants who move and cannot be interviewed in person.

### **A.3 Use of Information Technology and Burden Reduction**

Appropriate technology will be used to keep participant burden to a minimum. Cognitive interviews and focus groups will both be conducted by an interviewer or moderator. However, automated data collection methods such as computer assisted personal interviewing (CAPI) and audio computer assisted self-interviewing (ACASI), as well as web-based cognitive interviews and focus groups, may be used to reduce participant burden. In CAPI interviews, an interviewer asks a participant to answer questions and records responses into a laptop computer. In ACASI interviews, a participant uses a computer to answer questions on his/her own; the method includes audio capabilities where interview items (e.g., questions, response categories, and instructions) are read aloud. Both of these technologies reduce the burden on participants, as both eliminate the need for participants to read interview items and write responses. Cognitive interviews and focus groups about CAPI and ACASI may ask participants about their general experiences with the data collection methods, whether they preferred one method over the other and why, and about their understanding of the study questions being tested.

If needed, interviewers and moderators may also use hard-copy forms and questionnaires when conducting cognitive interviews and focus groups with

participants. These hardcopy materials will be developed in user-friendly formats to reduce the time needed for completion by participants.

The PATH Study instruments, consent forms, and other materials will be available in both English and Spanish. As appropriate, cognitive interviews and focus groups may be conducted on Spanish versions of the instruments, consent forms, and other materials. In such instances, the Spanish versions to be tested will be included in the substudy request submitted to OMB under this Generic Clearance.

#### **A.4 Efforts to Identify Duplication and Use of Similar Information**

Cognitive interviews and focus groups conducted under this Generic Clearance will not duplicate other instrument development activities by the PATH Study or by other studies, such as may be conducted by programs in sister agencies of the U.S. Department of Health and Human Services (HHS). Rather, each substudy will be for the purpose of addressing a specific informational need of the PATH Study. During the planning and development of a substudy for submission under this Generic Clearance, the PATH Study will first review the literature for information that may be relevant to ensure that the planned substudy fills a specific need, addresses unique questions, and will not be duplicative of existing efforts. In addition, to reduce duplication and associated participant burden, the PATH Study team will invite program leads on tobacco studies from sister HHS agencies to review the draft plans and protocols for each substudy in advance of submitting the substudy request to OMB.

The PATH Study's data collection instruments, consent forms, other materials are relatively new: Wave 1 was completed in December 2014, and Wave 2 is underway as of mid-2015. Many content areas (e.g., emerging tobacco product use) that are important to the PATH Study are largely unknown. Focus groups and cognitive interviews are useful methods for obtaining information on novel tobacco themes and questions, and they aid in the development and refinement of assessment instruments and materials. They

also are useful for detecting questionnaire flaws associated with non-sampling error, such as ambiguous items within the instrument.

## **A.5 Impact on Small Businesses or Other Small Entities**

There will be no impact on small businesses or other small entities. Small business entities or other small organizations will not be involved in the study.

## **A.6 Consequences of Collecting the Information Less Frequently**

Substudies under this Generic Clearance will facilitate the development and improvement of data collection instruments and materials for use by the PATH Study. It is important to test and refine such materials with demographically diverse respondents to make sure they are unambiguous, comprehensible, and processed in a similar way by everyone. In this way, the PATH Study can achieve the degree of standardization necessary in its data collection instruments to support meaningful data analyses, including comparing within-person changes and between-person differences within the cohort and at the population level, over time.

The consequences of collecting information under this Generic Clearance less frequently will be to increase the risk of non-sampling errors associated with questionnaire items that may be interpreted by different respondents in different ways. These types of errors are preventable when focus groups and cognitive interviews are used to assess such items prior to incorporating them into the instruments for the main study. Given the potential that non-sampling errors have to impact the accuracy, utility, and comparability of data collected from the large cohort, the PATH Study seeks to minimize their likelihood by conducting focus groups and cognitive interviewing early in the instrument development process. These methods are particularly important for the PATH Study, because it needs to develop new items to measure previously unmeasured behaviors or concepts, such as those related to

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emerging tobacco products, and to do so in time to inform the PATH Study's instruments for its next wave of data collection.

As mentioned in Section A.12, cognitive interviews and focus groups will be conducted with approximately 1,200 individuals annually.

## **A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This project fully complies with the guidelines of 5 CFR 1320.5.

## **A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency**

The 60-day Federal Register Notice, required by 5 CFR 1320.8 (d), soliciting comments on the information collection prior to submission to the OMB, was published on June 30, 2015 in the Federal Register (Vol. 80, No. 125, pp. 37276 - 37277).

Researchers who have special interest and expertise in the issues addressed by the PATH Study will be invited to provide their expertise in the development of substudies submitted under this Generic Clearance. In addition, NIDA's contractor for the PATH Study has highly-experienced methodologists and specialists in cognitive interviews and focus groups. Members of the PATH Study instrument development workgroup will also be consulted to ensure continuity between the main study and the specific substudy. A list of potential consultants is provided in Attachment 2.

## **A.9 Explanation of Any Payment or Gift to Respondents**

Substudies planned under this Generic Clearance will offer an incentive to participants to thank them for their participation and cover any costs they incur for transportation and parking. The incentive amounts will vary for  
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cognitive interviews and focus groups, depending on the level of difficulty in recruiting participants for each request, with the standard amount equal to \$40. Proposed incentive amounts and justification for them will be included in each request submitted under this Generic Request. Unless otherwise noted in a given request, all incentives will be provided in cash.

## **A.10 Assurances of Confidentiality Provided to Respondents**

The NIH Privacy Act Officer has reviewed the information contained herein and determined that the Privacy Act applies to data collected under this Generic Clearance. Information collected under this Generic Clearance is covered by NIH Privacy Act SORN 09-25-0200, “Clinical, Basic, and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD” published in the Federal Register on September 26, 2002 (67 FR 60776) (Attachment 3).

All data collection materials and instruments to be tested under this Generic Clearance will be reviewed and approved by the prime contractor’s Institutional Review Board (IRB) to ensure that human subjects are protected. The IRB review and approval process will be completed before any contacts with human subjects.

Each substudy request under this Generic Clearance will include a consent form and a plan for ensuring that personally identifiable information (PII) is not retained as part of the research. All substudy staff will be responsible for safeguarding schedules, consent documents, audiotapes and videotapes, questionnaires, and cash incentives to participants. These staff will be well trained in the PATH Study data security procedures and in confidentiality and privacy issues and procedures. Cognitive interviewers and focus group moderators will be required to sign a pledge of confidentiality (Attachment 4) and to complete training on standards and ethics in survey research, including the importance of confidentiality and informed consent. Staff will also be trained on study-specific procedures for maintaining participant

privacy and the confidentiality of data. These trainings are required before conducting any cognitive interviews or focus groups.

PII, including names and contact information, will be collected only for the purposes of subject recruitment for cognitive interviews or focus groups, to document informed consent, and to record any incentives received on receipts. PII will not be associated with information or data collected during a cognitive interview or focus group. Cognitive interviews and focus group data records will only include participant identifier (ID) numbers; and these data will only be retrievable by participant ID, not by any PII. A crosswalk linking PII with participant ID numbers will be kept electronically in a password-protected file accessible only to the recruiter and task lead. This crosswalk will be used only for recruiting purposes and to schedule cognitive interview and focus group sessions.

Upon completion of a cognitive interview or focus group, the data, any notes written on other pieces of paper, and the interview or group recording (if created) will be stored in a locked file cabinet (for hard copy forms) or electronically in a password-protected file (for electronic files). As needed, recordings may be labeled by participant or group identifier number, date, time, and project title. No other identifying information will be labeled on the recording. No participant names or other identifying information will be included in any reports, publications, or presentations of cognitive interview or focus group results. All data, recruitment forms, incentive forms, and crosswalks that link participant ID with PII will be kept until a recommendation report is written, and they will be destroyed 6 months after the report is completed.

## **A.11 Justification for Sensitive Questions**

Most of the questions contained in the PATH Study materials and instruments are not sensitive in nature, however, item sensitivity cannot always be predicted. An important purpose of conducting cognitive interviews and focus groups about potential questionnaire items and materials is to assess their level of sensitivity.

The PATH Study's instruments include questions on tobacco use; psychological problems and conditions; substance abuse; income; and sexual identity, orientation, and attraction. These questions relate to important outcomes and correlates of tobacco use and health and are included in both the adult and youth instruments. Cognitive interviews and focus groups will help to identify questionnaire items that participants may find sensitive or not want to answer, and may suggest other ways to ask such questions that minimize potential sensitivity without affecting the accuracy of responses.

As part of the informed consent process, participants will be told that their participation is voluntary, they may choose to not answer any question, and they may stop participation in the cognitive interview or focus group session at any time. Additionally, all data collection materials and instruments will be reviewed and approved by the prime contractor's IRB prior to the session.

## A.12 Estimates of Annualized Burden Hours and Costs

Table 1 presents the average annual hour burden for (1) screening respondents to participate in cognitive interviews or focus groups, and (2) participation in a cognitive interview or focus group session. With the exception of using only focus groups to examine the concepts to be measured, depending on the specific purpose of a substudy, cognitive interviews or focus groups could be used to support development of the PATH Study consent and assent forms, other forms and materials, and instruments.

Table 1. Hour burden estimates for screening respondents, and participating in cognitive interviews or focus groups

Activity Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Completing eligibility screener	Youth	1,600	1	10/60	267
	Adults	2,400	1	10/60	400

Examining concepts to be measured in PATH Study	Youth	100	1	90/60	150
	Adults	200	1	90/60	300
Examining assent forms for participation in PATH Study	Youth	200	1	90/60	300
Examining consent forms for participation in PATH Study	Adults	200	1	90/60	300
Examining other forms and materials to support PATH Study data collection*	Adults	200	1	90/60	300
Examining PATH Study questionnaires	Youth	100	1	90/60	150
	Adults	300	1	90/60	450
Total			5,300		2,617

\* For example, letters, brochures, or instructions for collection of biospecimens.

The average annual participant burden for both the screening and participation of respondents in cognitive interviews or focus groups planned under this Generic Clearance is estimated to be 2,617 hours, and a total of 7,851 hours over the 3-year approval period. These estimates cover the time for recruitment, screening, cognitive interviews or focus groups, and debriefing sessions following a cognitive interview or focus group.

Table 2 presents the annualized cost to: (1) screen participants for cognitive interviews and focus groups under this Generic Clearance, and (2) participate in cognitive interviews or focus groups.

Table 2. Annualized cost to respondents for screening respondents, and participating in cognitive interviews or focus groups

Activity Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Completing eligibility screener	Youth	1,600	1	10/60	267	\$4.25	\$1,135
	Adults	2,400	1	10/60	400	\$17.09	\$6,836
Examining concepts to be measured in PATH Study	Youth	100	1	90/60	150	\$4.25	\$638
	Adults	200	1	90/60	300	\$17.09	\$5,127
Examining assent forms for participation in PATH Study	Youth	200	1	90/60	300	\$4.25	\$1,275
Examining consent forms for participation in PATH Study	Adults	200	1	90/60	300	\$17.09	\$5,127
Examining other forms and materials to support PATH Study data collection*	Adults	200	1	90/60	300	\$17.09	\$5,127
Examining PATH Study questionnaires	Youth	100	1	90/60	150	\$4.25	\$638
	Adults	300	1	90/60	450	\$17.09	\$7,691
<b>Total</b>							<b>\$33,594</b>

\* For example, letters, brochures, or instructions for collection of biospecimens.

Estimates for adult hourly wages are based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics'

Occupational Employment Statistics, May 2104 National Occupational Employment and Wage Estimates United States. (See [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).) Estimates for youth hourly wages are based on the federal minimum wage. (See <http://www.dol.gov/dol/topic/wages/minimumwage.htm>.)

### **A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers**

There is no other annual cost burden to respondents or record keepers in substudies planned under this Generic Clearance, nor are there any capital, operation, or maintenance costs.

### **A.14 Annualized Cost to the Federal Government**

The PATH Study is conducted by a contractor with oversight, management, scientific direction, and analyses by federal and contractor staff at NIH/NIDA and FDA. The PATH Study contract is funded by FDA through an Interagency Agreement to NIH/NIDA using tobacco user fees assessed under the authority of the FSPTCA (PL 111-31, June 22, 2009). Contractor expenses for conducting cognitive interviews and focus group substudies under this Generic Clearance are for the design and development of the procedures and protocols, interviewer and moderator training, participant recruitment, preparation of needed forms and materials, provision of facilities and recording equipment, cognitive interview and focus group sessions, incentives, analysis of results, reporting of results, and recommendations for revisions to instruments or materials based on those results. Estimates in Table 3 are presented as the annualized cost to the U.S. Government for substudies under this Generic Clearance. The contract cost for those substudies is a subset of the cost of the entire PATH Study and not in addition to it.

Table 3. Annualized cost to the Government for Information Collection

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Government
<b>Federal oversight</b>					
NIH Project Oversight Officer	13/10	\$112,000	51.8%		\$58,000
<b>Contractor cost</b>					
Personnel (5)		\$87,000	63.6%	\$57,000	\$562,000
Other costs					\$398,000
<b>Total</b>					<b>\$1,018,000</b>

### A.15 Explanation for Program Changes or Adjustments

This is a revision request (OMB 0925-0663, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study to conduct cognitive interviews and focus groups, to support the development of the Study’s questionnaires and other materials. There is an increase of 617 estimated burden hours between the generic clearance approved by OMB in 2012 (2,000) and the current revision request (2,617). Factors accounting for the increase include the addition of: (1) focus groups, to complement cognitive interviewing as a method that will be used by substudies submitted under this Generic Clearance (see Sections A.1 and A.2); and (2) screening for respondents to participate in the focus groups.

As noted, the purpose of this Generic Clearance is to conduct cognitive interviews and focus groups to inform the development of the PATH Study’s questionnaires for use in the next and future waves of data collection. This was not possible when the new Generic Clearance (0925-0663) was approved by OMB on November 27, 2012 because its timeline lagged behind the development of the questionnaires for the PATH Study’s next two waves of data collection, i.e., Wave 1 and Wave 2.

Therefore, an additional factor that accounts for the increase in estimated burden in this revision request is that it repeats some of the previously listed substudies in the 2012 burden table, such as a substudy related to the consent and assent protocol.



NIDA and FDA are planning to conduct the substudies listed in this Generic Clearance, including those that are repeated from the 2012 burden table, in time to implement their findings in the development of questionnaires for use in the next wave and future waves of data collection with the PATH Study cohort. These substudies will involve adults and youth, males and females, and speakers in both Spanish and English to address the wording and refinement of questionnaire items, biospecimen collection protocols, and youth assent and parental and adult consent forms.

### **A.16 Plans for Tabulation and Publication and Project Time Schedule**

This revision request seeks OMB approval of the PATH Study's current Generic Clearance (0925-0663; expiration 11/30/2015) for 3 years. The substudies under this Generic Clearance will collect data through cognitive interviews and focus groups for qualitative data analysis. Specialists in conducting cognitive interviews and focus groups will use detailed notes and transcriptions from the interviews and groups to conduct qualitative data analyses and inform the development of the PATH Study's instruments and materials. Substudies to conduct cognitive interviews and focus groups are planned on an annual basis over the 3-year period of this Generic Clearance.

### **A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

This data collection activity does not seek approval to not display the expiration date for OMB.

## **A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

This data collection activity does not seek any exception to the certification statement associated with 5 CFR.1320.9, Certification for Paperwork Reduction Act Submissions.

## References

- Powell, R. A. & Single, H. M. (1996). Focus groups. *International Journal of Quality in Health Care*, 8 (5), 499-504.
- Willis, G. B. (2015). *Analysis of the cognitive interview in questionnaire design*. Oxford University Press.