Supporting Statement A
for
Request for Generic Clearance
Cognitive Testing of Instrumentation and Materials for the Population Assessment of Tobacco and Health (PATH) Study (NIDA)

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LIST OF ATTACHMENTS
(In order of appearance in Supporting Statement A)

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This request is for Office of Management and Budget (OMB) approval for cognitive interviewing and testing of instrumentation and materials for use in the Population Assessment of Tobacco and Health (PATH) study. The National Institutes of Health (NIH), through the National Institute on Drug Abuse (NIDA) and in partnership with the Food and Drug Administration (FDA), is conducting the PATH Study. The PATH Study (for which a separate information request is being submitted to OMB) is scheduled to begin data and biospecimen collection in the fall of 2013, with a field test in the fall of 2012. Questionnaire cognitive interviewing and testing, the subject of the current OMB request, are needed to inform the development of the instrumentation for the PATH Study baseline and follow-up waves of data and biospecimen collection. This is a new request.

The PATH Study. Under data collection authorization of Title 42 USC 285 (Attachment 1), NIDA's management of the PATH Study is in conjunction with Westat, the prime contractor. Through computer-assisted interviews and collection of biospecimens, this longitudinal cohort study will collect baseline and follow-up information on tobacco-use patterns; trends in risk perceptions and attitudes regarding harmful constituents and new and emerging products; and tobacco initiation, cessation, and relapse behaviors among youth aged 12-17 and adults ages 18 and older. The PATH Study will also examine intermediate endpoints and incident health outcomes associated with tobacco-use and related disease processes through the collection of biospecimens (buccal cells, urine, and blood) among consenting adults. The planned sample size is 59,000 participants. The target population is the civilian non-institutionalized population in the United States (U.S.), including Alaska and Hawaii; and will include persons (excluding active duty military) living in households and selected non-institutionalized group quarters.

The first (baseline) annual data and biospecimen collection for the PATH Study is planned for 12 months, beginning in September 2013. It will be followed immediately by a second wave of annual data and biospecimen collection, then by the third wave, then the fourth wave, with the expectation that the PATH Study will continue to follow participants for at least 5 years.

Cognitive Interviewing. In addition to the PATH Study's design features (described in a separate information request), cognitive testing can support achievement of study objectives by enhancing the recruitment and retention of study participants and the validity of the information collected from them. Specifically, cognitive testing of PATH Study survey questions, data collection materials (such as letters to study participants), and consent forms will help to improve the instruments, materials, and consent forms used in each wave of data and biospecimen collection. A detailed description of cognitive testing and methods used in cognitive testing is presented in Attachment 2

Proposed Generic Clearance Request. Several Federal agencies, including the Census Bureau and Bureau of Labor Statistics (BLS), have established cognitive laboratories or otherwise developed capacity for the conduct of cognitive interviews. These interviewing activities are currently conducted under Generic Clearances. To meet the ongoing need of the PATH Study for cognitive testing, this submission requests a Generic Clearance for conducting cognitive testing on instruments and materials that are included in that study.

This is a 3-year clearance request for cognitive interviewing and testing of instrumentation, data collection materials, and consent forms for the PATH Study, with terms similar to those granted under National Cancer Institute's Questionnaire Cognitive Interviewing and Pretesting Generic Clearance (OMB # 0925-0589, expiration date 4/30/2014). This data collection is under the authorization of Title 42 USC 285 (Attachment 1). As shown in section A.12, approval is sought for screening of 3,000 participants annually and cognitive testing with 1,000 participants annually. Upon approval, NIDA will submit individual or bundled sub-studies under this generic clearance. Only instruments, materials, and consent forms that have been approved by the

prime contractor's Institutional Review Board (IRB) will be included in requests submitted under this generic clearance.

A.2 Purpose and Use of the Information Collection

The purpose and use of collecting this information are to test specific survey questions, data collection materials, and consent forms to inform the design of the questionnaires, materials, and consent forms that will be used in the PATH Study baseline wave, slated to begin in September 2013, and its follow-up waves of data collection. Cognitive testing with a large sample (i.e., more than nine individuals) of young adults and other key subgroups will help to ensure that wording and concepts presented in the questionnaires are unambiguous and meet the measurement objectives for these subgroups. Results from the planned field test of the PATH Study instrumentation and data collection procedures will have implications for making changes to the final instruments and procedures to be used for the baseline data collection wave. Any changes to the instruments and procedures resulting from the field test will be evaluated to determine whether they should also undergo cognitive testing.. For example, the field test may identify specific survey questions as problematic. Cognitive interviews would be suitable here to test wording changes to these questions to ensure the changes fix the identified problems.

Beyond the baseline wave of the PATH Study data collection, results from cognitive testing will inform changes to the instruments for the follow-up waves. These changes could be substantive, for example, in response to the implementation of new regulations by FDA. They could also be related to changes in data collection mode that are anticipated for some participants, such as a web mode for those 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. All cognitive testing will be facilitated by an interviewer, however,

automated data collection methods such as computer assisted personal interviewing (CAPI) and audio computer assisted self-interviewing (ACASI), as well as web-based interviews may be used to reduce participant burden. In CAPI interviews, an interviewer asks a participant to answer questions and records responses into a laptop or tablet computer. In ACASI interviews, a participant uses a computer to answer questions on his/her own that 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. Interviewers using these methods for cognitive testing may ask participants questions about their experience with the data collection method as well as questions about their understanding of the survey questions being tested.

If needed, interviewers may also use hard-copy forms and questionnaires when conducting cognitive testing with participants. These will be developed in user-friendly formats to reduce the time needed for completion by participants.

The PATH Study instruments, data collection materials, and consent forms will all be available in the following languages in addition to English: Spanish, Mandarin, Cantonese, Korean, and Vietnamese. As appropriate, cognitive testing may be conducted on the alternative language versions of the instruments, materials, and consent forms. In such instances, the alternate language instrument, material, or consent form to be cognitively tested will be included in the request submitted under this generic clearance.

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

The cognitive testing to be performed under this generic clearance is not duplicative of other instrument development work related to the PATH Study or to other studies. No information to be obtained from the proposed cognitive testing currently exists. The PATH Study is a new data collection effort, and the consent forms, data collection materials, and many of its

survey items are new. Cognitive testing is necessary to assure that these newly developed data collection materials and instruments will yield timely and efficient production of results while also minimizing burden on participants. The cognitive testing will be conducted by methodological specialists to ascertain and correct potential questionnaire flaws or issues with the materials/instruments that may contribute to non-sampling errors in the survey, 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

Cognitive testing will be conducted only on new data collection materials and instruments developed specifically for the PATH Study, or on revised materials and instruments. Cognitive testing of data collection materials, consent forms, and instruments prior to their use in the field is important for ensuring that they are clearly understood by PATH Study participants and that they obtain the information necessary to meet the objectives of the PATH Study. The consequences of conducting cognitive testing less frequently—such as only during the baseline wave of data collection—risks the introduction of non-sampling errors during the follow-up waves and noncomparability of the baseline and follow-up data. As mentioned in section A.12, cognitive interviews will be conducted with approximately 466 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 May 23, 2012 in the Federal Register (Vol. 77, No. 100/p.30540). No comments on the collection of information were elicited by the 60-day Federal Register Notice.

Researchers who have special interest and expertise in the research areas explored in the PATH Study data collection materials and instruments will be contacted as necessary. As part of the contract that NIDA has with the prime contractor to conduct the PATH Study, cognitive testing expertise will be provided by methodological specialists. In addition, members of the PATH Study instrument development workgroup may be consulted to provide continuity between the main study and cognitive testing. A list of potential consultants is provided in Attachment 3.

A.9 Explanation of Any Payment or Gift to Respondents

For intensive forms of interviews (i.e., cognitive interviews), participants generally receive an incentive. For example, the National Cancer Institute's Questionnaire Cognitive Interviewing and Pretesting Generic Clearance (OMB # 0925-0589, expiration date 4/30/2014), National Children's Study Formative Research and Pilot Methodology Studies Generic Clearance (OMB # 0925-0590, expiration date 9/30/14), and the National Children's Study Neuropsychological Measures Formative Research Methodology Studies Generic Clearance (OMB # 0925-0661, expiration date 6/30/15) all propose incentives for cognitive interviewing participants.

Incentives for cognitive interviews are provided for reasons that include:

- Eligibility criteria for participants are usually specific. Some of these criteria are determined by the subject matter of the survey (e.g., questions may be only relevant to people with certain health conditions). Typically, more specific subject matter means more difficulty in recruiting eligible participants; and payments help to attract them.

- Intensive forms of interviews require an unusual level of mental effort, as participants are asked to explain their mental processes as they hear the question, discuss its meaning and point out any ambiguities, and evaluate the acceptability of response options that are provided.

- Participants are usually asked to travel to a cognitive laboratory or other testing location, which involves transportation and parking expenses. Many participants incur additional expenses due to leaving their jobs during business hours, making arrangements for child care, etc.

The Federal government's standard remuneration of respondents for cognitive testing is $40.00. This incentive is assumed to cover participant expenses. The remuneration may be reduced if the interview is of shorter duration or does not require the respondent to travel to the PATH Study site for cognitive testing. Higher remunerations may be requested on a case-by-case basis for particularly difficult recruitments.
NIH will provide a justification to OMB in their mini-supporting statement for proposed incentive greater than $40, with the understanding that there is a high bar for offering more than the Federal standard. Unless otherwise noted in a given request, all incentives will be provided in cash.

A.10Assurances 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 4).

All data collection materials and instruments to be cognitively 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. Examples of consent forms to be used for cognitive testing participants are presented in Attachment 5.

Every cognitive testing request submitted under this generic clearance will include, as part of the request memo, a consent form and a plan for ensuring that personally identifiable information (PII) is not retained as part of the research. Cognitive interviewing 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 will be required to sign a pledge of confidentiality (Attachment 6) 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 interviewing activities.

PII, including names and contact information, will be collected only for the purposes of subject recruitment for cognitive testing, to document informed consent to participate in testing, and to record any incentives received on receipts. PII will not be associated with information or data collected during a cognitive interview. Cognitive testing 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 sessions.

Upon completion of a cognitive interview, the data, any notes written on other pieces of paper, and the interview 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 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 results. All cognitive testing data, recruitment forms, incentive forms, and crosswalk that links participant ID with PII will be kept until a recommendation report is written and will be destroyed 6 months after the report is completed.

A.11Justification for Sensitive Questions

Many of the questions contained in the PATH Study materials and instruments are not sensitive in nature, however, exceptions are likely because item sensitivity cannot always be predicted. An important purpose of cognitive testing of questionnaire items and study procedures is to assess their level of sensitivity.

To meet the objectives of the PATH Study, its instruments include questions on tobacco use; psychological problems and conditions; substance abuse; income; and sexual identity, orientation, and attraction. These questions relate directly to key outcomes or major correlates of tobacco use and health and are included in both the adult and youth surveys. They are essential to develop meaningful population-based estimates on tobacco product use and its harms to public health, which will inform NIDA’s scientific mission and its efforts to establish a regulatory science framework for FDA’s tobacco product regulations. Cognitive testing of survey questions will help to identify items that participants may find sensitive or may not want to answer, which means that alternative ways to ask such questions can be developed to minimize their sensitivity and ensure the items will be accurately answered (and therefore, that responses are valid).

As part of the informed consent process, participants will be told that their participation is voluntary, that they may choose to not answer any question, and that they may end the cognitive testing session at any time (Attachment 5). Additionally, all data collection materials and instruments will be reviewed and approved by the prime contractor's IRB prior to any cognitive testing.

A.12 Estimates of Annualized Burden Hours and Costs

Average annual hour burden for the screening of PATH Study cognitive testing respondents is presented in Table 1, and the average hour burden for cognitive testing for the PATH Study is presented in Table 2.

Table 1. Hour burden estimates for screening of PATH Study cognitive testing respondents

Screening for Respondents	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response	Annual Hour Burden
Screener	Youth	1000	1	$^{10}/_{60}$	167
	Adult	2000	1	$^{10}/_{60}$	333
TOTAL		3000			500

Table 2. Hour burden estimates for PATH Study cognitive testing

Instrument/Form to be Tested	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response	Annual Hour Burden
Forms to support data collection*	Adult	200	1	1 $^{30}/_{60}$	300
Assent forms for participation in PATH Study	Youth	200	1	1 $^{30}/_{60}$	300
Consent forms for participation in PATH Study	Adult	200	1	1 $^{30}/_{60}$	300
PATH Study questionnaires	Youth	100	1	1 $^{30}/_{60}$	150
	Adult	300	1	1 $^{30}/_{60}$	450
TOTAL		1000			1500

* For example, letters, mailing envelopes, PATH Study brochures, instructions for collection of biospecimens.

The average annual participant burden for both the screening of respondents and cognitive testing for the PATH Study is estimated to be 2000 hours, and a total of 6,000 hours over the 3-year approval period. These estimates include: communication with the cognitive testing recruiter (who is the initial point of contact); responding to screening questions; cognitive testing of forms/instruments; and debriefing with cognitive interviewers following the testing to ascertain their observations and feedback on the tested items.

Annualized cost to participants for participating in screening for PATH Study cognitive testing is presented in Table 3, and annualized cost to participants for participating in PATH Study cognitive testing is presented in Table 4.

Table 3. Annualized cost to respondents for screening for PATH Study cognitive testing

Screening for Respondents	Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Screener	Youth	1000	1	$^{10}/_{60}$	167	$7.25	$1,208
	Adult	2000	1	$^{10}/_{60}$	333	$16.27	$5,423
TOTAL	Adult	3000			500		$6,632

Table 4. Annualized cost to respondents for PATH Study cognitive testing

Instrument / Form to be Tested	Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Forms to support data collection*	Adult	200	1	1 $^{30}/_{60}$	300	$16.27	$4,881
Assent forms for participation in PATH Study	Youth	200	1	1 $^{30}/_{60}$	300	$7.25	$2,175
Consent forms for participation in PATH Study	Adult	200	1	1 $^{30}/_{60}$	300	$16.27	$4,881
PATH Study	Youth	100	1	1 $^{30}/_{60}$	150	$7.25	$1,088

questionnaires	Adult	300	1	1 $^{30}/_{60}$	450	$16.27	$7,322
TOTAL		1000			1500		$20,346

* For example, letters, mailing envelopes, PATH Study brochures, instructions for collection of biospecimens.

The estimates for hourly wage of adult participants are based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics' Occupational Employment Statistics, May 2010 National Occupational Employment and Wage Estimates United States. See 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 this survey. There are no capital, operation, or maintenance costs for the PATH Study.

A.14 Annualized Cost to the Federal Government

The cost to the Federal government for oversight of the cognitive testing of PATH Study data collection materials, consent forms, and instruments is $174,000 for all 3 years or $58,000 annually. This estimate is based on the mean loaded salary (average of $116,000) of a .5 FTE Federal government employee responsible for overseeing this work. 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 the cognitive testing of PATH Study data collection materials, consent forms, and instruments is estimated to be $2.2 million for all 3 years or about $734,000 annually. These costs are for the design and development of the testing procedures and protocols, interviewer training, participant recruitment, preparation of needed forms

and materials, provision of facilities and recording equipment, interviews, incentives, analysis of testing results, reporting of results, and recommendations for revisions to instruments or materials based on those results. The contract cost of the cognitive testing is a subset of the cost of the entire PATH Study and not in addition to.

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

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

This generic clearance request is for cognitive testing of PATH Study materials and instruments, inclusive of developmental activities prior to field administration to guide future instrument and material designs/revisions. The majority of intensive interviewing investigations will be analyzed qualitatively. Researchers with cognitive testing experience and expertise will serve as interviewers, and they will use detailed notes and transcriptions from the in-depth interviews to conduct the qualitative analyses. The results of these investigations will be used primarily to develop reliable and valid survey instruments and methods. Cognitive testing is expected to be conducted annually as needed.

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.18Exceptions 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.