Supporting Statement A
for
Request for Generic Clearance for Methodological Studies in 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

This request is for Office of Management and Budget (OMB) approval for methodological studies 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's (FDA's) Center on Tobacco Products, is overseeing the PATH Study. This is a new 3-year clearance request for methodological studies that will support the PATH Study.

The PATH Study. On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (FSPTCA) was signed into law, authorizing the FDA to regulate tobacco product advertising, labeling, marketing, constituents, ingredients, and additives. A major goal of the PATH Study is to establish a science framework for FDA's tracking of potential behavioral and health impacts associated with changes in tobacco products in the U.S., including those enacted under the FSPTCA. The major objectives and requirements of the PATH Study are covered by the study's main information clearance request approved by OMB on 11/27/2012 (OMB Control No. 0925-0664); a separate generic clearance for cognitive testing was approved by OMB on 11/27/2012 (OMB Control No. 0925-0663) to support the cognitive testing needs of the PATH Study.

Under data collection authorization of Title 42 USC 285o, NIDA, in partnership with FDA, awarded the contract to conduct the PATH Study to Westat, (the prime contractor). This longitudinal cohort study will use computer-assisted interviews to collect baseline and follow-up information on tobacco-use patterns; trends in risk perceptions and attitudes regarding harmful constituents and new and emerging tobacco products; and tobacco-use initiation, cessation, and relapse behaviors among youth aged 12-17 and adults ages 18 and older. The PATH Study will also collect biospecimens (buccal cells, urine, and blood) from consenting adults to examine

intermediate endpoints and incident health outcomes associated with tobacco-use and related disease processes. The planned sample size is approximately 59,800 (42,730 adults and 17, 070 youth). 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.

The first annual field test for the PATH Study began in the fall of 2012; the first (baseline) annual wave of data and biospecimen collection for the study is scheduled to begin in September 2013. It will be followed immediately by the second annual field test and wave of data and biospecimen collection, then by the third, then the fourth, with the expectation of continuing to follow participants for at least 3 years.

Methodological Studies. Given that the PATH Study is a national longitudinal cohort study that involves annual follow-up of study participants, its methods require ongoing assessment and refinement to assure the study is achieving its objectives. The methodological studies described herein are designed for that specific purpose (i.e., to identify ways to improve the methodology underlying the PATH Study). Methodological studies covered under this clearance include those designed to streamline data collection procedures (e.g., increase precision of measures and/or reduce burden of measures); and improve recruitment, response rates, study retention, and follow-up rates. Two studies described in this information clearance request, one on the reliability of the questionnaires and another on comparing interview data with biological markers to assess levels of misreporting of tobacco use among respondents, are examples of planned methodological studies that are expected to provide information that will help to improve the study's data collection protocol. Other examples of methodological studies that may be submitted under this generic clearance include small-scale field tests of variations in the study protocol to assess their potential for use in a full wave (e.g., changes in the biospecimen collection protocol).

Collections submitted under this generic clearance will be limited to methodological studies; each will be limited in size, scope, and duration. Particular samples will vary by study and will be specified in each memo

submitted under this generic clearance request to OMB. The request memo for each specific methodological study under this generic request will clearly describe the study's purpose, scope, and duration. It will explain why and how the study is timely and consistent with the purpose of this generic clearance (i.e., to improve the data collection and its implementation). Finally, each information collection submitted under this clearance will include relevant forms, guides, or outlines for the study's data collection as well as its individual approval from the prime contractor's Institutional Review Board (IRB).

Data collection methods to be examined in the methodological studies planned under this generic clearance include the following.

Telephone and in-person surveys. The PATH Study is conducting two types of interviews: (1) in-person interviews in which interviewers ask respondents questions and enter their responses into a computer (Computer Assisted Personal Interview – CAPI) and (2) interviews where respondents enter their responses directly into the interviewer's computer (Audio Computer Assisted Self Interview - ACASI). A third type of interview of interest to the PATH Study involves the use of the telephone. Telephone interviews can be cost efficient and less burdensome for respondents when compared with in-person interviews. Under this generic clearance, a methodological study might be conducted to determine how helpful telephone methods are in achieving the study's goals of high response, retention, and follow-up rates among respondents, especially those who may be mobile or difficult to contact for their interviews at the household location.

Web and smartphone/mobile telephone surveys. Surveys are increasingly conducted using the internet (i.e., Web survey) as well by smartphone or mobile phones. Web surveys can be conveniently accessed by respondents on secure websites who, by using the study's individualized user ID and password, can complete their interviews online. Surveys can be securely administered and completed by smartphone or mobile telephone using a smartphone application, a simple messaging service (SMS), or interactive voice response technology (IVR). The use of one or more of these data collection approaches could be important as a backup for interviewing cohort

respondents who have moved or are unable to keep face-to-face annual appointments at their household. A methodological study under this generic clearance is planned to assess the strengths and weaknesses of these techniques as potential alternatives to the household interview. Under this generic clearance, a methodological study may be conducted to determine if smartphones are appropriate for the PATH Study's data collection, thus helping to facilitate the study's efforts to maintain high rates of response, retention, and follow-up, and to make participation less burdensome for the respondent.

Focus groups and individual in-depth qualitative interviews. Focus groups are group sessions guided by a moderator who follows a topical outline (or script) containing questions or topics on a specific issue rather than adhering to a standard questionnaire. Individual in-depth qualitative interviews also use informal topical outlines, but are conducted with a single individual rather than with a group. Methodological studies under this generic clearance may potentially involve the use of focus groups and/or individual qualitative interviews for the purpose of gathering in-depth information from local-area residents about contextual, environmental, social, and cultural factors they perceive as influential in shaping tobacco-product use attitudes and behaviors. Conducting focus groups studies under this generic clearance may help in formulating new questions about factors and emerging issues that may affect tobacco use behaviors and health in the PATH Study questionnaires.

Biospecimen collection. As in the main PATH Study, biospecimens may be collected from consenting adult respondents in some methodological studies proposed under this generic clearance. Biospecimens provide objective measures of nicotine exposure and can provide information to prospectively monitor indicators of tobacco use-related harm. Examples of biospecimens that may be proposed for collection in some studies include: blood, urine, and buccal cells. Under this generic clearance, studies may be submittedto help streamline the frequency and amounts of types of biological samples collected, and to reduce potential overlap in the information that can be obtained from different types of samples. Each of these would also help to reduce participant burden.

As shown in section A.12, approval is sought for methodological studies to improve data and biospecimen collection in the PATH Study with approximately 20,000 participants annually. Upon approval, NIDA will submit individual or bundled studies under this generic clearance. Only studies that have been approved by the prime contractor's IRB will be included in requests submitted under this generic clearance.

A.2 Purpose and Use of the Information Collection

The data collected under this generic clearance will be used to improve the PATH Study's implementation, data collection procedures, and techniques for attaining high response, retention, and follow-up rates. Data from these studies will help to inform the ongoing assessment and refinement of the PATH Study's methods to assure that they are optimal for measuring and accurately reporting population-based behavioral and health effects associated with the use of tobacco products in the U.S. Methodological studies planned under this generic clearance are expected to improve the overall design and efficiency of the PATH Study's data collection protocols. These improvements are also expected to help in minimizing the PATH Study's public information collection burden. This generic clearance request is focused on answering the following:

1. What are the most efficient and least burdensome methods for collecting self-report data and for collecting/shipping/and storing biospecimens to achieve consistently high levels of accuracy and precision in the measurement of tobacco use behaviors and health?

Identifying and testing options for the collection of self-report data and for collecting/shipping/and storage of biospecimens is expected to lead to improvements in the efficiency of administration of the PATH Study's instruments and the precision of its measures, both of which will help to reduce respondent burden. For example, Web data collection has potential for collecting follow-up information from respondents who move and for whom ACASI data collection would be costly. It may also prove more cost-effective for respondents who move to collect, package, and send their urine

specimens via the mail at the follow-up appointment than to arrange in-person visits to collect this biospecimen.

2. What are the best methods for incorporating new technologies to collect data in a longitudinal study?

The PATH Study is a longitudinal study. As such, it will face the challenges of maintaining contact with participants over time, retaining the cohort, and achieving high response rates. Testing new technologies to determine whether they can improve how the study meets these challenges is of great interest and potentially high benefit to the PATH Study. For example, techniques that prompt and improve recall, such as providing respondents with their responses to specific questionnaire items from the previous wave of data collection, may be helpful to the PATH Study. A study to compare the results of respondents who were provided with their previous answers (i.e., dependent interviewing) to those who were not provided with their previous answers (i.e., independent interviewing) would provide a way to determine how they differ, e.g., whether one method yields more or less reliable data than the other, and if so, to what extent.

3. What are the psychometric properties of the self-report measures of tobacco use and health used in the PATH Study?

A major goal of the PATH Study is to provide timely, accurate, population-based data on tobacco use behaviors and health that FDA can use as a basis for examining behavioral and health impacts of specific FSPTCA-related programs. Realizing this goal requires that the PATH Study instruments have proven high reliability (measurement precision or consistency) and validity (measurement accuracy). Many surveys have not assessed the consistency or reliability of participant responses to their questions. Those that have generally have used the reinterview. Respondents complete the main interview and then within a relatively short period of time (e.g., 10 to 14 days) are recontacted and asked to complete all or some of the same items a second time. For items that are time-dependent, the same reference period is used in both the initial interview and the reinterview. Survey responses to the same items are expected to change in the annual interval between follow-up interviews in the PATH Study. It is therefore important

that the study conduct a reinterview of respondents within a relatively short period of time to ascertain the reliability of responses to the same questionnaire items and to distinguish between what may be unreliable or inconsistent in a reinterview from what may be true change over time.

To test the validity of the PATH Study questionnaires, it will be necessary to verify the accuracy of information reported by respondents. Most studies that have examined the accuracy of reports about tobacco use have found relatively low levels of underreporting, except among specific subpopulations, such as teenagers and pregnant women. However, in many areas of the U.S., smoking and other forms of tobacco use have become more socially undesirable and sensitive in recent years in parallel with declines in the overall prevalence of smoking and with greater recognition of the health risks associated with tobacco use. As a result, misreporting and underreporting of tobacco use behaviors may be more likely today than was true 30 years ago. For this reason, it will be important for the PATH Study to examine and verify the accuracy of respondent self-report data through comparisons with other measures, such as biomarker data collected at the same time. The use of biomarker data to validate the accuracy of self-reports can help to identify items associated with invalid responses for purposes of re-wording or refining items or for making statistical adjustments in the analysis. Additionally, the flux in types of tobacco products that reach the marketplace points to the need for ongoing validity assessments to examine the accuracy of self-reported data relative to these new products.

4. What are the optimal levels and frequencies of providing incentives for achieving target response and retention rates in the PATH Study?

Because the PATH Study is a longitudinal study, achieving and maintaining high response and retention rates over time are of paramount importance. The literature shows that incentives are effective for achieving target response and retention rates among research participants. However, research is less clear about the optimal amount of an incentive to provide, how often to provide an incentive, and when it should be given to respondents to ensure their long-term participation in a longitudinal study. For example, a participant may become committed to participating in the

study as time goes on, such that reducing the incentive amounts will have little effect on his or her response rates in later waves of data collection. A methodological study of high interest for the PATH Study is to determine the effectiveness of different levels and frequencies of incentives over time for achieving and maintaining target response and cohort retention rates. Such data would provide an empirical basis for deciding on the most cost-effective incentives per wave of longitudinal data collection in the PATH Study, and in other such large longitudinal studies.

5. Should the PATH Study consider other measures to assess aspects of tobacco use and health not currently included in the PATH Study?

It is anticipated that the PATH Study questionnaires will change for each data wave to capture new information on tobacco product use and health that is contemporary with changing demographics, social and environmental influences, and the ever-changing marketplace. The capacity to stay flexible, such that items can be replaced or updated for each field test and corresponding wave, is a major challenge for the PATH Study, but one that must be met to measure and accurately report potential population-based behavioral and health impacts associated with changes in tobacco products, including changes that are based on the 2009 FSPTCA. This flexibility means the PATH Study will be able to formulate and test new self-report measures about the use of one or more new tobacco products or new items on different brands or types of tobacco products that have recently come to the U.S. marketplace, and to do so within a limited time period in order to include those new measures or items in the next version of a PATH Study questionnaire.

Examples of the types of methodological studies and information to be collected under the scope of the generic clearance requested are presented below. This is not an exhaustive list of all the studies to be submitted for review under this clearance mechanism once established; they are illustrative examples of studies to be proposed. Overall, the studies submitted under this generic clearance are expected to reduce respondent burden and improve the cost-effectiveness of methods for the PATH Study's collection of self-report data and biospecimens on tobacco use and health.

Comparison of Web and ACASI Administration of the PATH Study Questionnaires. One or more small-scale methodological studies may be submitted under this generic clearance to develop and test Web-based surveys for the PATH Study. The aim would be to establish the equivalence of data collected by the Web versus ACASI mode for possible use of the Web-based version in a follow-up wave. First, however, other research and findings on the use of Web-based surveys would be examined to ensure that this work builds on the existing evidence base and avoids duplication.

Research (e.g., Kreuter, et al., 2008) suggests that Web-based surveys not only have the same attributes as other methods of self-administration, they offer key advantages that can be especially helpful for the PATH Study's need to achieve high respondent retention at each follow-up wave. In addition, the efficiency, accessibility, and "user-friendliness" of the Web mode of survey administration can help to reduce respondent burden and lower survey administration costs. Before determining whether the Web mode would be an appropriate method for full-scale adoption by the PATH Study, however, it should be tested and compared to the ACASI mode in focused methodological studies. Potential methodological studies under this generic clearance would focus on assessing: (1) the differences between the Web and ACASI modes on the quality of data collected from a sample of PATH Study adult respondents who have internet access; (2) the potential effects of internet-access bias; and (3) the potential variations in response rates by mode of administration as well as by specific items or forms of tobacco use. Identifying potential differences in survey data collected by the Web versus by ACASI mode is important for understanding the relative strengths and limitations of the different methods, and for making necessary statistical adjustments in comparisons of groups using the different modes.

Comparison of the Collection of Biospecimens via the Mail versus In-Person. The PATH Study has interest in examining procedures involved and the outcomes of collecting urine by mail (i.e., guaranteed overnight delivery) rather than in-person for potential use in a follow-up interview. Before a study is submitted under this generic clearance, a full review of other research and findings on this topic would be necessary to make sure the

study builds on and extends the existing evidence base and avoids potential duplication. A study likely to be proposed on this topic would randomly assign PATH Study respondents who provide a urine sample at baseline to one of two conditions for the follow-up. In one condition, after the in-person interview, respondents will receive a urine collection kit in the mail with instructions on collecting, packaging, and mailing a urine specimen; these respondents will also be asked a brief set of questions about their experience by a telephone interviewer after they have mailed the specimen. The standard protocol will be used in the other condition such that respondents will be asked to provide a urine specimen by the PATH Study field interviewer as part of the in-person follow-up interview. If urine specimens provided via the mail are comparable to those collected at the in-person interviews and do not create more burden for respondents, it would suggest that this method of collection and shipment for urine specimens is an acceptable alternative for meeting the requirements of the PATH Study.

Reliability of PATH Study Questionnaires. A study is planned under this generic clearance to test the reliability of the PATH Study questionnaires among a subsample of the baseline respondents who accept invitations for a reinterview within 10 to 14 days after the initial interview. The reinterview questionnaire will be the entire extended interview, but not the Phase 1 screener or the specimen collections (and their associated questionnaires). Both adult and youth respondents will be invited to participate in reinterviews; and the adult reinterview sample would include both tobacco users and non-users.

To optimize its efficiency, the reinterview study will be conducted with a subsample of respondents selected from a subset of PATH Study primary sampling units (PSUs). Within these PSUs, individual cases will be selected for reinterview with subsampling probabilities inversely related to the initial selection probabilities. This will provide self-weighting samples within each of the three key groups (adult tobacco users, adult non-tobacco users, and youth) to help simplify the analysis. Item responses and response discrepancies will be compared with those from the first interview using standard measures of consistency.

Comparison of Self-Reports with Carbon Monoxide (CO) or Cotinine. A study that may be submitted under this generic clearance would seek to validate the PATH Study questionnaires among a random selection of PATH Study respondents to compare their self-reported data on recent tobacco use to measures of carbon monoxide in the breath or cotinine in the urine. Such comparisons will help in assessing the extent of potential under- or misreporting among PATH Study respondents. Biological marker data can also be used to identify respondents who are tobacco users or non-users and then to compare this to their self-reported responses in the interview. In addition to examining overall levels of misreporting and underreporting among those who test positive for tobacco use, this method will be used to analyze differences in the accuracy of self-report within and between subgroups of PATH Study respondents.

The purpose, study design, and intended study outcome(s) of these examples are presented in Attachment 1.

A.3 Use of Information Technology and Burden Reduction

A major reason the PATH Study has for using this generic clearance mechanism is to conduct methodological studies to test the use of new technologies and data collection methods to increase the efficiency of data collection procedures and reduce respondent burden. Because it is a longitudinal cohort study, the PATH Study should achieve high participant response and retention rates from one year to the next. Reducing respondent burden can benefit response rates and retention as well as study costs. This generic clearance mechanism will permit the PATH Study to test new technologies, including automated data collection methods, to improve data accuracy, quality, and utility while also reducing respondent burden, maintaining high response and retention rates, and controlling study costs. Examples of these automated methods include computer-assisted interviewing, automated data collection, Web surveys, smartphone/mobile phone surveys, text messaging, and IVR technology.

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

Studies to be conducted under this generic clearance do not duplicate other work being done on the PATH Study or by other research studies. Data collected under this generic clearance are specific to the needs of the PATH Study: to improve its implementation, data collection procedures, and techniques for attaining high response, retention, and follow-up rates, all of which are necessary to ensure the PATH Study meets its objectives of measuring and accurately reporting population-based behavioral and health effects associated with tobacco product use in the U.S. In addition, the methodological improvements and efficiencies gained from studies conducted under this generic clearance are expected to help reduce the PATH Study's public information collection burden. It would not be possible to collect these data under other circumstances due to the time constraints of seeking clearance for each individual data collection. Existing data sources will be used to the maximum extent possible before attempting to utilize additional field work and burden hours sought under this clearance.

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

These methodological studies are planned to be on-going and concurrent over the 3-year period of this request. They focus on enhancing the PATH Study's design, instrumentation, and data collection procedures. It is necessary for the PATH Study to have the capacity to conduct these small studies to assess its protocols on an ongoing basis. This will help to assure that its data advance the scientific knowledge base on tobacco use

behaviors and health in the U.S. population, thereby serving as a science framework for FDA's examination of potential behavioral and health impacts of specific FSPTCA related programs. Without these studies, data collection for the main PATH Study will likely be less effective, less efficient, and ultimately less informative than it is required to be.

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 November 26, 2012 in the Federal Register (Vol. 77, No. 227, p. 70451). Two comments were received. One was a letter in support of this request. The other was a resubmission of a letter submitted in response to the main PATH Study OMB clearance request. The comments and NIDA's responses to these comments are included in Attachment 2.

Consultation with project staff from NIDA and FDA, and with numerous outside agencies, institutions, and universities will occur in preparation for and in conjunction with the fielding of data collections under this generic clearance request. These individuals include the PATH Study questionnaire workgroup and sampling workgroup, which include individuals from Roswell Park Cancer Institute, Legacy/the Schroeder Institute for Tobacco, Pinney Associates, University of California, San Diego Moores Cancer Center, University of Waterloo, Dartmouth College, University of Illinois at Chicago, Westat, and PATH Study project staff from NIDA and FDA. These individuals have expertise in the fields of tobacco research, applied population-based research, and the use of both quantitative and qualitative research methodologies. Other than project staff at NIDA and FDA, persons who may

be consulted on one or more studies to be submitted under this request are listed in Attachment 3.

A.9 Explanation of Any Payment or Gift to Respondents

As with respondents in the main PATH Study and in its studies for cognitive testing (OMB Control No. 0925-0046 and OMB Control No. 0925-0589, respectively), respondents in the studies to be submitted under this generic clearance may receive an incentive for their time and effort (including any expenses incurred (for example, transportation costs). Offering an incentive to help attract the full range of needed participant types is important. For example, a potential methodological study submitted under this generic clearance could assess different levels and frequencies of incentives compared to the standard remuneration for different aspects of data collection or at different data collection waves to determine the relative effectiveness of different incentive levels and frequencies in cohort retention over time, in achieving the target response rates, or in recruiting and retaining difficult-to-reach participants or those who are mobile or live in dense metropolitan versus rural areas.

On-site testing: The Federal government's standard incentive for participating in 60-90 minute cognitive testing interviews or similar usability tests is $40.00. This incentive is assumed to cover participant expenses. In limited situations, justifications may be provided on a case-by-case basis for studies with particularly difficult recruitments or that involve the collection of biospecimens. NIDA understands that the bar is high for offering more than the Federal standard and will therefore provide full justification to OMB in the mini-supporting statement for any request to use more than the standard incentive of $40. Unless otherwise noted in a given request, all incentives will be provided in cash.

Other types of studies: Incentives are not the default for standard phone or Web-based surveys. For this reason, NIDA will provide a detailed justification to OMB when proposing to use an incentive in a study of phone or Web-based survey methods.

A.10 Assurances of Confidentiality Provided to Respondents

Concern for privacy plays a central role in the implementation of the main PATH Study as well as the methodological studies. In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)), the PATH Study was issued a Certificate of Confidentiality (COC) by the NIH and under the authority vested in the Secretary of the Department of Health and Human Services on August 31, 2012. The COC authorizes all person engaged in conducting the PATH Study to protect the privacy of individuals who are the subjects of research from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic. Because biospecimens may be collected in some methodological studies and some questions may be of a sensitive nature, the COC will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological, and social consequences. The COC issued to the PATH Study on August 31, 2012 is included in Attachment 4.

Law governing Federal employees conducting these methodological studies, 18 U.S.C. 1905, (which prohibits disclosure of individuals' identifying information or confidential statistical data by Federal employees) is also relevant to the maintenance of confidentiality of data. In addition, all study activities conducted under this generic clearance will be in compliance with 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-8(a) (January 2006), the Privacy Act of 1974, and the Systems of Records Notice 09-25-0200 (regulations pertaining to confidentiality of data). All data collection materials and instruments to be used in methodological studies to be conducted 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.

Every methodological study request submitted under this generic clearance will include, as part of the request memo, a plan for ensuring that personally identifiable information (PII) is protected and a consent form. As in the main PATH Study, respondent's PII will be protected in multiple ways. All staff involved in these studies will be proficient in data security, confidentiality, and privacy issues and procedures. All data gathered will be identified by unique identification numbers assigned to each respondent; and crosswalks that match these numbers to PII will be stored in secure, encrypted files accessible only to authorized staff whose roles on the study necessitate access. NIDA will not have access to identifying information, and personal identifiers will not be included in the data received by NIDA. As appropriate, data gathered in the field will be collected on laptop computers that use advanced data encryption to protect confidentiality of data. Data from the laptops will be transmitted securely and directly to the research data warehouse maintained by the prime contractor, reducing risks associated with unsecured electronic data collected on laptops or transported on removable media.

All methodological study respondents will be informed in writing, (in a consent form to be submitted with each study request to OMB), of the sponsor, the nature, purpose and uses of the data to be collected, legal authorities, the voluntary nature of the data collection, and the protection of their information. The consent form will also explain that the information they provide will be kept private under the Privacy Act.

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 5). In addition, Privacy Impact Assessments (PIAs) for the main PATH Study were promoted on July 6, 2012 (see Attachment 6). This generic clearance request for methodological studies uses the same system and security environment and applications as the main PATH Study.

A.11 Justification for Sensitive Questions

Many of the questions that will be included in the data collection activities to be proposed under this generic clearance will not be of a sensitive nature and should not pose a problem to respondents.
However, it is possible that some sensitive questions may be included in studies proposed under this request. As mentioned in Section A.1, a major goal of the PATH Study is to establish a science framework based on the measurement and accurate reporting of population-based behavioral and health data associated with the use of tobacco products in the U.S. These data will help to inform FDA's decisions about future changes in tobacco products to meet the objectives of the 2009 FSPTCA. To achieve this purpose, the PATH study asks questions about tobacco use behavior and health, including major correlates of tobacco use and health (e.g., substance abuse, income, psychological problems and conditions; and sexual identity, orientation, and attraction). As noted in A.10, PII may be collected from respondents. For these studies, the request memo submitted under this generic clearance will include a plan for ensuring that respondents PII is protected.

As all of the studies to be submitted under this clearance will be related to the goals of the PATH Study, some questions of a sensitive nature may be included in some studies. For these studies, a full explanation of the need for the sensitive questions will be included in the memo submitted to OMB. Additionally, all data collection materials and instruments for these studies will be reviewed and approved by the prime contractor's IRB prior to submission to OMB.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

The average annual hour burden for the PATH Study methodological studies is presented in Table 1.

Table 1. Hour burden estimates for PATH Study methodological studies

Data Collection Activity	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response	Annual Hour Burden
In-person and telephone surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Web and smartphone/mobile phone surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Focus groups and individual in-depth qualitative interviews	Adults	1000	1	2	2,000
	Youth	1000	1	2	2,000
Biospecimen collection	Adults	1,000	1	15/60	250
TOTAL		20,000			29,750

The average annual participant burden is estimated to be 29,750 hours, and a total of 89,250 hours over the 3-year approval period.

Annualized cost to participants associated with the PATH Study methodological studies is presented in Table 2.

Table 2. Annualized cost to respondents for PATH Study methodological studies

Data Collection Activity	Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
In-person and telephone surveys	Adults	5,000	1	90/60	7,500	$16.27	$122,025
	Youth	3,500	1	90/60	5,250	$7.25	$38,063
Web and smartphone /mobile phone surveys	Adults	5,000	1	90/60	7,500	$16.27	$122,025
	Youth	3,500	1	90/60	5,250	$7.25	$38,063
Focus groups and individual in-depth	Adults	1000	1	2	2,000	$16.27	$32,540
	Youth	1000	1	2	2,000	$7.25	$14,500

qualitative interviews							
Biospecimen collection	Adults	1,000	1	15/60	250	$16.27	$4,068
TOTAL		20,000			29,750		$371,284

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 methodological studies of the PATH Study is $1,392,000 for all 3 years or $464,000 annually. This estimate is based on the mean loaded salary (average of $116,000) of four FTE Federal government employees responsible for overseeing this work. In addition, contractor expenses for conducting the methodological studies of the PATH Study are estimated to be $2,292,000 or $764,000 annually. These costs are for: study design; development of data collection materials and instruments; participant recruitment; data collection; incentives for participation; data analysis; and reporting of results. All of the costs to the Federal government are a subset of the cost of the entire PATH Study, and are not an addition. An additional $340,000 of government funds

could be allocated for contractor expenses to conduct these methodological studies if necessary as part of the prime contractor's contract with the government. These funds are in addition to the PATH Study.

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

Due to the nature of this clearance, there is no definite or tentative time schedule at this point. Studies to be conducted under this generic clearance are expected to continue until the OMB approval expiration date. Each study submitted under this generic information clearance request will include a corresponding schedule for its activities and completion.

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

Kreuter, F., Presser, S., and Tourangeau, R. (2008). Social desirability bias in CATI, IVR, and Web surveys: The effects of mode and question sensitivity. *Public Opinion Quarterly*, 72, 847-865.