Supporting Statement A for:

The Population Assessment of Tobacco and Health (PATH) Study (NIDA)
–
Generic Clearance for Methodological Studies

OMB No. 0925-0675, Expiration Date: 5/31/2016

Reinstatement without Change

Yellow highlights indicate changes to submission from prior approval.

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This is a reinstatement without change (of OMB number 0925-06764, expiration date 5/31/2016) for the Population Assessment of Tobacco and Health (PATH) Study to conduct methodological substudies to improve its methods for data and biospecimen collection. The PATH Study is collecting behavioral data and biospecimens among a national longitudinal cohort to assess within-person changes and between-person differences in tobacco-product use behaviors and related health conditions over time. 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.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This request is for Office of Management and Budget (OMB) approval of a reinstatement without change of the Generic Clearance for Methodological Studies in the Population Assessment of Tobacco and Health (PATH) Study (OMB number 0925-0675, expires 5/31/2016). 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 3-year reinstatement without change request for methodological substudies 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 detailed in the Study's main information clearance request (OMB number 0925-0664, expiration date 8/31/2018); a separate Generic Clearance for cognitive interviews and focus groups was approved by OMB (OMB number 0925-0663, expiration date 3/31/2019) to support the cognitive interviewing needs of the PATH Study in developing its data collection instruments and related materials.

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 uses 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 also collects biospecimens from consenting adults (urine and blood) and youth (urine) to examine intermediate endpoints and incident health outcomes associated with tobacco-use and related disease processes. 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.

Methodological Substudies. Given that the PATH Study is a national longitudinal cohort study that involves ongoing follow-up of Study participants, its methods continue to require ongoing assessment and refinement to assure the Study is achieving its objectives. The methodological substudies described herein are designed for that specific purpose (i.e., to identify ways to improve the methodologies that underlie the PATH Study). Methodological substudies of interest for this reinstatement request are 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 such substudies are described below, 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. These substudies

exemplify the types of methodological substudies that will help to improve the PATH Study's data collection and analytical protocols.

These methodological substudies use a variety of approaches and are limited in size, scope, and duration. Particular samples may vary by substudy, to be specified in each substudy memo submitted under this Generic Clearance. The request memo for specific substudies describe the substudy's purpose, scope, and duration; explain why and how the substudy is timely and consistent with the overall goals and objectives of the PATH Study; include any relevant forms, guides, or outlines for the substudy's data collection; and include its individual approval from the prime contractor's Institutional Review Board (IRB).

Data collection methods to be examined in the methodological substudies under this Generic Clearance are as follows.

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. Examining the use of telephone interviews for the PATH Study has importance because this method could prove helpful in achieving the substudy'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 an 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 substudy under this Generic Clearance is planned to assess the strengths and weaknesses of these techniques as potential alternatives to the household interview. If found appropriate for the PATH Study's data collection, these techniques may help 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 substudies under this reinstatement request for the PATH Study's Generic Clearance for Methodological Studies may 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. Such qualitative information can be helpful for formulating new questions about factors and emerging issues that may affect tobacco use behaviors and health in the PATH Study questionnaires.

Biospecimen collection. In the main PATH Study, biospecimens are collected from consenting adult and youth respondents to provide objective measures of nicotine exposures and of potential tobacco use-related harm. Methodological substudies conducted under this Generic Clearance may collect biospecimens to help (a) improve the main Study's biospecimen collection protocol; (b) streamline the frequency and amounts of biological samples collected; (c) reduce potential overlap in the information that can be obtained from different types of samples; and (d) reduce participant burden. Examples of biospecimens that may be proposed for collection include blood

(from consenting adults only) and urine (from either or both of adults who consent and youth who assent, following the consent of their parents).

As shown in Section A.12, this reinstatement request seeks OMB approval to conduct methodological substudies with approximately 20,000 participants annually to help improve data and biospecimen collection by the PATH Study. Upon OMB approval of this request, NIDA, in partnership with FDA, will submit various types of methodological substudies for OMB review and approval. Only substudies that have been approved by the prime contractor's IRB will be included in requests submitted to OMB under this Generic Clearance.

A.2 Purpose and Use of the Information

The purpose of substudies under this Generic Clearance is to improve the PATH Study's data collection procedures; techniques for achieving high response, retention, and follow up rates; and efforts to minimize the public burden associated with its data collection.

This Generic Clearance for Methodological Studies (0925-0675) was approved by OMB on May 22, 2013. The first opportunity to submit a substudy to OMB under the Generic Clearance that had potential to affect the main Study's next wave of data and biospecimen collection occurred on March 24, 2014 when OMB approved a substudy intended to inform measures of the tobacco-use behaviors of electronic cigarette and hookah users for the Wave 2 questionnaires. However, before it could begin, NIDA and its FDA partner concluded that this substudy would not yield findings in time for developing the PATH Study Wave 2 questionnaires. Consequently, and to save costs, the substudy was canceled on April 3, 2014.

The PATH Study's timeline for instrument development for the next wave of data collection has since become more closely aligned with the timeline for conducting methodological substudies under this Generic Clearance. For example, for the PATH Study's development of the Wave 4 questionnaires, there was sufficient lead time to submit a substudy memo to OMB for focus

groups on the use of electronic cigarettes in combination with other types of tobacco products, and on exposure to social media that featured tobacco products. Approved by OMB on August 11, 2015, the substudy was able to make its findings available for the PATH Study's development of measures on use of electronic cigarettes in the Wave 4 questionnaires.

Under this reinstatement request for the PATH Study's Generic Clearance for Methodological Studies, NIDA and its FDA partner are planning the types of substudies listed in this section in time to make their findings available for use in future waves, such as Wave 5 and/or Wave 6. These and other substudies are expected to address 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 continue to 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 substudy 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, for example, 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). Few surveys have 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-report can also help to identify items associated with more invalid responses compared to others for purposes of re-wording or refining the item or for making statistical adjustment in the analysis. Additionally, the constant flux in types of tobacco products that reach the marketplace points to the importance of ongoing validity assessments to examine the accuracy of self-reported data relative to these new products.

4. 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 continue to 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, continues to be 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 substudies and information to be collected under this reinstatement request for the PATH Study’s Generic

Clearance for Methodological Studies are presented below. This is not an exhaustive list of all the substudies to be submitted to OMB for review under this Generic Clearance, but rather these are examples of the types of substudies to be proposed. A common characteristic for each of these substudies is that it is 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. The purpose of this substudy is to examine the equivalence of Web and ACASI data. The literature (e.g., Tourangeau et al., 2013) suggests that Web surveys preserve the advantages of other methods of self-administration; however, establishing that Web and ACASI yield comparable data for the PATH Study is required before the PATH Study can consider adopting this method at scale. For this substudy, a sample of adults will be selected from a limited number of geographical areas to participate in an experiment that compares Web and ACASI versions of the same questions. Approximately half of the sample will be assigned to complete the ACASI version of the questions at a baseline point (Time 1) and approximately 6 months later (Time 2); the remainder will be assigned to complete the ACASI version of the questions at Time 1 and the Web version at Time 2. Although the Web does permit the use of sound files, the necessity of including sound in the Web version of the questionnaire is unclear. Many respondents in ACASI surveys seem to rely on the visual presentation of the questions rather than the aural presentation. Thus, in one design, ACASI would be compared with a purely visual Web survey; in another, three groups would be compared (ACASI, Web with sound, and Web without sound).

The main outcome variables would be response rates and the estimated prevalence of various forms of tobacco use (e.g., the proportion of persons who report that they smoke or who report using some form of smokeless tobacco). Variation in response rates or in patterns of responses among the groups could help in identifying strategies to improve each method relative to the other and to make statistical adjustments, such as incorporating control variables, when analyzing data pooled across the groups.

Comparison of the Collection of Biospecimens via the Mail versus In-Person. This substudy will examine the procedures involved and the outcomes of collecting urine by mail (i.e., guaranteed overnight delivery) rather than in-person at the follow-up interview. A sample of adults (non-PATH Study respondents) will be randomly assigned to one of two conditions for the substudy. In one condition, after completing an 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 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 this method of collection and shipment for urine specimens is an acceptable alternative for meeting the requirements of the PATH Study.

Psychometric Properties of the PATH Study Questionnaires. To examine the psychometric properties of the PATH Study questionnaires, such as reliability, a sample of individuals will be selected for an interview and a reinterview within 10 to 14 days after the initial interview. Both adult and youth respondents will be invited to participate in the interview and reinterview; and the adult sample would include both tobacco users and non-users. This substudy is focused on characteristics of the PATH Study questionnaires rather than on the collection of biospecimens.

To optimize its efficiency, this substudy can be conducted with a sample selected from a subset of PATH Study primary sampling units (PSUs). Within these PSUs, individual cases can be selected for reinterview with subsampling probabilities inversely related to the initial selection probabilities. This allows for self-weighting of samples within each of three key groups (adult tobacco users, adult non-tobacco users, and youth) to help simplify the analysis. Item responses and response discrepancies in the

reinterview can be compared with those from the first interview using standard measures of consistency.

Comparison of Self-Reports with Carbon Monoxide (CO) or Cotinine. A methodological substudy of interest to the PATH Study involves comparing self-reported data on recent tobacco use to measures of carbon monoxide in the breath or cotinine in the urine. Such a substudy would provide insights on the extent of potential under- or misreporting among a sample of respondents who complete the PATH Study questionnaires. 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 can be used to analyze differences in the accuracy of self-reports within and between diverse subgroups of respondents.

The purpose, study design, and intended study outcome(s) of these examples are presented in Attach1. Examples of methodological studies to inform the PATH Study.

A.3 Use of Information Technology and Burden Reduction

A primary purpose of this Generic Clearance request is to conduct methodological substudies to help improve the efficiency and accuracy of the PATH Study's data and biospecimen collection procedures. In addition to the accuracy and efficiency of its data collection, the substudies under this Generic Clearance will inform the PATH Study's efforts to reduce respondent burden, control costs, and enhance response rates and retention. NIDA and its FDA partner plan to use this Generic Clearance for substudies to examine a range of methods, 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 are 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

The substudies to be conducted under this Generic Clearance do not duplicate other work being done on the PATH Study or by other research studies related to tobacco product use behaviors and health outcomes. The purpose of data collected under this Generic Clearance is unique to the PATH Study: to improve its implementation, data collection procedures, and techniques for attaining high response, retention, and follow-up rates, all of which will help 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 substudies 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

Methodological substudies under this reinstatement request for the PATH Study's Generic Clearance for Methodological Studies are planned as on-going and concurrent over the 3-year period of the reinstatement request period. They focus on enhancing the PATH Study's design, instrumentation, and data collection procedures. The capacity to conduct methodological substudies is essential for the PATH Study to assess and continually improve its data and biospecimen collection protocols. This will help to assure that its data are serving to advance the scientific knowledge base on tobacco use behaviors and health in the U.S. population and thereby providing a science framework for FDA's examination of potential behavioral and health impacts of specific FSPTCA-related programs. Without the ability provided by this Generic Clearance to conduct the types of methodological substudies described herein, the PATH Study would not have a way to assess and improve the effectiveness, efficiency, and timeliness of its data collections in achieving its scientific objectives.

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

A.8.1 Comments in Response to the Federal Register Notice

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 March 11, 2016 in the Federal Register (Vol. 81, No. 48, pp. 12913 - 12914). No comments were received.

A.8.2 Efforts to Consult Outside Agency

Consultation with project staff from NIDA and FDA, and with numerous outside agencies, institutions, and universities will continue to occur in preparation for and in conjunction with the fielding of data collections under this Generic Clearance request. Outside organizations include the Roswell Park Cancer Institute, Truth Initiative, University of California San Diego Moores Cancer Center, University of Waterloo, Dartmouth College, the Medical University of South Carolina, SRI International, and Westat. Individuals from these organizations 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 substudies to be submitted under this request are listed in Attach2.List of consultants.

A.9 Explanation of Any Payment or Gift to Respondents

As with respondents in the main PATH Study and in its substudies for cognitive interviews and focus groups (OMB number 0925-0046 and OMB number 0925-0589, respectively), respondents in the substudies to be submitted under this Generic Clearance will receive an incentive for their time, effort, and any expenses incurred (for example, transportation costs). Offering an incentive to help attract the full range of needed participant types is important.

The Federal government's standard remuneration of respondents for participating in types of substudies under this Generic Clearance 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 substudies 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.

A.10 Assurances of Confidentiality Provided to Respondents

Concern for privacy continues to play a central role in the implementation of the main PATH Study as well as the methodological substudies. 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 substudies 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 Attach3.Certificate of Confidentiality.

Law governing Federal employees conducting these methodological substudies, 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 substudy 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 substudies 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 substudy 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 substudies 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 substudy 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 substudy respondents will be informed in writing (in a consent form to be submitted with each substudy 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.

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) (Attach4.NIH Privacy Act and System of Records Notice). The PATH Study contract requires the prime contractor to design, develop, and/or operate a Federal agency system of records for the Study in accordance with the Privacy Act. In addition, Privacy Impact Assessments (PIAs) for the main PATH Study were

promoted on July 6, 2012 (see Attach5.Privacy Impact Assessment). This Generic Clearance request for methodological substudies 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 substudies 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 substudies, the request memo submitted under this Generic Clearance will include a plan for ensuring that respondents PII is protected.

As all of the substudies to be submitted under this Generic Clearance will be related to the goals of the PATH Study, some questions of a sensitive nature may be included in some substudies. For these substudies, 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 substudies 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 methodological substudies under this Generic Clearance are presented in Table 1.

Table 1. Estimated annualized burden hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
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 respondent burden is estimated to be 29,750 hours, and a total of 89,250 hours over the 3-year approval period. These estimates are based on extensive experience with similar data collection activities and types of respondents.

Annualized cost to respondents associated with the methodological substudies under this Generic Clearance is presented in Table 2.

Table 2. Annualized cost to respondents

Type of Respondent	Number of Respondents	Average Burden Per Response (in hours)	Hourly Wage Rate*	Respondent Cost
Adults	5,000	90/60	$17	$127,500
Youth	3,500	90/60	$4	$21,000
Adults	5,000	90/60	$17	$127,500
Youth	3,500	90/60	$4	$21,000
Adults	1000	2	$17	$34,000
Youth	1000	2	$4	$8,000
Adults	1,000	15/60	$17	$4,250

*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 2014 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.

The average annual cost to respondents is estimated to be $343,250, and a total of $1,029,750 over the 3-year approval period.

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 associated with the substudies under this Generic Clearance.

A.14 Annualized Cost to the Federal Government

The total cost to the Federal government for methodological substudies under this Generic Clearance is $8,749,074 for all 3 years or $2,916,358 annually. The cost to the Federal government for oversight of these

methodological substudies is $1,400,664 for all 3 years or $466,888 annually; this estimate is based on the mean loaded salary (average of $116,722) of four FTE Federal government employees responsible for overseeing this work. In addition, contractor expenses for conducting the methodological substudies under this Generic Clearance are estimated to be $7,348,410 for all 3 years or $2,449,470 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.

Table 3. Annualized Cost to the Federal Government

Staff/Item	Grade / Step	Salary	% of Effort	Fringe (if applicable)	Annualized Cost
NIDA and FDA Federal staff oversight	13/9	116,722	4.0		466,888
Contractor cost					
On-site salaried staff		70,334	3.33	56.21	365,863
Field managers/ supervisors		51,483	1.8	46.55	135,807
Field interviewers		37,107	10.6	46.55	576,431
Subcontractors					24,264
Travel					23,816
Field expenses					137,255
Respondent incentives					800,000
Other ODCs: printing, supplies, shipping, computing, telephone, etc.					47,632
Overhead excluding fringe					338,402

A.15 Explanation for Program Changes or Adjustments

This is a reinstatement without change request for the PATH Study's Generic Clearance for Methodological Studies (OMB number 0925-0675, expiration

date 5/31/2016), to add back the burden hours for this collection. This reinstatement is necessary due to a delay in publication of the 30-day Federal Register Notice. The burden hours for the Generic Clearance approved by OMB in 2013 are identical to those in this reinstatement request.

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

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

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

The OMB control number will be displayed (expiration date).

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None.

Reference

Tourangeau, R., Conrad, F., and Couper, M. (2013). *The science of Web surveys*. New York, NY: Oxford University Press.