Supporting Statement A
for
Population Assessment of
Tobacco and Health (PATH) Study (NIDA)

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LIST OF ATTACHMENTS
(Appearance in Supporting Statement A)

A. Justification

A.1 Circumstances Making Collection of Information Necessary

A.1a Overview

This request is for Office of Management and Budget (OMB) approval for the Population Assessment of Tobacco and Health (PATH) Study longitudinal data collection scheduled to begin in the fall of 2013 (with a field test in the fall of 2012) by the National Institutes of Health (NIH), through the National Institute on Drug Abuse (NIDA), in partnership with the Food and Drug Administration (FDA). This is a new request.

Under data collection authorization of Title 42 USC 285o (Attachment 1), NIDA is conducting the PATH Study through Westat, the prime contractor. Through computer-assisted interviews and collection of biospecimens, the PATH 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 tobacco products; tobacco initiation, cessation and relapse behaviors among youth aged 12 to 17 and adults aged 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 adults. 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.

This request for OMB approval is for the first annual field test and first (baseline) annual wave of data and biospecimen collection of the PATH Study. The field test will include up to 590 adult respondents and 100 youth respondents, to test the PATH Study’s data and biospecimen collection procedures and operations prior to implementation of the baseline data and

biospecimen collection. A more detailed description of the field test is provided in Section B.4. The baseline wave is planned for 12 months, followed immediately by a second field test and 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 respondents for at least five years. OMB approval is requested for the first annual field test and baseline data collection activities; separate OMB approvals will be sought for each subsequent annual field test and follow-up wave.

A.1b Critical Need for the PATH Study Data

Approximately 443,000 U.S. deaths each year are from cigarette use and second hand smoke exposure (Hyland et. al., 2003), and an estimated 8.6 million smokers have at least one serious illness due to smoking (Adhikari, et al., 2008). According to the 2009 National Survey on Drug Use and Health (NSDUH), each day approximately 3,450 young people between 12 and 17 years of age smoke their first cigarette, and an estimated 850 youth become daily cigarette smokers (SAMHSA, 2010).

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (FSPTCA) was signed into law. The FSPTCA amended Section 201 of the Food, Drug, and Cosmetic Act (FD&C) (21 U.S.C. 321) by inserting Chapter 9 (“Tobacco Products”), Section 901, which authorizes FDA to regulate tobacco-product manufacturing, distribution, and marketing, including regulations of: product labeling; health warnings; tobacco product standards; good manufacturing practices; and tobacco product constituents, ingredients and additives. FDA will undertake these regulatory actions with the overall goals of: (1) reducing youth tobacco use; (2) helping those who use tobacco to quit; (3) promoting public understanding of the contents and the consequences of use of tobacco products; and (4) informing future regulatory actions FDA may undertake to protect the Nation’s public health.

The FSPTCA stipulates which issues FDA is required to address and gives it broad authority to enact or facilitate regulations. However, a solid evidence base is needed both to evaluate specific actions taken by FDA to demonstrate their effectiveness, and to provide the basis for FDA as it considers future regulatory actions. To accomplish this, the NIH, through

NIDA, is partnering with FDA's newly established Center for Tobacco Products (CTP) in a large-scale collaboration to conduct the PATH Study. This national longitudinal study of tobacco use and health will provide epidemiological, population-based data about attitudes and perceptions related to the use of different existing and emerging tobacco products; patterns and trends in use of existing and emerging tobacco products; knowledge of the contents of tobacco products and of the consequences of their use; and on near- and longer-term health outcomes associated with tobacco product use. These data will advance the scientific knowledge base on tobacco use behaviors and health; and serve to establish a science framework for FDA's tracking of potential behavioral and health impacts of programs to reduce tobacco-related diseases, disabilities, and deaths in the U.S. population.

The PATH Study also fills a data gap with its longitudinal cohort design. It is the only national longitudinal study of tobacco use. As such, the PATH Study provides a unique opportunity to monitor and assess changes over time in patterns of use of tobacco products among study respondents.

A.2 Purpose and Use of the Information Collection

A.2a Objectives and Purposes/Uses

Enactment of the FSPTCA granted FDA regulatory authority over tobacco products to protect public health and reduce tobacco use among Americans, particularly young people. Thus far, regulations implemented include: (1) banning the manufacturing and sale of any artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco; (2) restricting the use of "light," "low," or "mild," or similar descriptors in the labeling and advertising of tobacco products; (3) developing proposed new graphic health warnings for cigarette packages and advertisements; and (4) proposing required health warnings on smokeless tobacco. FDA's authority extends to roll-your-own and smokeless

tobacco products; and, through the rulemaking process, can extend to other tobacco products, such as cigars, pipe tobacco, hookahs, and e-cigarettes.

The PATH Study will collect national longitudinal survey data from a cohort of approximately 59,800 current, former, and never tobacco product users ages 12 years and older in the U.S. Biospecimens will also be collected from adult respondents to assess objective measures of exposure and prospectively monitor indicators of tobacco use-related harm. These data will provide the evidence base for evaluating behavioral and health impacts of programs, including those under the FSPTCA. For example, longitudinal data from the PATH Study will aid in informing changes over time potentially related to new larger pictorial warning labels placed on cigarette packs, including changes in smokers' awareness of the new labels; in their understanding and beliefs about the dangers of smoking; and in their smoking behaviors, such as making quit attempts or successfully quitting. Understanding similar measures among young people and those at risk of starting smoking will help in assessing the potential effectiveness of the new labels in deterring smoking initiation, as will measures among those who quit smoking help in assessing whether the labels influence continued abstinence. Evidence from countries that have implemented similar warning labels suggests that their effectiveness diminishes over time, indicating that new labels may be necessary to reinforce the warnings and maintain their effectiveness. Data from the PATH Study will provide the evidence base to determine if or when this occurs in the U.S., which FDA can use as a basis for making decisions on future changes in cigarette warning labels.

The PATH Study has seven overarching objectives rooted in the shared scientific needs of NIDA, in service to its research mission, and of FDA, to its mandate under the FSPTCA:

- **Objective 1:** Identify and explain trends in tobacco-use patterns, including the rate and length of use by specific product type and brand, product/brand switching, uptake of new products, and dual- and poly-use of tobacco products.
- **Objective 2:** Identify trends in risk perceptions regarding harmful constituents, new and emerging tobacco products, filters and other

design features for current, future and modified-risk tobacco products and product standards, and packaging/labeling; also identify trends in other attitudes that potentially affect use, such as social acceptability and individual preferences.

- **Objective 3:** Characterize the natural history of tobacco cessation and relapse in the era of tobacco regulation, to include trends in readiness and self-efficacy to quit, motivations for quitting, the number and length of quit attempts, methods used to quit, the length of abstinence, and the distribution of nicotine use/addiction phenotypes.

- **Objective 4:** Compare intermediate endpoints (such as markers of exposure and tobacco-related disease processes); and, ultimately, short- and long-term incident health outcomes and cause-specific mortality among users of different products, by making use of archival medical records, registries, the National Death Index (NDI), and/or, as available, National Social Security death files and the Division of Vital Records of state health departments.

- **Objective 5:** Evaluate the behavioral and health impacts of specific FSPTCA related-programs on risk perceptions and other attitudes associated with use patterns, cessation outcomes, and tobacco-related intermediate endpoints and health outcomes, accounting for other determinants (e.g., demographics, local tobacco-control policies, and economic, social network, peer group, and family factors).

- **Objective 6:** Assess differences over time in attitudes, behaviors, and key health outcomes between and within racial-ethnic, gender, and age subgroups; high risk subgroups, such as young adults, pregnant women, and persons with co-occurring substance use disorders and mental illness.

- **Objective 7:** Assess and compare smaller samples of former and never users of tobacco products for trends in relapse and uptake, risk perceptions, intermediate endpoints of disease processes, incident health outcomes, and cause-specific mortality associated with tobacco products.

Before the main PATH Study, a field test is planned to examine the overall flow of methods, procedures, systems, and the data obtained. Only nonsubstantial changes are anticipated as a result of the field test before proceeding with the main study.

Table 1 below summarizes types of measures to be examined in the field test. Whether any changes will be necessary for the main study will depend on the following:

1. Extent of deviation from the benchmark indicated in this OMB submission (e.g., the average interview length);

2. Extent of deviation from a standard required for scientific reasons (e.g., the average duration that biospecimens may be in transit before sample degradation occurs);

3. Deviation from generally accepted metrics for in-person, household surveys (e.g., a non-response rate to questionnaire items that exceed a given threshold);

4. Qualitative measures (e.g., based on review of the computer-assisted recorded interview (CARI) that captures exchanges between the interviewer and respondent);

5. Assessment of results from the two field test experiments (see Attachment 19).

Table 1. Examples of measures examined in the field test to inform the final design of the baseline data collection

Methods, Procedures, and Systems	
Field Operations	o Interview length o Staff time needed to achieve a completed interview
Biospecimen Collection	o Provision rate for blood, urine, and buccal cell samples o Comparison of nicotine questions from the tobacco form to the extended interview o Rate of successful collection of samples among those who consent o Rate of successful scheduled visits o Average time between interview and visit o Distribution of times from collection to processing
Processing at the Repository	o Success in obtaining at least the minimum number of aliquots from each collected biospecimen o Monitoring and tracking selection, requisitioning, and shipment of stored aliquots to analytic laboratories

Table 1. Examples of measures examined in the field test to inform the final design of the baseline data collection (continued)

Methods, Procedures, and Systems	
Sampling	o Compare actual to expected: o Unweighted yields of occupied dwellings, households with youth, adults by age and race group o Rates at different stages of sampling o Rates of false positive/false negative tobacco use classification by household informant in the household screener vs. self-report in the second-phase screener o Coverage ratios o Comparison of weighted count of field test dwelling units (adjusted for nonresponse) to an independent estimate of occupied dwellings in the Field Test PSUs will provide information on frame coverage
Flow of Scientific Information	
Questionnaire Performance	o CARI review o Low variance items o Items that produce inconsistencies o One-way frequency distributions of both continuous and categorical variables
Suitability of Collected Biospecimens for Analysis	o Measured levels of each analyte compared to previously established reference ranges for tobacco users and non-users to confirm biospecimen suitability.

A.2b Information to be Collected

The PATH Study will obtain completed interviews at baseline from a nationally representative sample of respondents 12 years of age and older. A household screener will be conducted in sampled households to select the PATH Study sample of adults and youth. For adults, a second-phase individual screener will be administered to adults selected from the household screener, to confirm or correct the household screener information. Responses to the second-phase screener will form the basis for applying the final adult sampling criteria, based on tobacco use status, age, and race. (See Section B.1 for details on the sampling design). Once selected, an adult extended interview will be administered to adults age 18 and older, a youth extended interview will be administered to youth ages 12 to 17 years, and a parent survey will be administered to parents of youth respondents. Additionally, biospecimens will be collected from adults who respond to the PATH Study adult extended interview. Table 2 lists the PATH

Study baseline wave instruments and briefly describes the purpose and content of each. The instruments are included in Attachment 2. Attachment 3a has been added which presents the data sources, domains/questionnaire component, and analysis plan for each PATH Study Objective.

Table 2. PATH Study instruments and data collected

PATH Study Instrument	Data Collected
Household Screener – Adult Household Respondent	Number and names of people in household; Sex, age, active duty military status, ethnicity, race for each household member; Multiple-birth status for same-age youth; Tobacco use status for all adults; Relationships among all sampled household members; Residential tenure; Contact information for household respondent; Initial contact information for sampled adults and parents of sampled youth and shadow sample youth. Data are reported in CAPI mode by one household respondent about other household members.
Adult – Individual Screener	Demographics (sex, age, active duty military status, ethnicity, race); main tobacco use characteristics for various tobacco products (the basis for final adult sample selection). Data are reported in ACASI mode by each adult respondent about him or herself.
Adult – Extended Interview	Tobacco use history for each tobacco product respondent uses; Reasons for using each tobacco product; self-reported dependence on nicotine and tobacco products; Interest in/experience with quitting; Notice of/reactions to tobacco product packaging and health warnings; Perceived risk of tobacco products; Media awareness and use; Secondhand smoke exposure; Peer and family influences; Health effects; Advertising and promotion of tobacco; Other substance use; Additional demographics; Contact information.
Adult – Biospecimen Collection Forms	Chemotherapy status, hemophilia or blood-clotting problems, oral health issues, last time of urination, time of last meal, fluid intake, and tooth brushing.
Adult – Tobacco Use Form	Specific time of use of 10 different tobacco products, nicotine replacement therapies, or prescription drugs for tobacco cessation, and quantity used.
Adult – Follow-up/Tracking Participant Information Form	Detailed contact information for people who have moved between waves.
Parent Interview – Parent of Youth	Respondent's relationship to the child, education, and tobacco use status (if not ascertained elsewhere); Household rules about tobacco; Perception of child's tobacco use; Child's curfew, school performance, school missed due to illness, health (height, weight, health effects, medications, emergency room visits); Parents who live elsewhere; Tobacco availability at home; Detailed contact information if not ascertained elsewhere.
Youth – Extended	Demographics (sex, age, ethnicity, race); Main tobacco use

Interview	characteristics; Tobacco use history for each tobacco product the respondent may use; Tobacco susceptibility (non-users); Reasons for using tobacco and specific tobacco products; Self-reported dependence on nicotine and tobacco products; Interest in/experience with quitting; Notice of/reactions to tobacco product packaging and health warnings; Perceived risk of tobacco products; Accessibility of tobacco; Media awareness and use; Secondhand smoke exposure; Peer and family influences; Health effects; Advertising and promotion of tobacco; other substance use; additional demographics.
Youth -- Follow-up/Tracking Participant Information Form for Youth (completed by parents)	Detailed contact information for people who moved since the last PATH interview.

Core information for the PATH Study will be collected in the adult extended interview, the youth extended interview, and the biospecimens (for the adults).

Adult and Youth Extended Interviews

The core content of the adult and youth extended interviews is based on conceptual models of how and why tobacco regulations exert an influence on proximal and distal behavioral and health outcomes (see Attachment 3b). Both the PATH Study adult and youth instruments include questions related to tobacco warning labels; product regulation; misleading brand descriptors, such as “light” and “mild”; advertising and promotion; and contraband. They include questions that address potential impacts of tobacco regulations on tobacco use behaviors and health, including tobacco product use, cessation, relapse, and initiation patterns and knowledge, attitudes, beliefs, and risk perceptions toward the use of tobacco products, as well as questions designed to characterize the general population, including demographics; environmental factors and family and peer influences, general health, and health effects that may be due to use of tobacco products.

Existing national surveys were used to inform the content of the PATH Study instruments. Tobacco questions in the PATH Study instruments were adapted from the Current Population Survey – Tobacco Use Supplement (CPS-TUS), an instrument that captures the level of information on tobacco use needed to meet the requirements of the PATH Study. Tobacco use questions in the National Health Interview Survey (NHIS) are similar to those in CPS-TUS, indicating that the PATH Study includes both the standard measures used in these existing surveys as well as expanded measures that are tailored to meet the unique informational requirements of the PATH Study. Questions on physical health endpoints were drawn from the National Health and Nutrition Examination Survey (NHANES) or structured similarly as items in NHANES to assess PATH Study-specific tobacco-related health conditions. NHANES is the only other national survey that has includes both a tobacco use section and collects biospecimens.

The PATH Study requires the collection of participants’ baseline health status to anchor a starting point from which to examine longitudinal associations between tobacco product use regulations and changes in tobacco use behaviors and health. Baseline and ensuing health status data from this participant cohort will allow for comparisons in the onset and progression of

various health conditions and intermediate endpoints of incident health outcomes among never, former, and current users of different types of products. Similarly, these data will inform new taxonomies of tobacco use subgroups of particular analytical interest, such as users who switch to other, new tobacco products such as Snus, who use multiple types of tobacco products, or who seek ways to reduce their health risks while continuing to use, such as switching to e-cigarettes. Items in the health outcomes section of the adult extended interview will also identify pregnant women who have been or are current users of tobacco products. Other items assess changes in risk perceptions about the dangers of smoking if/when graphic warnings on cigarettes are placed on packs and about perceived harm of smoking around children.

Biospecimens

Biospecimens will be collected from consenting adult respondents (age 18 and older) in the PATH Study to assess markers of nicotine exposure and to detect and compare intermediate endpoints of incident health outcomes associated with the use of tobacco products. These data will be analyzed, correlated, and used to validate self-reported behavioral and health data from the survey and to identify potential health effects or markers of disease associated with the use of tobacco. At baseline and annually, adult respondents will be asked to provide a sample of urine and buccal cell swabs. At baseline and in Wave 3, adult respondents will be asked to provide blood samples. Biospecimens will be coded, de-identified, shipped, preserved, analyzed, and shared in accordance with rigorous provisions promulgated by the NIH on data access and security within the context of the privacy laws under which it operates (see Section A.10).

Each of the three types of biologic samples yields information that other sample media do not. These specimens are important for the PATH Study because collectively, they provide a panel of biomarkers of exposure and susceptibility to disease associated with the use of tobacco products. For example, urine provides evidence of exposure to a key tobacco-specific nitrosamine, NNAL, which is not generally measured in blood or other types

of biospecimens. Blood provides a wide range of markers from exposure (cotinine) to indicators of risk that is difficult to obtain from urine. Analysis of urine for NNAL and blood for cotinine makes it possible to differentiate people who use tobacco products by nicotine source, such as from smoking or from nicotine patches. Buccal cells are directly affected by tobacco use. They make it possible to examine genetic and epigenetic changes to cells in the mouth that may have been directly damaged by the inhalation (in the case of smoking) or ingestion (in the case of smokeless use) of tobacco products and their carcinogens. Attachment 4 provides a list of specific analytes that will be analyzed for the baseline data collection. Biospecimen assays from the field test will focus on measures that address the suitability of each sample for the various assays performed (e.g., sufficient sample volume).

The remaining part of Section A.2.b elaborates on the need for and function of other specialized instruments listed in Table 2.

Household Screener/Adult Individual Screener

The household screener combines typical screener functions (e.g., enumerating the household, collecting basic demographic information about each member, collecting some household-level data, selecting subjects for the study) with a special purpose for the PATH Study, i.e., to collect minimum information on each adult's tobacco use in order to classify him/her with sufficient validity to select subjects according to the PATH Study's sampling strata on tobacco use crossed by other demographic characteristics.

The PATH Study sampling plan anticipates some amount of misclassification of household members' tobacco use status using this traditional household screening approach, which employs a single household informant as the screener respondent to provide needed information about every household member. Such misclassification may include false positives (those identified as tobacco users who are not actually tobacco users by the PATH Study's criteria) and false negatives (those identified as not using tobacco but actually use, based on the PATH Study's criteria).

Reasons for such misclassification include:

1. Lack of awareness by the household informant of each of the other members' tobacco use;

2. Lack of awareness by the household informant that a household member has quit using tobacco;

3. Concealment of tobacco use from the household informant by other members (e.g., teenagers or young adults concealing their smoking from their parents);

4. Reticence by the household screener respondent to self-report tobacco use in the HH screening interview, which is administered aloud by an interviewer using a CAPI instrument;

5. A lack of awareness by the household informant that other members of the household are using less visible or salient forms of tobacco than smoking, such as new and emerging products that are consumed orally without combustion; and

6. A similar lack of knowledge about a member's occasional or low levels of use, which may just not be known by the proxy respondent.

Given the potential for such misclassifications, the adult individual screener was developed as a second-phase screener to administer to each individual adult selected as a likely sampled subject based on the information obtained from the first-phase household screener. It addresses the issues above by (1) providing privacy via the ACASI mode so that no one else in the household will know the person's answers about tobacco use; this can help to foster an important sense of comfort, privacy, and candor on the part of the respondent and (2) asking directed and detailed questions about many types of tobacco products to help capture all those who are tobacco users or non-users as defined by the PATH Study's uniquely broad and intricate standard of tobacco use, one that may not be considered by the average person.

Further, the PATH Study seeks to obtain information from users and former users of all tobacco products, some of which may have low prevalence of use or are newly emerging products. Despite the various directed questions and illustrative show cards used in the household screener, false negatives

(those sampled as non-users) from the household screener are expected to include a disproportionate number of such product users. As a result, the PATH Study expects to sample more non-users in the first-phase household screening process than are needed to achieve the sampling plan target size for the non-user stratum. Upon completion of the second-phase individual adult screener, confirmed non-users will be subsampled at a rate needed to achieve the sampling plan target size for the non-user stratum; false negatives sampled from the first-phase household screener (i.e., sampled as non-users but subsequently classified as users in the second-phase screener) will be retained at a high rate.

Overall, the two screeners are designed to provide the means for efficiently identifying and oversampling the rare population of tobacco users (estimated at ~25% of all adults) by covering users of all forms of tobacco with high validity, as based on the PATH Study's definitions. The first-phase household screener also collects information needed to select youth and shadow samples, which are based solely on age eligibility and a probability of selection set to obtain the desired sample sizes.

See Section B.1 for further details on the within-household sample design.

Tobacco Use Form

The Tobacco Use Form is administered immediately before collecting any biospecimens. It collects the time of immediate recent use of various types of tobacco products and other sources of nicotine, such as pharmaceutical smoking cessation medications. Its purpose is to inform and qualify the laboratory analyses of the biospecimens, which are sensitive to recent use of various tobacco and nicotine-containing products. The tobacco and nicotine questions in the adult extended interview do not capture this time-sensitive information with sufficient precision (i.e., the adult extended interview captures tobacco product use over a broader period of time). The Tobacco Use Form will be administered at each visit when a specimen is collected, including visits that do not involve the extended interview (e.g., during the

follow-up home visit including a blood draw, which may be up to 2 weeks following the interview).

Parent Interview

Once youths are selected for the PATH Study sample, the parent interview collects personal information about the parent of a sampled youth, some general characteristics of the household as a whole, information about the youth that can be obtained more accurately and reliably from a parent, and contact information to support reaching the parent and youth for future data collection activities. The parent interview focuses on gaining information about the youth respondent's life that may be associated with tobacco use, and includes questions on parental supervision, school performance, and tobacco use by youth. Demographic information will also be verified in the parent interview. This is necessary because the household screener respondent may have been incorrect, or the youth may have had a birthday since the screener was conducted, which may place him or her in the adult sample stratum (18 years and older) rather than the youth sample stratum.

A.2c Uses of Information by NIDA

NIDA will use data collected by the PATH Study to address its program, policy, and research goals as mandated by its mission to bring the power of science to bear in understanding substance use and addiction. NIDA's mission also serves as a scientific complement to the needs of FDA to establish an evidence-based framework that will support its regulatory mandate under the FSPTCA. For these purposes, NIDA will use data from the PATH Study to understand and to inform how and to what extent critical changes in individual and population-level patterns of tobacco use behaviors, including key transitions in the course of nicotine dependence (from the earliest experiences of initiation, to daily use, poly-tobacco use, cessation attempts, and relapse) and in tobacco use-related health outcomes, are associated with the implementation of specific tobacco related policies and programs and within the continually changing tobacco product marketplace.

Specifically, data from the PATH Study will help elucidate the factors that potentially influence tobacco use behaviors among youth and adults; that shape beliefs, attitudes, and perceptions regarding new tobacco products (e.g., e-cigarettes, dissolvable tobacco products, and snus); that impact tobacco use-related health outcomes among key population subgroups, such as ethnic and racial minority groups, groups distinguished by gender or age, or between youth who are monozygotic or dizygotic twins; and that enhance knowledge of physiological changes over the natural course of nicotine dependence and longer-term disease processes consequent to use of and exposure to tobacco products.

In summary, NIDA will use information from the PATH Study to fulfill its mission to understand substance use and addiction and to support its unique partnership with FDA in establishing a regulatory science framework to guide effective policy decisions by FDA under the mandate of the FSPTCA.

A.2d Use of Information by Other Agencies and Organizations

As NIDA’s principal partner in conducting the PATH Study, FDA has specific plans for use of its data to meet its mandate by the FSPTCA for meaningful and effective tobacco product regulations. As mentioned in Section A.1, the FSPTCA authorizes FDA to regulate tobacco-product advertising, labeling, marketing, constituents, ingredients and additives; it also mandates FDA to report back to Congress within specific periods of time its progress and effectiveness in implementing key FSPTCA provisions. The PATH Study is critical to facilitating this process. It will provide current epidemiological data on tobacco use behaviors and health. The longitudinal component will serve to establish a science framework for FDA's evaluation of behavioral and health impacts of specific FSPTCA related-programs. These data have highly specific, practical utility for FDA as feedback on its efforts and progress in meeting its obligations. Additionally, the nationally representative longitudinal cohort design will help FDA implement and evaluate its population harm reduction approach in implementing the FSPTCA.

An important component of the PATH Study is the collection of biospecimens from respondents. NIDA supports FDA's approach for analyzing these biospecimens, which is through an inter-agency agreement with the Centers for Disease Control and Prevention (CDC). This agreement is for the analyses of biospecimens collected in the PATH Study to compare intermediate endpoints (i.e., markers of exposure and tobacco-related disease processes) and short- and long-term incident health outcomes. Examples of specific analytes that biospecimens collected in the study will be tested for are included in Attachment 4.

Because they are an invaluable research resource, data from the PATH Study will be shared with the scientific community. PATH Study survey data will be deposited into a repository for data sharing purposes with qualified researchers who apply to the PATH Study Data Access Committee and obtain a Data Use Certification (DUC). NIDA and FDA will collaborate in developing plans for the repository for the PATH Study data and biospecimens, as well as plans for data disclosure, sharing, and confidentiality for qualified researchers with interests in analyzing the PATH Study data.

Data sharing plans promulgated by the NIH dictate dissemination of appropriately de-identified data. After biospecimen and survey data collected by the PATH Study are stripped of personally identifiable information (PII) and subjected to disclosure limitation procedures, they may be deposited in a repository such as the National Addiction and HIV Data Archive Program (NAHDAP) at the University of Michigan's Inter-University Consortium for Political and Social Research (ICPSR); data from other NIDA-funded research projects, including surveys, are routinely deposited in NAHDAP for public or restricted use.

A.3 Use of Information Technology and Burden Reduction

Appropriate technology will be used to keep respondent burden to a minimum, and the Privacy Impact Assessments (PIA) for the PATH Study Management System were promoted on July 6, 2012 (see Attachment 5).

Examples of information technology approaches to be used to minimize burden during the PATH Study data collection include:

1. Use of an automated computer-assisted personal interviewing (CAPI) household screener to determine household eligibility and to select sample persons for the PATH Study;

2. Use of automated audio computer-assisted self-interviewing (ACASI) extended instruments (separate instruments for youth and adults) and an automated CAPI parent instrument to collect PATH Study data;

3. Use of lead-in questions and logic-based question routing to skip entire sections or questions that are not relevant to a sample person;

4. Use of flashcards or on-screen displays of lists and images to aid sample persons with multiple response categories;

5. Arrangement of sections and questions in the PATH Study extended interviews that will make sense to the sample person and will facilitate the flow of administration from one topic area to another;

6. Use of data collectors who are bilingual in English and Spanish, and English and one of four Asian study languages (Mandarin, Cantonese, Korean and Vietnamese); and

7. Use of versions of all instruments, consent forms and other survey documents in Spanish and the four Asian study languages for households where English is not spoken or one of these languages is the respondent's preferred language for the interview.

The majority of the PATH Study data will be gathered via computer-assisted questionnaires (i.e., CAPI or ACASI). The adult and youth questionnaires are designed with separate modules, and all but a few sections have lead-in questions that respondents can check for relevance in order to quickly skip out of non-relevant modules. This design was successfully used in the National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC) study (OMB #0925-0628, expiration date 4/30/2014). Based on experiences with brief tests of the PATH Study surveys with fewer than 9 individuals, the average adult and youth respondents were asked questions in about one-third of the total number of sections in either survey. Further,

within each survey section, about one-third of the associated questions were applicable to any particular respondent, leaving two-thirds inapplicable and, therefore, requiring no answer from either the adult or youth respondent taking the survey.

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

To determine if an existing data source could be used to accomplish the objectives of the PATH Study, a search was made of the research literature on tobacco use and associated health outcomes and websites of all NIH institutes and other federal agencies (including CDC). Nine national studies of tobacco use were identified. While several other national studies of tobacco use in the United States were identified, the PATH Study is unique in several important respects and, as such, does not duplicate these studies. Additionally, none of the other studies are sufficient to meet the analytic objectives of the PATH Study. A list of these studies, along with a summary of their key design features, is presented in Attachment 6 and a more detailed justification is provided here.

Longitudinal Design. The PATH Study's longitudinal design uniquely positions it to examine changes over time in respondent's tobacco use behaviors, including tobacco use initiation; and in respondent's attitudes, perceptions, and knowledge about the contents of tobacco products relative to contemporary changes in Federal programs. Aside from smaller-scale research grants for tobacco surveys, the PATH Study is the only national longitudinal study of tobacco use. The large, longitudinal design of the PATH Study means that it will have the statistical power necessary for accurately measuring changes in behavior and other attributes associated with changes in an exposure (in this case, exposure to tobacco products and tobacco regulations). In addition, no other nationally-representative longitudinal study has the capability to follow youth as they age into young adulthood. The PATH Study provides this capability, which is critical to the needs of NIDA and the FDA to understand factors associated with tobacco initiation among youth and young adults. It is equally critical for measuring

relationships between the ever-changing tobacco product marketplace and new and emerging patterns in the use of multiple tobacco products among youth and adults.

Large Sample Size. The PATH Study's large sample size allows for refined subgroup analyses not possible in most other national surveys of tobacco use. The PATH Study sample (n=59,800) will provide the most reliable national estimates of the incidence and prevalence of tobacco use (especially of use of emerging products), tobacco dependence, effects of product regulation, and health outcomes to date. No other national study of tobacco use and health has been conducted in the U.S. with such a large sample, thereby permitting reliable incidence and prevalence estimates. Moreover, the PATH Study's probability-based sample is sufficiently large to provide estimates for subgroup characteristics, such as by race, ethnicity, gender, pregnancy status, or co-occurring health disorder. In addition, the PATH Study will oversample Blacks/African Americans to ensure adequate representation of this subpopulation for reliable statistical analyses.

Focus on FDA Regulatory Issues. The PATH Study is the only national longitudinal study of its kind that will take place in parallel with the rollout of tobacco product regulations by FDA as authorized by the FSPTCA. This means it will provide a feedback loop for examining the effects of new regulations specific to FDA's mandate to regulate tobacco products, such as the requirement for warning labels and regulations on misleading brand descriptors, marketing, and contraband. The PATH Study's flexibility to add questionnaire content in follow-up waves that is responsive to new Federal programs distinguishes it from all other national surveys.

Inclusion of Wide Array of Tobacco Products. The PATH Study is the only survey to assess the wide array of tobacco products now available. No other national tobacco survey covers the use patterns of all of the many forms of tobacco that are now on the marketplace, which has diversified significantly in the past 5 years. The PATH Study surveys include detailed questions about 10 different tobacco products (cigarettes, cigars, cigarillos, little filtered cigars, pipe, hookah, dissolvable tobacco, e-cigarettes, snus, and other smokeless tobacco). Many other nationally representative general

population surveys may have items on cigarette smoking or on the use of tobacco products in some form, but the PATH Study survey is unique in having detailed questions on the use of all these products individually. As mentioned, the survey is also adaptive: In follow-up waves, new questions can be added and older items can be removed in response to the ever-changing tobacco product marketplace.

Biospecimen Collection. The PATH Study biospecimen protocol allows for rigorous assessment of tobacco exposure and disease progression, as specimens will be gathered over time from the same respondents. Few national tobacco studies include such longitudinal biospecimen collection.

Youth and Adult Sample. The PATH Study is positioned to assess tobacco product uptake, cessation, and relapse, as well as changing tobacco use behaviors, such as product switching and substitution among youth and adults. Additionally, this study can track youth as they progress into young adulthood. No single national tobacco survey includes both youth and adults to study these tobacco use transitions and trajectories in such detail.

Distinction of Other Tobacco Surveys from the PATH Study. The PATH Study differs in important ways from other national surveys of tobacco use. The National Adult Tobacco Survey (NATS), for example, is a national survey designed in part to evaluate CDC's National Tobacco Control Program by collecting data that align with the formal and well-established Key Outcome Indicators, a comprehensive framework that CDC has developed over time to measure the effectiveness of such programs. The PATH Study is a natural history, epidemiological study of tobacco use and health and is not designed for such evaluations. Monitoring the Future is the nation's primary tool to monitor trends in illicit drug use among 8th, 10th, and 12th graders (Johnston, et al., Vol. I, 2012; ibid, Vol. II), which is different from and beyond the scope of the PATH Study. Each other national tobacco survey has its unique benefits that the PATH Study is not positioned to replicate (see Attachment 6).

A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in the PATH Study.

A.6 Consequences of Collecting the Information Less Frequently

If the PATH Study is conducted less frequently than planned (i.e., annually), NIDA will be unable to achieve its scientific mission and unable to support FDA, and FDA will be unable to achieve its regulatory mandates as authorized by the FSPTCA. The PATH Study will inform FDA's development and implementation of regulations on the manufacture, distribution, and marketing of tobacco products; and its efforts to educate the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

The longitudinal design of the PATH Study underscores the importance of maintaining its schedule of regular, annual waves of data collection with the same study respondents. The PATH Study will use follow-up, retention, and tracking materials (Attachment 7) to maintain contact with each respondent and to schedule regular, annual appointments with each respondent for their annual follow-up interviews. Less frequent data collection would impact the study's ability to retain cohort respondents and achieve its annual and overall target response rates. This would have implications for the scientific quality and utility of study data, particularly data that would inform the development of new FSPTCA-related policies and programs.

Not conducting the PATH Study as scheduled (or delaying its annual follow-up interviews of each cohort respondent) would significantly reduce FDA's ability to capitalize on the strengths of the cohort study design to examine the direct effects of enacted policies on tobacco use uptake, cessation, and relapse in the population. The dynamic environment of ever-changing policies and tobacco industry efforts requires annual data and biospecimen collection. Data collected less frequently would significantly decrease the

capacity of the study to meet the scientific needs of NIDA and FDA to establish a science framework that informs FDA's efforts to protect the Nation's public health.

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.8a Federal Register Notice

The 60-day Federal Register Notice, required by 5 CFR 1320.8 (d) to solicit comments on the information collection prior to submission to the OMB, was published on May 18, 2012 in the Federal Register (Vol. 77, No. 97 pgs. 29667 - 29668). Two comments were received. One was a letter in support of the collection of data for the PATH Study. The other offered four suggestions to "improve the quality, utility, and clarity of information NIDA intends to collect in the PATH Study." The comments and NIDA's responses to these comments are included in Attachment 8.

A.8b Efforts to Consult Outside Agency

Individuals from within NIH, FDA, and other units within DHHS and numerous outside agencies, institutions, and universities were consulted from October 2011 to the present, and these consultations are ongoing. The individuals consulted 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 FDA. These workgroup members represent experts in the fields of tobacco research and

survey methodology, and provided significant input on questionnaire content, sampling design, and methodology. Numerous other individuals also contributed their expertise regarding sample design and methodology, questionnaire content, and related survey issues. The names, affiliations, and phone numbers of all individuals consulted are presented in Attachment 9. During the aforementioned consultations, all issues raised were satisfactorily resolved.

A.9 Explanation of Any Payment or Gift to Respondents

Many in-person household-based surveys have experienced decreasing response rates in recent years. Table 3 illustrates declining response rates for several major in-person household-based surveys with respondents age 12 years and older.

Table 3. Response rates for in-person household-based surveys

National Health Interview Survey (NHIS) Adult Questionnaire (1 adult per household)	National Crime Victimization Survey (NCVS) (persons 12+ in household)	National Survey on Drug Use and Health (NSDUH) (1-2 persons 12+ per household)
80.4% (1997)[1]	90.0% (1997)[2]	71.3% (2002)[3]
67.8% (2007)[4]	86.0% (2007)[2]	66.1% (2007)[5]

Response rates are unweighted.

[1]NCHS (2000).

[2]BJS (2007).

[3]SAMHSA (2003).

[4]NCHS (2008).

[5]SAMHSA (2008).

To assist in meeting the response rate goals of the PATH Study, multiple incentives are proposed (see Table 4). A $2 incentive is proposed to be included in the advance mailing letters sent to households sampled for the PATH Study to ensure that potential respondents read the letters. Research has found that including an incentive in mailings increases the likelihood that respondents will read the letter (Singer, 2002).

The amount of incentive to provide respondents for their time to complete the household screener interview will be experimentally tested as part of the field test. An incentive for the first-phase household screener is expected to produce a high response rate, which is key for the first step in establishing the participant cohort for this multi-year longitudinal study. The field test experiment will randomly assign respondents to receive $0, $5, or $10 for completing the first-phase screener interview. It will also assess two versions of the screener, one short and one long. Decisions about which level of incentive to use for the baseline data collection will be based on: (1) the screener response rate; and (2) the best combination of incentives and screener versions to maximize the accuracy of the screener data without raising overall cost or lowering response rates to the screener and the main interview. A detailed description of the experiments to be conducted during the field test is provided in Attachment 19.

Table 4. PATH planned incentives

	Field Test	Baseline
Advance Mailing	$2	$2
Household Screener (Phase 1 Screener)	$0, $5, or $10	TBD
Adult Visit #1 (conducted by interviewer)		
Adult Extended Interview	$35	$35
Biospecimen collection	$10	$10
Adult Visit #2 (conducted by health professional) -- additional biospecimen collection	$25	$25
Parent Interview*	$10	$10
Contact Information Update**	$10	$10

* Parents receive $10 for each interview they complete for a youth, and may complete a total of 3 interviews for 3 youth to receive a maximum of $30

** An adult respondent will receive $5 for updating his/her contact information up to two times between data collection waves, for a total of $10. A youth respondent will receive $5 each time, up to two times, their parent updates the youth's contact information, for a total of $10.

An incentive of $35 is proposed for adult respondents who complete the adult extended interview at the first home visit. This $35 incentive payment is solely tied to a respondent's participation in the extended interview, regardless of whether he or she consents to provide biospecimens. In addition, at the first home visit, an incentive of $10 is proposed for adult respondents who consent to and provide biospecimens and information to the interviewer. An incentive of $25 is planned for adult respondents who consent to and provide additional biospecimens and information to a health professional at a second home visit. An incentive of $10 is planned for parents who complete a parent interview. An incentive of $25 is planned for youth who complete the youth extended interview. Several research studies have shown the importance of providing a significant incentive at the baseline interview to increase response rates (Rogers, 2011; Goldenberg, et al., 2009). Use of separate incentives for completion of different components of a study has been used by other studies approved by OMB (e.g., National Children's Study OMB #'s 0925-0661 expiration date 6/30/2015, and 0925-0647 expiration date 1/31/2015).

To ensure retention of PATH Study respondents over time, an incentive is proposed for adult respondents who provide updates to their contact information in between data collection waves. Adults will receive $5 each time they update their contact information up to a total of $10 per year. Youth respondents will receive $5 each time their parent updates their

contact information up to a total of $10 per year. Research also supports the use of incentives between data collection waves as they boost response rates and increase the amount of updated locator information received from respondents (McGonagle, et al., 2011; Castiglioni, et al., 2008).

The incentive payments will be mentioned in the advance letter sent to each selected household prior to contact by the data collector, in the study brochure enclosed with the letter, and in the consent document provided to each respondent prior to the start of the PATH Study extended interview (see Attachments 10 and 11). These materials will clearly state that the household screener will identify whether any household member is eligible to be selected for the PATH Study; that an incentive will be provided as a thank you for completing the screener; and if selected for the study, that incentives will be provided as a thank you for completing each visit and associated tasks (the first adult visit for completing the adult extended interview and, separately, for consenting to and providing biospecimens; a second adult visit for consenting to and providing additional biospecimens; the parent interview; the extended youth interview; and for providing contact information for future follow-up by the PATH Study).

Biospecimens will only be collected from adults who complete the PATH Study extended interview. Adults who consent to and provide biospecimens and information during the same household visit as the extended interview will receive an additional incentive of $10. Adults who consent to and provide biospecimens and information at a follow-up home visit will receive an additional $25.

Thus, as part of the PATH Study baseline data collection and prior to the first follow-up data collection wave, an adult respondent may receive up to $92 as a thank you for participating in the PATH Study: $2 in the advance mailing, a maximum of $10 for the household screener, $35 for the extended interview at a first home visit (OMB approved a $90 incentive for the NESARC study [OMB # 0925-0628 expiration date 4/30/2014], which did not include a separate visit to collect blood from study respondents), $10 for biospecimens and related information at the first home visit, $25 for biospecimens and related information at a second home visit, and a maximum of $10 for

updating their contact information. Parents may receive up to $30 for completing parent interviews for a maximum of three youth ($10 as a thank you for completing each parent interview). A youth respondent may receive up $35 for participating in the PATH Study: $25 for completing the youth extended interview, and a maximum of $10 for having their parent provide updated contact information.

The PATH Study proposes to pay some of the incentives by means of cash or check, and others by means of debit cards. For small, stand-alone incentives (advance mailing, household screener, parent interviews, and contact information updates), the study will use cash or checks. For larger incentives that may be combined for a given respondent (first and second home visits), the study will use debit cards. Trained field interviewers will distribute a blank debit card to each respondent who completes the first visit, and the PATH Study will transfer the correct funds to the debit card within approximately 72 hours. If the respondent consents to a second home visit for additional biospecimen collection, the incentive for that follow-up visit will also be transferred to the card.

A.10Assurances of Confidentiality Provided to Respondents

A.10a Overview

Concern for privacy plays a central role in the implementation of the PATH Study. Such protection is provided to respondents under the authority of 42 U.S.C. 241(d).The authority of 42 U.S.C. 241(d) has been delegated by the Secretary of Health and Human Services to NIH of which NIDA is a part. Any person engaged in the research to which this section applies desiring authorization to withhold names and other identifying characteristics of individuals who are subject to such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, NIDA for an authorization of confidentiality (also called a Certificate of Confidentiality or COC). Persons authorized by NIH to protect the privacy of research subjects 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 will be collected and some questions may be of a sensitive nature, the COC will afford a greater level of protection to avoid compelled "involuntary disclosure" (e.g., subpoenas) of name and other identifying information about any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the COC is in effect.

Law governing Federal employees conducting this survey, 18 U.S.C. 1905, is also relevant to the maintenance of confidentiality of data in the PATH Study. Law 18 USC 1905 prohibits disclosure of individuals' identifying information or confidential statistical data by Federal employees.

In addition, all study activities under this contract will be conducted 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).

The PATH Study will implement a range of procedures to protect respondents' PII and the confidentiality of all data. All data collection staff will be proficient in data security, confidentiality, and privacy issues and procedures. PATH Study field interviewers will be required to sign a pledge of confidentiality (see Attachment 12) and to complete training on standards and ethics in survey research that includes detailed content on topics such as confidentiality and informed consent.

The privacy of study respondents will be protected through field procedures ensuring that interviews are not overheard by others in the home and the use of ACASI (Audio Computer-Assisted Self- Interview technology), which uses headphone s to increase comfort levels and encourage honesty in answering sensitive questions. In the field, data 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.

Data will be identified by unique identification numbers assigned to each respondent. These will then be used to link responses to the PATH Study extended interview and the biospecimen collection. 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. The prime contractor will transfer all data for the PATH Study and associated products and documents to NIDA at the time of compiling final data files, and will not retain any records of the data. Procedures for the storage and disposition of data collected as part of the PATH Study are described in Section A.10b.

All PATH Study respondents will be informed of the sponsor, the nature, purpose and uses of the survey data, legal authorities, the voluntary nature of the survey, and the protection of the information in an advance letter (Attachment 10) mailed to all dwelling units 1 to 2 weeks prior to the data collector’s visit. Prior to administration of the household screener, the data collectors will ask if the household received the introductory letter. Those respondents who do not recall receiving or reading the letter will be provided with a copy of it, and sufficient time will be allowed for them to read it and ask any questions related to the letter.

All respondents will be informed in writing that the information they provide will be kept private under the Privacy Act. All respondents have the right to not answer particular questions without any consequence. An informed consent form, which includes descriptions of risks, benefits, and privacy protections, will be reviewed with each potential PATH Study respondent and will be signed by all those choosing to participate in the study. Separate consent forms (see Attachment 11) and procedures have been developed for adults and youth. For youth, parental permission will be obtained in writing prior to seeking youth assent to participate in the PATH Study. There is also a separate consent form for adult biospecimen collection. Information in the consent documents is presented in language that is easily understood and

covers many topics, including the (1) voluntary nature of the data collection; (2) purposes and uses of the data; (3) storage and use of the biospecimen samples; (4) privacy of the information; (5) whether study results or information are available to the respondent; (6) benefits/risks; and (7) contact information regarding questions about the survey.

As noted previously in A.3, two PIAs for the PATH Study were promoted on July 6, 2012 (see Attachment 5). The PATH Study received approval (see Attachment 13) from the prime contractor's Institutional Review Board (IRB) and has submitted an application for a NIH Certificate of Confidentiality from NIDA.

A.10b Storage and Disposition of the Information

Information collected in the PATH Study 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 14). The NIH Privacy Act Officer has also reviewed the information contained herein and determined that the Privacy Act applies to the PATH Study data collection.

Compliance with the Privacy Act includes protections on identifying information residing in computer files. Data will be maintained in separate, encrypted tables, with password protection and access limited to authorized personnel. The PATH Study will comply with the Federal Information Processing Standards (FIPS PUB 41) and Computer Security Guidelines for Implementation of the Privacy Act of 1974, and FIPS PUB 73 ("Guidelines for Security of Computer Applications"). All staff members will complete regular trainings on information security, including the NIH training on data security. Authorized users will have access to research data free of PII only behind a secure data firewall that will not permit downloading or printing of data. In addition, no individual names or other identifiers will ever be reported to NIDA, FDA, or to any other government agency.

Study data will be identified and retrieved by a study number only. Investigators will not have access to PII. The majority of data collected in this study will be captured electronically, avoiding concerns of hard-copy storage of materials that contain PII. Hard-copy data forms will be identified only by a study identification number and will be stored in locked files at the contractor's facilities. The datasets collected will be maintained until the completion of the study or until they are no longer required for research purposes.

The prime contractor for the PATH Study is responsible for storing identifiers in a secure, database environment in accordance with the security guidelines defined by the Federal Information Security Management Act (FISMA) and NIST Special Publication 800-53 for Moderate information system security. All systems and databases handling or storing PII and/or PHI (protected health information) will be reviewed for FISMA compliance by the NIDA Chief Information Officer (CIO) and Information Systems Security Officer (ISSO), and will not be operated in production mode until granted an Authority To Operate (ATO) by NIDA. All computerized data will be maintained in a manner that is consistent with the FISMA Moderate requirements. No reports or analysis files will contain PII. A complete list of the procedures the contractor will take to keep the study data private are found in Attachment 15.

Access to study data is limited to the staff working on the study, and all staff members will sign a pledge of confidentiality prior to beginning work (Attachment 12). In addition, all contract staff members are required to undergo background screening commensurate with their role on the project and their access to study data, and are required to complete NIH Computer Security Awareness Training as well as Privacy Awareness Training.

The prime contractor will share PII only with a single subcontractor responsible for collecting blood and urine biospecimens from consenting adult respondents. This subcontractor and their staff phlebotomists will receive PII because they will need to visit adult respondents who consent to provide biospecimens to obtain samples of their blood and urine. As with the prime contractor, this subcontractor will not receive any PII until their secure

database environment is in accordance with the security guidelines for FISMA Moderate information system security, and is reviewed for FISMA compliance by the NIDA CIO and ISSO and given ATO by NIDA.

A detailed inventory of all files, including hard copy consent forms, which include respondent names, and all other PII, will be secured separately from research data and accessible only to authorized staff. All records, including hard copies of informed consent and other documentation, will be retained and disposed of under authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1B “Keeping and Destroying Records” (HHS Records Management Manual, Appendix B-361) (see Attachment 14).

A.10c Plans for Data Sharing

NIDA will collaborate with FDA in planning a repository for the PATH Study survey data, including plans for data disclosure, sharing, and confidentiality for qualified researchers interested in working directly with NIDA and FDA to analyze the PATH Study data and biospecimens. Data sharing plans promulgated by the NIH dictate dissemination of appropriately de-identified data; and, as explained in Section A.2d, PATH Study data that have been stripped of PII and subjected to disclosure limitation procedures may be deposited in a repository such as the ICPSR’s NAHDAP, where data from NIDA-funded research projects are routinely deposited for public or restricted use.

Researchers interested in accessing PATH Study data will be required to apply to the PATH Study Data Access Committee (DAC), to be established by NIDA and the FDA. This committee will work with the data repository, such as ICPSR’s NAHDAP, to manage access to the data repository and track the progress of researchers who receive approval.

Upon receiving DAC approval, researchers will be required to submit a Data Use Agreement to the data repository, such as NAHDAP/ICPSR (see

Attachment 16) to gain access to the restricted data files. These data files will include PATH Study survey data and may include data from biospecimens, however, qualified researchers interested in accessing PATH Study biospecimens to conduct analyses will be required to apply to the PATH Study Biospecimen Access Committee (BAC). This committee will manage the: sharing of biospecimens; instruct the PATH Study biospecimen repository subcontractor to ship specimens to approved labs/researchers; track the progress of researchers; and if necessary recall biospecimens.

A.11Justification for Sensitive Questions

As mentioned in Section A.1, data from the PATH Study will serve as a science framework for the evaluation of Federal programs to reduce tobacco-related diseases, disabilities, and deaths in the U.S. population. In order to meet this purpose, the PATH Study asks questions about tobacco use. Additionally, as described in Section A.2, the PATH Study has seven objectives rooted in the shared scientific needs of NIDA, in service to its research mission, and of FDA to its mandate under the FSPTCA. To meet these objectives, the PATH Study surveys include questions on other sensitive topics including: 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.

A.11a Tobacco

The mission of CTP at FDA is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products; and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others. The PATH Study is central to this mission and will provide population-based scientific evidence to both evaluate and inform

FDA's programmatic decisions. The tobacco use questions are the critical core of the PATH Study surveys – without these questions, FDA's ability to achieve its mandated mission would be significantly impaired.

The majority of the PATH Study survey items are about tobacco use. Most of the items are similar to or slight variations of items common to other widely used surveys of tobacco use and health behavior that have been approved by OMB. These questions are not generally considered sensitive by respondents. The PATH Study adult survey contains questions that assess tobacco use in great detail and breadth. Answers to these questions will provide a resource to NIDA and FDA to understand risk factors associated with tobacco use initiation, as well as motivations for product-switching, use of multiple tobacco products, and quitting. Such questions are not generally considered sensitive when administered to adults.

Similar to the adult survey, the PATH Study youth survey contains questions that assess attitudes toward tobacco, and tobacco use in great detail and breadth. These questions, especially when asked of underage children, may be considered sensitive by at least a portion of parents or youth. (As described in Section A.10 several procedures will be implemented in the field to protect youth's privacy and ensure that he/she feels comfortable in answering the questions). The youth tobacco use questions are modeled on the Center for Disease Control's National Youth Tobacco Survey (OMB # 0920-0621 expiration date 1/31/2015), however, they have been expanded to cover a more diverse and specific array of tobacco products.

The PATH Study parent survey includes questions about the youth's tobacco use and future tobacco use. These are intended to provide context for the youth responses, and will be critical for future waves of data collection, particularly data on the youth's tobacco-use trajectory. Understanding the trajectories and transitions in tobacco use behaviors (e.g., onset, daily use, multiple product use, quitting attempts, relapse, and cessation) are essential to communicate effectively about tobacco products and the consequences of their use, as FDA is mandated by the FSPTCA to do by educating young people.

A.11b Psychological Problems and Conditions

Tobacco use is highly associated with an array of psychological problems and conditions, including depression and anxiety. Adults (John, et al., 2004) and youth (Udaphyaya, et al., 2002) with mental health concerns use tobacco at higher rates and find it more difficult to quit using tobacco (Snyder, 2006). Epidemiologic and clinical studies have shown that psychiatric disorders are important moderators of nicotine dependency severity (as measured by Fagerstrom Test of Nicotine Dependency or FTND scores, for example), withdrawal, craving, quitting, and responses to changes in cigarette pricing. As reported by Legacy (2011): “People with mental illnesses smoke at rates almost twice as high as the general population (41 percent versus 22.5 percent, respectively). Nearly half the cigarettes smoked in the United States (44-46 percent) are consumed by people with co-occurring psychiatric or addictive disorders. The smoking prevalence rates are even higher (60-80 percent) for those who are diagnosed with depression, bipolar disorder, or schizophrenia.”. Moreover, remission from nicotine was moderated by comorbid psychiatric disorders and substance use disorders, findings that have been replicated in other cross-sectional and longitudinal analyses. In summary, including these constructs in PATH Study surveys is critical for good science to fully understand the implications of how various program and policy changes may affect tobacco use behaviors in the population.

Questions dealing with depression, anxiety and personality traits and disorders have appeared frequently in other national surveys of the general population since the early 1980s. These include the National Institute of Mental Health’s Epidemiological Catchment Area Survey (ECA), fielded between 1981 and 1985 and its 1990-1992 and 2001-2002 National Comorbidity Surveys (NCSs); supplements to the National Center for Health Statistics (NCHS) National Health Interview Survey in 1983, 1988, and 1991; CDC’s Behavioral Risk Factor Surveillance Surveys since 1980; and in 15 National Institute on Alcohol Abuse and Alcoholism (NIAAA) supported national surveys conducted by the Alcohol Research Group since 1991. An analysis of all these surveys indicates that questions about psychological problems and conditions were not considered sensitive by respondents.

Nonresponse for these questions was extremely low (i.e., less than 4.0 percent), comparable to questions not normally regarded as sensitive.

The PATH Study has developed a handout (Attachment 17) that provides respondents with national help lines for problems with tobacco, alcohol, drug, and mental health issues. This handout will be provided to all interviewed persons who express an interest in getting help with one of these problems.

To assess psychological problems and conditions, the PATH Study adult and youth surveys include items from the Global Appraisal of Individual Needs Short Screener (GAIN SS). These are a series of questions designed to identify respondents who have one or more behavior health disorder, including internalizing or externalizing psychiatric disorders and substance use disorders.

A.11c Substance Abuse

Substance abuse and tobacco use are frequently comorbid conditions. In numerous household surveys conducted since 1960 in the U.S., the results indicate that such questions have not been considered sensitive by respondents. Item nonresponse for such questions was low (generally less than 5.0 percent), and interview break-offs and refusals related to these questions were negligible (less than 1.0 percent). Examples of these surveys, all of which obtained OMB approval, include: the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH) conducted since the early 1980s (OMB #0930-0110, expiration date 8/31/2014); the Bureau of Labor Statistics' National Longitudinal Survey of Youth (NLSY) conducted periodically since 1973 (OMB# 1220-0109, expiration date 12/31/2013); and CDC's National Health and Nutrition Examination Survey (NHANES) (OMB # 0920-0237, expiration date 11/30/12).

A.11d Income

The PATH Study surveys do not include questions about salary, which is considered by many people to be sensitive. Instead, the adult and parent surveys include items about household income. Obtaining information about household income is of critical importance for conducting non-response analysis, and for understanding how tobacco use varies across individuals in households of varied income levels.

A.11e Sexual Identity, Orientation, and Attraction

A growing research base indicates that the prevalence of tobacco use among gay, lesbian and bisexual and transgender (LGBT) individuals in the U.S. is higher compared with persons who are heterosexual (Blosnich, et al., 2011). Pollard et al (2011) found that, for females, a change from self-reported heterosexual attraction to lesbian or bisexual attraction was more predictive of higher smoking trajectories and differences in smoking patterns when compared with females who reported no change in sexual attraction. These differences point to the need for careful analyses of the PATH Study data to understand the factors and differences in tobacco use behaviors and health outcomes by sexual identity and orientation in the U.S.

The PATH Study adult survey includes three items from the National Health Interview Survey 2013 (Miller, et al, 2011) that ask about sexual identity/orientation. The PATH Study youth survey includes the same three items for youth ages 14 to 17 years of age. Items similar to these have been tested and used in the 2001 to 2009 school-based survey, the Youth Risk Behavior Surveillance System (YRBS), conducted among students in the same age group (14 to 17 years) in grades 9 to 12 (Centers for Disease Control and Prevention, 2011). The NHIS does not ask about sexual attraction.

The PATH Study includes one item on the respondent’s level of attraction to both sexes, asked of adults (#AM0021 in the adult survey) and of youth ages 12 to 17 years (#YM0021 in the youth survey). This item is from the National

STD and Behavior Measurement Experiment (NSBME), as modified from the National Survey of Sexual Attitudes and Lifestyles (NATSAL); (Villarroel, et al., 2008). It was selected and recommended for inclusion in the PhenX Toolkit by an NIH panel of experts for use in all studies that measure sexual attraction (Hamilton, et al., 2011).

A.12 Estimates of Annualized Burden Hours and Costs

Average hour burden for the PATH Study field test is presented in Table 5, and the average annual hour burden for the baseline wave is presented in Table 6.

Annualized cost to respondents associated with the PATH Study field test is presented in Table 7, and annualized cost to respondents associated with the PATH Study baseline wave is presented in Table 8.

Burden estimates were based on the informal pre-testing of each instrument with fewer than 9 individuals. These estimates include the time needed to respond to the entire interview, read the introductory letter, and to potentially respond to the data quality verification interview.

Table 5. PATH Study field test hour burden estimates

Type of Respondent and Instrument	Estimated Number of Respondents	Estimated Number of Responses Per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Adults – Household Screener	1,823	1	$^{17}/_{60}$	517
Adults – Individual Screener	840	1	$^{6}/_{60}$	84
Adults – Extended Interview	590	1	$1\ ^{9}/_{60}$	679
Adults – Biospecimen Collection: Urine	590	1	$^{8}/_{60}$	79
Adults – Biospecimen Collection: Buccal Cell	590	1	$^{8}/_{60}$	79
Adults – Biospecimen Collection: Blood	590	1	$^{18}/_{60}$	177
Adults – Tobacco Use Form	590	1	$^{2}/_{60}$	20

Adults – Follow-up/Tracking Participant Information Form	590	2	$^{6}/_{60}$	118
Youth – Extended Interview	100	1	$^{35}/_{60}$	58
Adult – Parent Interview	100	1	$^{19}/_{60}$	32
Adults – Follow-up/Tracking Participant Information Form for Youth (completed by parents)	100	2	$^{8}/_{60}$	27
Total				1,870

Table 6. PATH Study baseline hour burden estimates

Type of Respondent and Instrument	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Adults – Household Screener	102,263	1	17/60	28,975
Adults – Individual Screener	63,000	1	6/60	6,300
Adults – Extended Interview	42,730	1	1 9/60	49,140
Adults – Biospecimen Collection: Urine	42,730	1	8/60	5,697
Adults – Biospecimen Collection: Buccal Cell	42,730	1	8/60	5,697
Adults – Biospecimen Collection: Blood	42,730	1	18/60	12,819
Adults – Tobacco Use Form	42,730	1	2/60	1,424
Adults – Follow-up/Tracking Participant Information Form	42,730	2	6/60	8,546
Youth – Extended Interview	17,070	1	35/60	9,958
Adult – Parent Interview	17,070	1	19/60	5,406
Adults – Follow-up/Tracking Participant Information Form for Youth (completed by parents)	17,070	2	8/60	4,552
Total				138,514

Table 7. PATH Study field test annualized cost to respondents

Type of Respondent and Instrument	Number of Respon-dents	Frequency of Response	Average Time Per Respon-dent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Adults – Household Screener	1,823	1	17/60	517	$16.27	$8,404
Adults – Individual Screener	840	1	6/60	84	$16.27	$1,367
Adults – Extended Interview	590	1	1 9/60	679	$16.27	$11,039
Adults – Biospecimen Collection: Urine	590	1	8/60	79	$16.27	$1,280
Adults – Biospecimen Collection: Buccal Cell	590	1	8/60	79	$16.27	$1,280
Adults – Biospecimen Collection: Blood	590	1	18/60	177	$16.27	$2,880
Adults – Tobacco Use Form	590	1	2/60	20	$16.27	$320

Adults – Follow-up/Tracking Participant Information Form	590	2	6/60	118	$16.27	$1,920
Youth – Extended Interview	100	1	35/60	58	$7.25	$423
Adult – Parent Interview	100	1	19/60	32	$16.27	$515
Adults – Follow-up/Tracking Participant Information Form for Youth (completed by parents)	100	2	8/60	27	$16.27	$434
Total				1,870		$29,862

Table 8. PATH Study baseline annualized cost to respondents

Type of Respondent and Instrument	Number of Respon-dents	Frequency of Response	Average Time Per Respon-dent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Adults – Household Screener	102,263	1	17/60	28,975	$16.27	$471,415
Adults – Individual Screener	63,000	1	6/60	6,300	$16.27	$102,501
Adults – Extended Interview	42,730	1	1 9/60	49,140	$16.27	$799,500
Adults – Biospecimen Collection: Urine	42,730	1	8/60	5,697	$16.27	$92,696
Adults – Biospecimen Collection: Buccal Cell	42,730	1	8/60	5,697	$16.27	$92,696
Adults – Biospecimen Collection: Blood	42,730	1	18/60	12,819	$16.27	$208,565
Adults – Tobacco Use Form	42,730	1	2/60	1,424	$16.27	$23,174
Adults – Follow-up/Tracking Participant Information Form	42,730	2	6/60	8,546	$16.27	$139,043
Youth – Extended Interview	17,070	1	35/60	9,958	$7.25	$72,192
Adult – Parent Interview	17,070	1	19/60	5,406	$16.27	$ 87,947
Adults – Follow-up/Tracking Participant Information Form for Youth (completed by parents)	17,070	2	8/60	4,552	$16.27	$74,061
Total				138,514		$2,163,790

The estimates for hourly wage of adult respondents is 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.13Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

The PATH Study has no other annual cost burden to respondents or Record Keepers. This study has no capital, operation or maintenance costs.

A.14Annualized Cost to the Federal Government

The total estimated annual cost of the 5-year PATH Study to the Federal government is $ $696,000. This estimate is based on the mean weighted salaries (average of $116,000 each) of the 6 FTEs of federal staff responsible for this work. It includes quantification of hours (full time) plus estimates for operational expenses (including equipment, overhead, printing, and support staff) that would not be incurred without this collection of information. 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 information collection activities, including the design and development of the sample, field testing, interviewer training, mailing list compilation and maintenance, printing forms and materials, mailing and enumeration, data and biospecimen collection, editing, coding, tabulation, data analysis, and the reporting and dissemination of results are estimated to be a total of $125.9 million for all 5 years, and $25.2 million annually.

A.15Explanation for Program Changes or Adjustments

This is a new collection of information.

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

A.16a Plans for Tabulation and Publication

The plans for tabulation, statistical analysis, and publication of the PATH Study data are driven by the major objectives presented in Section A.2. The first step in the plan is to estimate the incidence and prevalence of key outcome measures, such as: product/brand switching, uptake of new products, and dual- and poly-use of tobacco products (Objective 1); risk perceptions regarding different products (Objective 2); and quitting and relapse (Objective 3).

The second step will be to conduct cross-tabulations related to major outcome variables by key demographic variables, such as race/ethnicity, gender, and age (Objectives 6 and 7), which may appear in published articles alone or as preliminary statistics for more multivariate substantive analyses. For example, a cross-tabulation analysis may be conducted on awareness of health outcome labels on cigarette packages (an outcome measure) across sociodemographic factors (see Table 2 in Attachment 18).

The third analytic step will address more substantive research questions, and will require multivariate statistical analyses. In these analyses, relationships between Federal programs and trends in tobacco use, cessation, and relapse patterns, changes in risk perceptions, and tobacco-related intermediate endpoints and health outcomes will be examined (Objectives 5 through 7). The major outcome variables represent dependent variables, while tobacco policy variables and major demographic and socioeconomic variables will serve as independent, confounding, mediating or moderator variables. Many of these analyses will be done using logistic regression models, however, the specific multivariate procedures to be performed on the data primarily will depend on: (1) basic characteristics of the outcome data (e.g., their continuous or discrete nature); (2) specific hypotheses or research questions being addressed; (3) whether the data meet underlying assumptions of the

statistical model; and (4) sample size and power considerations for the specific multivariate analysis.

Additionally, as mentioned in Section A.2d, FDA has established a partnership with CDC to analyze the PATH Study biospecimens. These analyses will focus on comparing intermediate endpoints (i.e., markers of exposure and tobacco-related disease processes) and health outcomes. Examples of the specific analytes for which the biospecimens will be tested are presented in Attachment 4.

A.16b Project Time Schedule

The following tables outline the key activities and time schedules for the PATH Study field data collection and baseline wave of data collection.

Table 9. Field test timeline

Activity	Time Schedule
Complete training materials and computerized instrument	2 Weeks after OMB approval
Finalize all computerized programs and survey forms	2 Weeks after OMB approval
Conduct field test	Upon receipt of OMB approval
Submit Change Request for the main study to OMB based on the results of the field test	3 – 4 ½ Months after OMB approval
Process and clean questionnaire data	2 – 4 Months after OMB approval
Data Analyses	3 – 4 Months after OMB approval
Report summarizing field test results	5 Months after OMB approval

Table 10. Baseline timeline

Activity	Time Schedule
Assuming non-substantive changes from the field test, begin baseline data collection	11 Months after OMB approval
Process and clean questionnaire data	12 – 36 Months after OMB approval
Data Analyses	13 – 36 Months after OMB approval
Publish preliminary study results/release limited access data files for questionnaire data	24 Months after OMB approval
Publish preliminary study results/release limited access data files for biospecimen data	24 Months after OMB approval

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

This data collection activity does not seek approval not to 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.

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