

Supporting Statement A For:

**NEXT SERIES OF TOBACCO USE SUPPLEMENTS TO THE
CURRENT POPULATION SURVEY (TUS-CPS) (NCI)**

**Reinstatement with Change for
OMB #: 0925-0368, Exp. 3/31/2013**

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A. Justification

This is a request for reinstatement with change of the, “Next Series of Tobacco Use Supplements to the Current Population Survey (TUS-CPS) (NCI).” The 2014-15 Tobacco Use Supplement-Current Population Survey (TUS-CPS) will be conducted by the Census Bureau and is co-sponsored by the National Cancer Institute (NCI) and the Food and Drug Administration (FDA). Fielded since 1992, most recently in 2010-11, this survey is part of a continuing series of surveys (OMB No. 0925-0368) sponsored by NCI that has been administered triennially as part of the Census Bureau's and the Bureau of Labor Statistics' CPS. For the TUS-CPS, data will be collected from the U.S. civilian non-institutionalized population on smoking, other tobacco use, including switching, flavors, dependence, cessation attempts, and policy and social norms. The TUS-CPS has been a key source of national, state, some local-level, and health disparity data on these topics in U.S. households because it uses a large, nationally representative sample. Thus over time, the TUS-CPS has come to meet the goals of a broad array of agencies both within the Department of Health and Human Services (HHS), such as the Centers for Disease Control and Prevention (CDC) and others outside HHS. The 2014-15 TUS-CPS is designed to meet both co-sponsors' goals, and is expected to continue to meet some of other agency goals such as those for CDC. The NCI and FDA are co-sponsoring the 2014-15 TUS-CPS through parallel, but separate interagency agreements with the Census Bureau. The NCI is particularly focused on policy information such as home and workplace smoke-free policies, cigarette price, and impact of these measures on subsequent purchase and use behavior; and changes in social norms and attitudes related to tobacco use. The FDA aims to support research to aid the development and evaluation of tobacco product regulations. The research findings generated from this program are expected to provide data to inform FDA regulation of the manufacture, distribution, and marketing of tobacco products to protect public health, as well as provide valuable tobacco control information to NCI, CDC and other stakeholders. A unique feature is the ability to link TUS-CPS with other social and economic Census Bureau and Bureau of Labor Statistics data, other sponsor-supported supplement data, and health endpoint information through the National Longitudinal Mortality Study¹. Data will be collected in July 2014, January 2015, and May 2015 from about 255,000 respondents.

A1. Circumstances Making the Collection of Information Necessary

A1a. Overview

This request is for the Office of Management and Budget (OMB) approval for the “Next Series of Tobacco Use Supplement (TUS) to the Current Population Survey (CPS)” in 2014-2015, a triennial (now quadrennial) cross-sectional survey of tobacco use using a large, nationally representative sample of about 255,000 adults within a given survey period.

¹ <http://www.census.gov/did/www/nlms/> ; <http://surveillance.cancer.gov/disparities/nlms/>

The 2014-2015 TUS-CPS is being cosponsored by the National Cancer Institute (NCI) and Food and Drug Administration (FDA) in interagency agreements with the Census Bureau. The TUS-CPS will provide information on national and state-level prevalence estimates of tobacco use including switching between products, flavors, measures of dependence, cessation attempts, as well as home and workplace smoke-free policies, cigarette price, use of quit lines and internet cessation tools, and changes in tobacco use related social norms and attitudes. While both co-sponsoring agencies have overlapping interests in tobacco use, NCI, CDC and others are particularly interested in changes in tobacco control policy and social norms (especially at the state level and for subgroups with various health disparities) to provide information needed to measure progress toward tobacco control by the Risk Factor Monitoring and Methods Branch (RFMMB) of the Applied Research Program (ARP) within the Division of Cancer Control and Population Sciences (DCCPS), and other agencies such as OSH/CDC. FDA's Center for Tobacco Products (CTP) is particularly interested in estimating the burden of a range of tobacco products such as e-cigarettes, dissolvables, hookah, large and small cigars, and the extent to which it is concentrated in particular subgroups. NCI, CDC and others will benefit from this information as well...Additionally, the linkage of TUS-CPS data (dating back to the 1990s) to the National Longitudinal Mortality Study (NLMS) will provide FDA information on the health effects related to use of these tobacco products. Taken together, TUS-CPS is uniquely suited to inform FDA in its tobacco regulatory decisions aimed at protecting public health. Protecting public health is also a shared goal of NCI, CDC and others, By harmonizing on TUS-CPS to meet the needs of both co-sponsoring agencies and as a consequence continuing to meet the needs of others, we will place burden on the public once rather than twice.

Legal justification for a national survey of adult tobacco use can be found in the Family Smoking Prevention and Tobacco Control (TCA) and Federal Retirement Reform Act² which authorizes the FDA to conduct research to support tobacco regulation. Also the Public Health Service Act (Section 410, 42 USC § 285; Section 411, 42 USC § 285a; Section 412, 42 USC § 285a-1) and

² The Family Smoking Prevention and Tobacco Control (TCA) and Federal Retirement Reform Act was enacted after being signed by the President on June 22, 2009 (Public Law 111-31).
<http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>

Section 413, 42 USC § 285a-2 outlines the mission of the National Cancer Institute (NCI) and authorizes NCI to collect this information.

In previous OMB submissions, HHS/NIH/NCI were granted approval (OMB #0925-0368) on 01/02/1992, 04/28/1995, 08/05/1998, 01/13/2000 (revised and approved on 06/01/2001), 01/23/2003, 04/12/2006, and 3/16/2010 for data collections which consisted of Tobacco Use Supplements (TUS) to the CPS (1992-1993, 1995-1996, 1998-1999, a correction of limited data in 2000, 2001-2002, 2003, 2006-2007, and 2010-2011) to the civilian non-institutionalized population).

The proposed clearance package, “The Next Tobacco Use Supplement to the Current Population Survey (TUS-CPS)” in 2014-2015, is being processed as a reinstatement with change due to the scheduling and funding of the Tobacco Use Supplement with the Census Bureau. The TUS-CPS is part of the regularly scheduled cycle with the Census Bureau, which collects this information now every 4 years, with all of its other on-going and cyclical supplements.

A1b. Critical Need for TUS-CPS Data

Tobacco control and surveillance research is one of the most important efforts of the Department of Health and Human Services (DHHS) fulfilling the mission outlined in the Public Health Service Act and in support of many of the health goals for the nation for Year 2020 and a pillar of the DHHS’ Tobacco Control Strategic Plan. According to the 2014 Surgeon General Report, since 1964, smoking has been responsible for over 20 million American deaths. Tobacco harms nearly every organ in the body (2004 Report of the Surgeon General; Adhikari et.al, *MMWR* 2008;57(45):1226-28). Cigarette smoking is responsible for more than 30 percent of all cancer deaths annually in the United States. The DHHS has established a goal of no more than 12 percent smoking prevalence for the nation by the year 2020.

One of NCI’s goals is to understand the causes of tobacco use, addiction, and tobacco-related cancers and apply this knowledge to their prevention and treatment. One means for achieving this goal is to expand efforts to define the behavioral and social bases of tobacco use, addiction

and cessation, impact of policies on these, and translate this knowledge into new interventions and policies. To a great extent, NCI addresses this objective by conducting a series of tobacco use supplements (TUS) to the CPS.

The TCA was signed into law on June 22, 2009 and gives the FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. Examples of specific FDA authorities include premarket applications for new and modified risk tobacco products, tobacco product standards, health warnings on cigarettes and smokeless tobacco products and advertisements, advertising and promotion restrictions, and industry registration and listing of ingredients. The FDA's CTP aims to prevent Americans from starting to use tobacco, encourage current users to quit, and to decrease the harms of tobacco product use. Tasked with this mission, the FDA's CTP requires solid evidence as a basis of regulatory efforts.

Passage of the TCA and recognizing the need for time-critical data to monitor the impact of new regulatory actions, CTP is cosponsoring the 2014-2015 TUS-CPS with the NCI. TUS-CPS provides national level estimates critical to understanding the burden of tobacco use (including rarer and emerging tobacco products) in the U.S. and the extent to which it is concentrated in particular subgroups. With the large sample size, TUS-CPS is particularly equipped to provide smaller subsample estimates with greater precision. In addition, TUS-CPS as a serial cross-sectional survey can be used to monitor trends in these population estimates over time and can be used to evaluate the impacts of policy action. Some additional measures added to meet CTP's data needs include detailed information on e-cigarettes, dissolvables, and flavors across all non-cigarette tobacco products. Collaborating on TUS-CPS with NCI, FDA aims to maximize existing resources while minimizing burden to the public.

Examples of how the TUS-CPS Questionnaire serves as basis for NCI initiatives include the following:

- NCI supported Cancer Intervention and Surveillance Modeling Network (CISNET) which uses information on national trends in cigarette smoking for diverse US sub-populations to model how tobacco control interventions, screening modalities, treatments and public policies may affect lung cancer incidence and mortality. TUS-CPS is a primary resource

for modeling tobacco use and/or policy and other intervention strategies in models of lung cancer mortality that account for tobacco control initiatives and subsequent tobacco use and exposure.

- Tobacco Research Network on Disparities (TReND) which aimed to understand and address tobacco-related health disparities on understudied and underserved populations by advancing the science, translating that scientific knowledge into practice, and informing public policy. This initiative has increased the capacity of researchers to submit seminal grant proposals in this area including secondary data research involving data from the TUS-CPS.
- NCI State and Community Tobacco Control Initiative (SCTC), National Institute of Human Genome Research (NIHGR) “PhenX” Initiative, and FDA-NIH Grant Funding Initiatives: TUS data supports developmental and primary research in these domains. It also provides a population-based model to anchor new tobacco-related research to national, regional, or state findings (e.g., for PhenX Tobacco, Alcohol, and Other Substances Toolkit TUS-CPS is designated as a model for several adult tobacco use measures for measuring cigarette smoking exposure and phenotypes for future genome-wide association studies (<http://www.phenx.org> or <https://www.phenxtoolkit.org>).
- HHS Healthy People (HP) 2020 Objectives, NCI Cancer Trends Progress Report, State Cancer Profiles uses long-term trend data from the TUS for several national and state tobacco control measures unique to its survey series.

The Census Bureau will collect TUS data from the civilian non-institutionalized population on, cigarette smoking and other tobacco product prevalence and patterns of use; attempts at cessation including switching to different products and use of quit lines and web-based tools; home and workplace smoke-free policies; and changes in tobacco use related social norms and attitudes. This survey will provide invaluable information to NCI, FDA, Centers for Disease Control and Prevention (CDC) and other government agencies, other scientists, and the general public (public use files will be created) necessary for tobacco control research, and assessing the impact of tobacco regulation on tobacco use, as well as measure progress toward tobacco control. The timing of this information is critical given the rapid emergence of a number of tobacco use behaviors, especially e-cigarette use. In addition, it’s been four years since last collection of state price and purchasing behavior nationwide and other social norms related to second-hand smoke policies.

The major strengths of the TUS-CPS Questionnaire include the following:

- **Long-term trends:** Consistent and standard data collection over the 1990's and the 2000's allow for comprehensive study of long term trends in tobacco use patterns, tobacco control intervention dissemination and effects, and social norms for each of the states, some sub-state groupings as well as nationwide.
- **Linkages to health and other data:** Of interest are the linkages to all-cause and cause-specific mortality data and cancer registry data through the National Longitudinal Mortality Study (NLMS). The NLMS is a linked database housed at the US Census Bureau that includes: 1) baseline data from the March Annual Social and Economic Supplement (ASEC) to the CPS; 2) data from other CPS supplements such as the TUS; 3) disease outcome data from the National Center for Health Statistics' National Death Index and the NCI SEER cancer registries; and 4) diagnosis, treatment and cost data from CMS Medicare claims. Information about the NLMS is available at <http://www.census.gov/did/www/nlms/> and <http://surveillance.cancer.gov/disparities/nlms/>. These linkages and other CPS supplements not specifically linked to the NLMS database but linkable to the TUS provide rich demographic, economic and occupational data from the Core CPS survey on labor force parameters, the American Time Use, Internet Use, Food Security, Education, Voting and Registration and other topic-specific supplement information.
- **Large sample size (~255,000 adults):** The CPS affords the opportunity to assess tobacco control for some sub-state levels or communities on the order of 100,000 population. Furthermore, the large sample size of the CPS allows for assessment of tobacco control disparities among important demographic sub-populations (e.g., minority, low income, etc.) across the nation, regionally and for large states as well as stable estimates of other tobacco use (e.g. smokeless, cigars, pipes) and emerging tobacco products in these same sub-populations.
- **Minimizing burden and cost:** It would be prohibitive in cost to conduct such a large-scale survey such as the TUS independently. Because of the cost efficiency and reduction in respondent burden (that is, not having to duplicate collection of demographic information), as well as the trend data already collected with this mechanism in the 1990's and 2000's, the CPS is chosen as the vehicle to accomplish this goal.

As mentioned in Supporting Statement A, Section A1a, by harmonizing on TUS-CPS to meet the needs of both agencies, NCI and FDA will place burden on the public once rather than twice.

A2. Purpose and Use of the Information

A2a. Objectives and Purposes/Uses

The TUS-CPS questionnaire (**Attachment 1**) will be used to evaluate and monitor: (1) changes in smoking and tobacco use prevalence (by specific type of tobacco product), quit attempts,

switching to various products in attempts to quit, and successful quit rates; and (2) changes in and effects of regulations, policies (including price increases), other interventions, home and work smoke-free policies, potential exposure to secondhand smoke (SHS) and changes in social norms and attitudes which influence tobacco use nationally and within communities for each of the U.S. states. The survey results will be used to monitor prevalence of tobacco use, policies relevant to tobacco use including price increases and impact of price-reducing strategies,, and changes in these indicators since the 1990's and 2000's. TUS-CPS data, specifically the use of the large range of tobacco products (e-cigarettes, small and large cigars, hookah, etc.) as well as quit behaviors will enhance the evidence base available to FDA to inform its regulatory decisions and development of regulatory actions under the TCA.

A2b. Information to be Collected

i. Prevalence and Patterns of Tobacco Use

The TUS- CPS will permit the monitoring of changes in the rate of current, former, and never users of the major forms of tobacco according to various demographic variables collected in the CPS, with an emphasis on cigarette smoking. A standard battery of questions for cigarette smoking that have been in **continuous use** in other federally sponsored surveys (including the TUS-CPS and the National Health Interview Survey (NHIS) for about 2-4 decades), will permit the NCI and FDA to estimate and classify the number and percent of the population by the following characteristics in each state as well as nationwide:

- classified as current, never, or former users of cigarettes;
- according to the number of cigarettes smoked daily and level of addiction;
- classify light and intermittent (some day) smoking patterns;
- according to the age regular smokers initiated their usage behavior and in what state they lived at the time of initiation;
- according to those who have ever made a serious attempt to stop, and those who have done so recently and those who have recently been successful in quitting;
- according to type of cigarette smoked (i.e., menthol, non-menthol);

- current and former smokers adoption of new tobacco industry smokeless products and their impact on continuing smoking versus attempts to quit;
- classified as current or former users of other tobacco products, by type of product and dual use with cigarettes; and
- assessing emerging tobacco products such as electronic cigarettes and dissolvables as well as use of flavored products

ii. Changes in Policies, Intervention Dissemination, Social Norms and Attitudes

The environment in which smokers live and work can play a significant role in motivating smokers to seek assistance to quit smoking. A significant body of information exists which suggests that changes in social norms and values can serve as markers for predicting changes in behavior both at the community and individual levels. Questions are included on the supplement which enable the monitoring of these changes in each of the states and nationwide and among subpopulations with health disparities. These include smoking practices in the workplace, home, and attitudes about allowing smoking in various public places and some private spaces where others share space in close proximity (e.g., multi-unit housing and cars). Where appropriate, these questions were originally developed from those used in previous surveys at the federal level and funded by outside agencies. These include NHIS, COMMIT, and the Roper survey (conducted for the Tobacco Institute) and questions fielded on some state adult tobacco surveys that follow CDC guidelines. These questions have been cleared by OMB through our previous OMB packages and new questions have been reviewed by cognitive specialists and put through a general consistency test for purposes of timing and flow (see Supporting Statement B, Section B4).

Data from the TUS and from the CPS allow the following estimates of the number and percent of the population who will be further classified by various demographic variables and smoking status:

- those who have rules about smoking in the home
- rules of protection of workers from second-hand smoke (SHS) at work in both indoor public/common areas and work areas
- those workplaces that offer a smoking cessation program

- use of quit lines and internet web-based tools
- those who support the view that various public places should be smoke-free
- tobacco users classified by type of last cigarette purchase, cost of the cigarettes, and where last purchase occurred to measure impact of price increases and price-reducing strategies on tobacco use behavior;

A2c. Reports and Publications Using Past Tobacco Use Supplement Data

Data collected to date have yielded nearly 200 publications, reports and book chapters (see **Attachment 2** which is a list of publications from our TUS-CPS searchable database available to the public on our website - <http://appliedresearch.cancer.gov/tus-cps/publications.html>), and many more presentations and other means of dissemination at conferences and workshops. Findings have been published in well-known medical, public health, economic, occupational, and other social science journals. Results have also been reported in special monographs and publications such as several Surgeon General's Reports, NCI Tobacco Control Monographs, NCI Cancer Trends Progress Reports, NCI CISNET publications, OSH/CDC State Tobacco Highlights Reports, Institute of Medicine, and Congressional Budget Office (CBO) reports, and publications by private institutions such as Robert Wood Johnson Foundation (RWJF), the American Cancer Society, the American Legacy Foundation, and many members of the National Bureau of Economic Research (NBER also provides public application files for our data). The publications cover the whole gamut of topics that TUS-CPS measures from smoking initiation through cessation and the tobacco control interventions/policies that impact them for various geographical sub-populations and health disparate groups. Many papers address the first FDA issue on the impact of menthol in cigarettes on the public's health used TUS-CPS series data. Initial data from the May 2010 survey was presented to the FDA-CTP Tobacco Products Scientific Advisory Committee (TPSAC) on January 2011 and was mentioned in their menthol report to FDA. The May and August 2010 data were presented at the 2012 World Conference on Tobacco or Health, and data on e-cigarettes from May 2011 was presented at the 2014 Society for Research on Nicotine and Tobacco meeting.

Our latest TUS-CPS 2010-2011 series data has been released to the public as public use files and we conducted a webinar on September 2013 for both new and veteran users of our data to educate them about novel and complex research analyses afforded by the long-term nature and unique linkages to other data to spur future novel and efficient uses of this resource. Some of the data highlights for 2010-11, as well as data from 1998-2006/07 are presented on the ARP/DCCPS/NCI Website (<http://appliedresearch.cancer.gov/tus-cps/results.html>).

A2d. Use of Information by Other Agencies and Organizations

FDA has specific plans for use of its data to meet its mandate by the TCA for meaningful and effective tobacco product regulations. As mentioned in Section A1, the TCA 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 TCA provisions. The TCA mandates the regulation of tobacco products using a population health standard including users and non-users of tobacco products. TUS-CPS is critical to facilitating this process. Its nationally representative cross-sectional design will provide epidemiological, population-based data on tobacco use behaviors and attitudes to help inform FDA's regulatory decisions and actions under the TCA. Examples of how TUS-CPS data could inform FDA include estimating the prevalence of flavored product use by specific product, relative prevalence of small and large cigar use across socio-demographic groups, and mortality risks of primary and secondary cigar smoking.

In May 1999, the CDC launched the National Tobacco Control Program (NTCP). Their cooperative agreement with states recommends several program goal areas in its comprehensive framework for statewide programs, including preventing initiation of tobacco use among young people, promoting quitting among adults and young people, eliminating exposure to second-hand smoke, and identifying health disparities among population groups. As in the past the TUS-CPS data has been used by CDC to contribute toward their collective information to monitor and/or evaluate progress toward their goals. We expect that they will continue to use the 2014-15 TUS-CPS in this manner.

As with all CPS data collection efforts, results from the proposed data collection will be made available through public use data files by the U.S. Census Bureau. Public release of the TUS-CPS 2014-2015 data is slated for June 2016, approximately 1 year after the last wave of data collection. This amount of time is needed for completing editing, weighting work, initial analysis as well as the technical documentation for all 3 waves. Recent experiments with releasing each wave of data separately had shown to be inefficient, and researchers had largely preferred to wait for data from all 3 waves in order to take advantage of TUS-CPS's large sample size. For internal HHS use, data with minimal documentation will be available 12 months after the first wave of data collection approximately July 2015 and subsequent data about 8 months after each of the two other waves.

Thus, researchers, grantees, public health officials at the national, state and local level, and others will be able to analyze CPS and its Tobacco Use Supplement state-specific and large community data for a variety of purposes. Analyses will be published in scientific journals, included in future NCI CTPR Updates, NCI-CDC State Cancer Profiles' dynamic public use web tool, and will likely appear in future NCI Monographs, Surgeon General Reports, MMWR reports and our TUS-CPS web site. As stated earlier in Section A1, the TUS-CPS data has also been used as a model for the PhenX Toolkit an initiative of NIH's National Human Genome Research Institute (NHGRI); the basis of many state and national prediction modeling efforts to judge the potential of reaching state-specific, and national HHS Healthy People goals.

A3. Use of Improved Information Technology and Burden Reduction

By the time the final "Tobacco Use" supplement is fielded, the Bureau is scheduled to interview approximately 15% percent of the CPS sample households using their Computer Assisted Telephone Interviewing (CATI) facilities in Hagerstown, MD; Tucson, AZ and Jeffersonville, IN. The remaining sample households will be enumerated either by personal or telephone interviews with data being captured through Computer Assisted Personal Computer Interviewing (CAPI). The CAPI system is essentially the same as the CATI system, but data is collected locally, either in person or over the telephone, and entered into a personal computer rather than captured from a central CATI site. The primary advantage of both the CATI and CAPI systems is to make

interviewing more efficient and, in turn, reduce respondent burden. Data quality will increase by eliminating errors through flagging of invalid entries at the time of survey administration.

The Privacy Impact Assessment (PIA) has been completed and was promoted to the Department of Health and Human Services on September 28, 2012. The name of the IT system is “NIH NCI Tobacco Use Supplement to the Current Population Survey (TUS-CPS)” (**Attachment 3**).

A4. Efforts to Identify Duplication and Use of Similar Information

A4a. Efforts to Identify Duplication

Tobacco-related data collections supported by the Federal government and subject to OMB review require strategic coordination and harmonization to assure they maximize the utility of data collected, minimize burden on participants, and comply with HHS standards. To achieve these objectives, NIH and FDA are working with the Assistant Secretary for Planning and Evaluation (ASPE) at HHS to facilitate the coordination and integration of tobacco-related information collection efforts, to the extent feasible, practicable, and desirable, across HHS agencies. From a feasibility perspective, the current funding mechanism for FDA (the TCA) requires that the research data collected by the TUS-CPS be relevant to FDA’s regulatory priorities, needs, and authorities related to the manufacture, marketing, and distribution of tobacco products. Consequently, within the limits and authorities of the TCA, the TUS-CPS has flexibility to integrate the data-collection needs of other HHS agencies, such as by including questionnaire items and priority measures of shared interest. Additionally, data needs that fall outside of FDA authority may potentially be integrated with priority measures for NCI as part of NCI’s interagency agreement with Census.

There are national surveillance surveys on tobacco use in the U.S. (see **Attachment 4** Table: Comparison of Key Features of Adult National Tobacco Surveys). Key features of the TUS-CPS distinguish it from tobacco-specific surveillance surveys, as described below.

NCI has determined through several advisory committees that the TUS-CPS is the only feasible mechanism for measuring changes at the individual state level and some substrate levels, and

generally for satisfying the needs described in A.1, above. Other related surveys, such as the NHIS, the National Health and Nutrition Examination Survey (NHANES), the Behavioral Risk Factor Surveillance System (BRFSS), the National Adult Tobacco Survey (NATS), the National Survey on Drug Use and Health (NSDUH), and the PATH study are inadequate for NCI program evaluation and surveillance. Specifically, one or more of the following apply to each of those surveys: 1) Those surveys do not include the necessary tobacco indicators for measuring initial and intermediate policy and social norm-oriented outcomes; 2) They do not require that all states administer the same tobacco measures at the same time with the same procedures; 3) They have insufficient sample sizes for estimating prevalence and activity at the state-specific or sub-state level (e.g., creating major media market areas from combining some of these geographic entities, and measuring important estimates of state cigarette price and smokers' price-reducing strategies); 4) They use different definitions of tobacco use prevalence than those commonly used by NCI and its collaborators; 5) They don't provide long-term trend data; and 6) They don't provide linkages to disease and other rich occupation, social and economic data.

In addition, TUS-CPS due to its large sample size allows stable estimates on specific racial and ethnic sub-populations (e.g. CPS sample size for Asian Americans is eight times larger than that of NHIS), it can further subdivide common racial/ethnic groups that are estimated by other surveys (e.g., provide estimates for ethnic subgroups of Hispanics), and other important demographic subpopulations for assessing tobacco control disparities across the nation, regionally and for large states. Note that these subpopulation estimates can address specific tobacco objectives from Healthy People 2020 as well.

A4b. Use of Similar Information

While each of the surveys cited above collect tobacco data, each does this within the context of a set of other related variables (see the column "Unique features" in the Table in **Attachment 4**). The annual NHIS Core and periodic Cancer Control Supplements contain relatively limited national tobacco information on a smaller adult sample size at any given time point which can be related to a range of health issues including utilization of services and limitations of activity. The NHANES with an even smaller sample size especially for adults assesses national tobacco use in

conjunction with disease, nutrition and health indicators, and in particular with biomarkers collected as part of laboratory-based health examination. The NSDUH asks tobacco use in context with other substance use and mental health. While the NSDUH includes data on adults as well as teens, it focuses on a "teen" definition of smoking which emphasized experimentation, whereas the TUS-CPS focuses primarily on adults and an "adult" definition of smoking. The "adult" definition of smoking from the TUS-CPS is necessary for understanding quitting behavior, dependence, and long range effects of tobacco control policies and other tobacco control interventions. Although the Core instrument for the state-based BRFSS, for which CDC provides some technical assistance, does include a few questions on tobacco use, this information has limited utility. The administration of only a few tobacco related questions is of limited use unless supplemented by an additional BRFSS smoking module. However, the use of this module is variable, and determined each year on a state-by-state basis (fewer than half of the states use an optional tobacco module in any given year). Across states, a number of statistical methodologies are used, which pose some challenges for purposes of comparisons between states, especially aggregation to a national or regional level estimate of smoking prevalence.

Additionally, other surveys such as the NCI Health Information National Survey (HINTS) and the NATS collect tobacco use information. HINTS assesses changes in health communication, use of cancer-related information, people's resources to obtain health information, access issues, cancer knowledge, cancer perceptions, and cancer risk behaviors, including skin protection and tobacco use. HINTS is conducted with a total sample of approximately 3,500 persons per cycle (e.g., for 2013/2014). In the next year, NCI will propose a HINTS-FDA module that will take advantage of this unique health communication survey to field a special module to collect data relevant to the TCA. Data will be used to inform FDA's tobacco prevention campaigns and tobacco control outreach and education. The goals of the proposed HINTS-FDA module as they relate to FDA's CTP are: 1) To examine the public's communication and media use patterns as they relate to tobacco use and advertising; 2) To examine attitudes and perceptions about the harms of tobacco products (including their constituents), potential modified risk claims, and messages designed to increase cessation and prevent tobacco initiation; 3) To assess the credibility of health information sources and channels; and 4) To collect data to evaluate the

reach and impact of CTP's current outreach and media efforts. These risk perceptions and sources of information are not tracked by TUS. Additionally, no tobacco use prevalence estimates are generated with HINTS or HINTS-FDA. Thus there is little duplication between HINTS and TUS-CPS.

NATS is a random-digit dialed sample of non-institutionalized adults > 18 years of age telephone survey originally developed by the Office of Smoking and Health at CDC and later conducted in collaboration with FDA. Topics including cigarette use patterns, purchasing behavior (cigarettes), use of other tobacco products, dependence (all tobacco), and cessation overlap with that of TUS-CPS. While there is overlap in many topics covered, some measures are harmonized, while others approach a topic with a different perspective, or in greater depth. This is not surprising given their different lengths and contexts. In the development of NATS, care was taken to harmonize with both TUS-CPS and NHIS to the extent feasible. Thus, TUS-CPS will continue to be an important source of some of these tobacco measures, also extending analysis by state, sub-state, small sub-groups, and major media market-defined areas.

The 2009-10 NATS was funded by CDC's Office on Smoking and Health (OSH) to evaluate the National Tobacco Control Program at both the state and national level. CDC-OSH developed the 2009-2010 NATS as the first adult tobacco survey designed within the framework provided by the CDC report titled, "Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs." FDA-CTP funded the 2012-13 and 2013-14 NATS as a partnership with CDC-OSH to collect time-critical national data to monitor the impact of new regulatory actions. However, as part of an ongoing assessment of its tobacco-related surveillance and monitoring activities, FDA has decided not to continue funding the NATS beyond the 2013-14 wave. At the present time, it is not known if CDC-OSH will continue to conduct the survey periodically to support tobacco control program evaluation.

Thus, since funding is not currently available for future NATS, FDA and NCI will partner with CDC/OSH and coordinate with HHS/ASPE on planning of content for future TUS-CPS full series, recognizing the limits of survey administration time for accommodating all we would like

to add to the TUS-CPS' established core set of tobacco-related questions. We will jointly determine its periodicity, within the constraints of Census Bureau CPS Supplement scheduling. As requested, we will also closely coordinate with OSH and ASPE on activities related to any future NATS waves, or other CDC, FDA, or HHS surveys that include tobacco-related content that address gaps to improve our overall efficiency as a Department in addressing the shared and specialized survey data needs across agencies.

Finally there is the very comprehensive longitudinal cohort study of tobacco use and health, PATH, which seeks to broadly gather and analyze epidemiological data on use of the full range of tobacco products available now and in the future, as well as data on attitudes, biomarkers, and health, to support and inform FDA's regulatory decisions and actions. Although as a longitudinal study it is expected that PATH data will allow the generation of cross-sectional tobacco and health related prevalence estimates, it has not been specifically designed for such purposes. PATH will present prevalence data from TUS-CPS and other HHS' nationally representative signature studies along with their own data. Thus, it is particularly important and fortuitous there has been purposeful harmonization both in the past for TUS-CPS and NHIS and in the present for PATH, TUS-CPS and NHIS. For example, for electronic cigarettes all three surveys are aligned in how they ask about ever use. An example of efficiency and response burden reduction goals is the decision to cut some questions on cessation treatment from the 2010-11 TUS-CPS developing the 2014-15 survey. This was facilitated by having the nearly concurrent 2015 NHIS-CCS maintain these types of questions that had been previously harmonized with TUS-CPS questions since 2010.

In conclusion, there are no existing comparable data sources that can produce state-specific or sub-state estimates for monitoring and evaluating detailed information on dependence, tobacco-specific products including emerging product use, use of quit lines and quitting behavior as well as initial and intermediate outcomes of tobacco use as outlined in Section A2. Unlike other national surveys, the TUS-CPS has the context of rich demographic, economic and occupational data from the Core CPS survey on labor force parameters, and due to its panel design, allows users to merge the special annual March Demographic Supplement providing additional data with

the TUS conducted in a separate month. Furthermore, TUS-CPS will provide pertinent tobacco control risk factor information for each state which can be used along with state registry information to develop cancer prevention and control interventions and programs, as well as a direct way of linking the rich TUS-CPS tobacco use and policy and intervention data to all cause mortality data and cancer registry data through the NLMS.

Because of the consistency in methodology, the 2014-2015 TUS-CPS will provide ongoing data for monitoring and evaluating initial and intermediate outcomes (e.g. workplace policies, home smoking rules and other social norms including, attitudes toward - and compensatory behaviors as a result of - tobacco control policies) as well as final outcomes.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A6. Consequences of Collecting the Information Less Frequently

As a cross-sectional survey conducted once every 3 or 4 years, the burden of TUS-CPS is much smaller than had it been an annual survey. Less frequent data collection would have implications for the scientific quality and utility of study data, particularly data that would inform the development of new TCA-related policies and programs in a timely manner.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The Census Bureau collects these data for NCI in a manner which is consistent with the guidelines in 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8a. Comments in Response to the Federal Register Notice

Notice of this study was published in the Federal Register on January 22 (Volume 79, P. 3598) and allowed 60-days for public comment. There were a total of three comments. Two of the three comments were requests for a copy of the questionnaire and plans for the TUS-CPS. A

copy of the questionnaire and the SSA and SSB Supporting Statements were sent to the two requestors. One of these requestors commented in support of FDA's co-sponsorship with NCI of the TUS-CPS and NCI/NIH working with sister agencies and HHS to harmonize and coordinate tobacco use information across various federal surveys. It further stated the importance of this kind of HHS evaluation with sister agencies, made specific suggestions what this should include, and concluded with offering assistance. Additionally, the third public comment was a comment was about spending of tax-payers' dollars. A summary table of the requests for information and comments received, and the NCI responses to the comments, are part of the document in the "**Public Comments-Responses File**" submitted with the rest of the OMB package.

A8b. Efforts to Consult Outside the Agency

Previous TUS-CPS submissions have worked with many influential people (**Attachment 5**) who have helped provide expertise on research and development. For the sake of brevity, only the most recent expert consults from outside NCI and FDA will be discussed. These individuals provide expertise in research and development, and comment on topics and wording. Gary Giovino, John Pierce, David Abrams, and Charlotte Schoenborn have been actively engaged in discussions of TUS questions since the inception of the TUS-CPS. These and most of the others mentioned below and in **Attachment 5A** aided with the development of the 2003 Tobacco Use Special Cessation Supplement and determined what to incorporate from 2003 and 2006-07 into the 2010-2011 survey.

From the experience of the 2006-07 and 2010-11 TUS, the new emerging environment of other non-cigarette tobacco products and e-cigarettes, and from discussion with these and other outside consultants, we made changes to the 2014-2015. The nature of the comments ranged from results of methodological grant and contract research (Cristine Delnevo, Victoria Castleman, Martha Stapleton), the literature, emerging policy issues (Stephen Babb, Brian King, Michael Pesko, Frank Chaloupka, Shu-Hong Zhu) and consideration of complementing other tobacco surveys and sources of available data (Jennifer Pearson, Donna Vallone, Karen Messer, Geoffrey Fong, Andrew Hyland). These recommendations are reflected in the revisions to the TUS for the 2014-15 fielding.

Building upon HHS sister agencies' attention to harmonization and complementarities of tobacco control related items, where appropriate and most efficient, NCI and FDA have engaged staff from CDC-NCHS and OSH, NSDUH, and members of the PATH team in finalizing 2014-2015 TUS items.

A9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to be made to respondents.

A10. Assurance of Confidentiality Provided to Respondents

The Census Bureau collects these data for the Bureau of Labor Statistics (CPS) and NCI and CDC Tobacco Use Supplements (TUS) in compliance with Title 13, United States Code, Section 9, the Privacy Act of 1974 and OMB Circular A-130. The Census Bureau follows procedures to ensure confidentiality during all phases of data collection, editing, and transmission. Approximately 1 week before the start of interviewing, each new or returning sample household receives an advance letter (**Attachment 6**). This letter explains the voluntary nature of the survey and cites the legal authority for conducting the survey. Additionally, CPS procedures require that interviewers ask if the respondent received the letter. If not, the interviewer provides a copy to the respondent and allows sufficient time for the respondent to read the contents. When necessary, interviewers provide to households a brochure entitled, "How the Census Bureau Keeps Your Information Strictly Confidential," which further states the confidentiality assurances associated with the data collection effort and the Census Bureau's past performance in assuring confidentiality (**Attachment 7**).

All information given to Census Bureau employees is kept confidential as mandated by Title 13, United States Code, Section 9. Each interviewer has taken an oath to this effect and is subject to a jail term, a fine, or both if he/she discloses any information given to him/her. The Privacy Act does not apply to the data collected for the supplement. According to the NIH Privacy Act Officer, "The NCI will receive, through its interagency agreement with the Bureau, a data set

devoid of personal identifiers. This arrangement between the NCI and the Bureau is somewhat analogous to the finding of Privacy Act Non-applicability where one entity is receiving information from a 'contractor-owned' system, i.e., in such cases, the contractor has an existing database and the Project is not requiring that a new system be developed". The Statement of Non-applicability of the Privacy Act is contained in **Attachment 8**.

This data collection is exempt from 45 CFR 46 (Regulations for Protection of Human Subjects). **Attachment 9** contains a letter of exemption.

A11. Justification for Sensitive Questions

NCI does not collect personally identifiable information (PII). Census has PII for its own purposes of collecting the CPS which is not an NCI survey (see **Attachment 8** - Memo of Non-applicability of the Privacy Act) and Section A10. The survey items are for the most part not of a sensitive nature and are commonly found in surveys of health behavior and on previous versions of the TUS-CPS. There are no sensitive questions concerning illegal drug use or other criminal acts.

A12. Estimates of Hour Burden Including Annualized Hourly Costs

The respondent burden from this survey will result solely from the time spent hearing the instructions and questions and responding to them during the course of the interview. No research or recordkeeping will be required of the respondents. The estimated average length of each respondent interview for the Tobacco Use Supplement is 6 minutes. The actual respondent burden is dependent upon the smoking status of the respondents. Smoking status estimates from Census for individuals aged 18 and older from the 2010-11 TUS (16% current smokers, 19% former smokers and 65% never smoked) were used as weights to estimate average amount of respondent time.

This estimate includes the approximately 85,000 individuals surveyed with the supplement in each of the 3 months: July 2014 (85,000), January 2015 (85,000) and May 2015 (85,000) over a period of 2 years. The number of individuals (255,000) to be surveyed with the 2014-2015

Tobacco Use Supplement reflects a maximum³ based on an estimate of the individuals to be surveyed by the Census Bureau in 2014-2015 and the supplement response rates from the earlier Tobacco Use Supplements. The estimated total respondent burden is 25,500 hours over the 2 year clearance period. This results in an average annual burden of 12,750 hours per year (Table A.12-1).

The total respondent burden has been reduced since the 2010 submission from 40,500 for the main 2010-11 TUS-CPS fielding (total 2010 submission was 45,000 hours including the May 2011 follow-up) to the current request of 25,500 hours for this submission. The reason for this reduction lies in both a decrease in the total number respondents (from 270,000 to 255,000) as well as a decrease in the average burden per respondent (from 9 to 6 minutes per questionnaire).

Table A.12-1 Estimates of Annual Burden Hours

Type of Respondent	Number of Respondents	Responses per Respondent	Average Burden Per Response (in hour)	Annual Burden Hours
Individuals	127,500	1	6/60	12,750

³ Note that the estimates in Table A.12-1 represent a maximum number of respondents and a maximum average time. Since proxies get a shorter questionnaire, the total burden time is likely lower than the estimates in this table reflect.

The annualized cost to respondents is based on the mean hourly wage rate of \$22.01 per hour (May 2012 National Occupational Employment and Wage Estimates from Bureau of Labor Statistics⁴) of estimated respondent burden and a total of 12,750 hours of respondent time. Annualized, this cost is \$280,628 (Table A.12-2). The estimated total cost to the respondents would be \$561,255 over 2 years.

Table A.12-2 Annualized Cost to Respondents

Type of Respondent	Number of Respondents	Annual Burden Hours	Hourly Wage Rate	Total Respondent Cost
Individuals	127,500	12,750	\$22.01	\$280,627.50

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

A14. Annualized Cost to the Federal Government

FDA and NCI share in the costs for the Interagency Agreements with the Census Bureau for the subject of this request. The fielding of the next TUS-CPS in 2014-2015 will have annual costs of \$ 1.35 million (FDA \$1.08 million and NCI \$0.27 million) resulting in a total combined cost of \$2.7 million over two years. Costs include those related to coordination activities, data collection (includes training of interviewers), developing and testing the questionnaire software (CAPI and CATI), sampling statements (presentation of CPS statistical properties and how they specifically apply to the supplement) such as sample design and generalized variance estimation, and processing items (including computer programs, development of training materials, editing, transmission, and documentation).

NCI and FDA will also allocate staff time to monitor the project, participate in planning and design activities, and to analyze the results of the first wave of data collection. The NCI and FDA

⁴ http://www.bls.gov/oes/current/oes_nat.htm#00-0000

combined annualized cost to the Census Bureau is \$1,350,000, to HHS Federal employees is \$99,820.20 and for the contractors \$120,179.80. It is estimated that the annualized cost to the Federal Government is \$1,570,000 which amounts to \$3,140,000 in total over the two-year information collection (Table A.14-1).

Table A14-1 Annualized Cost to the Federal Government

Staffing	Task	Annualized Cost
Interagency Agreement	Project management and coordination activities, data collection, developing and testing the questionnaire software, sampling statements, and processing items and documentation	\$1,350,000
NCI	Project and Program Director, Health Statistician Grade 14, Step 9 (50% time over 12 months)	\$67,297.50
FDA	Epidemiologist, Grade 13, Step 2 (35% time over 12 months)	\$32,522.70
NCI Contractor	Project Data and System Management Support, Web Management support, programming for analysis, managing data and requests, testing and translation of instruments	\$120,179.80
Total		\$1,570,000

A15. Explanation for Program Changes or Adjustments

This is a program change of OMB #0925-0368 (the Tobacco Use Supplement to the CPS (TUS-CPS)). This information collection is being submitted as a “Reinstatement with Change” due to the scheduling and funding of the Tobacco Use Supplement with the Census Bureau. The Census Bureau previously scheduled TUS-CPS approximately every 3 years but has changed to every 4 years during certain months of the year. The annual hours requested for this project are estimated to be 12,750 burden hours per year, for a total of 25,500 hours over the 2 year clearance period.

Since this is a reinstated request, the current burden is 0 hours. It would not make sense to compare the “annual” burden from the previous submission since this request is for 2 years and the previous submission was for a 3 year time frame. However, the “total” burden has been reduced since the 2010 submission which was 40,500 hours (for only the main TUS-CPS 2010-11 fielding), to the current request of 25,500 hours for this submission. The reason for this reduction is the result of both a decrease in the total number respondents (from 270,000 to 255,000) as well

as a decrease in the average burden per respondent (from 9 to 6 minutes per questionnaire). The decrease in burden per respondents represents NCI's and FDA's decision to field a shorter instrument, and reduce household respondent burden (see Supporting Statement B for more details). Additionally, there will be no follow-up sample added to the 2014-15 TUS-CPS fielding, as there was in May 2011 as part of the 2010-2011 TUS-CPS series (this made the total 2010-11 burden for the main survey and follow-up 45,000 hours).

A16. Plans for Tabulation and Publication and Projected Time Schedule

Tobacco control goals include: Preventing initiation and/or progression of tobacco use among young adults, promoting quitting among young adults and young adults in general, eliminating secondhand smoke (SHS), and identifying and eliminating health disparities among population groups. In order to evaluate progress in these goal areas, state-based tobacco control programs and tobacco control research centers will need to measure initial and intermediate outcomes of programmatic interventions, such as changes in smoke-free policies at the workplace or smoking rules at home and increased and more successful quit attempts.

Descriptive and more complex multiple regression analyses will be conducted, as well as the modeling of trends for each of the indicators (discussed in Supporting Statement A, Section A.2 and further outlined in **Attachment 10**) and the factors that predict them (using 1992-2015 data). In addition, the TUS- CPS data will allow investigators to create a retrospective cohort to estimate smoking initiation rates, and successful quitting rates and provide some variables that can be used to create upstream tobacco control indices to evaluate relative changes over time of tobacco regulation controlling for other environmental and policy influences. See **Attachment 10** for examples of analyses.

The following is a time schedule based on tasks involved for this information collection and plans for preparing for publication (Table A.16-1). Though the three waves of information collection are planned to be completed by the end of the first year, the team would like to build in an extra year in case there are unpredictable and unforeseen delays in fielding the questionnaire, and thus this request is for approval of a two-year time frame.

Table A16-1 Time Schedule for Information Collection and Publication

Task	Time Schedule
Finalized questionnaire software	1 week after OMB approval
Field questionnaire wave #1	2-4 weeks after OMB approval - July 2014
Complete editing and weighting work wave #1	10 months after OMB approval
Field questionnaire wave #2	7 months after OMB approval - January 2015
Initial analysis for checking wave #1	10-13 months after OMB approval
Complete editing and weighting work wave #2	13 months after OMB approval
Field questionnaire wave #3	11 months after OMB approval - May 2015
Initial analysis for checking wave #2	13 - 15 months after OMB approval
Complete editing and weighting work wave #3	18 months after OMB approval
Initial analysis for checking wave #3 and all waves combined	18-21 months after OMB approval
Prepare summary tables for TUS-CPS website in preparation for subsequent public release of data and Technical Documentation for data for all 3 months	21-24 months after OMB approval
Release data files to public on Census FTP site	24 months after OMB approval – June 2016
Initiate drafting manuscripts for publication	24+ months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

All instruments will display the OMB expiration date.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.