Supporting Statement A For:

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

[Formerly titled: American Stop Smoking Intervention Study for Cancer Prevention Final Evaluation: Tobacco Use Supplement to the 1998-99 Current Population Survey]

Reinstatement with Change Request of

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A. Justification

A1. Circumstances Making the Collection of Information Necessary

The Risk Factor Monitoring and Methods Branch (RFMMB) of the Applied Research Program (ARP) within the Division of Cancer Control and Population Sciences (DCCPS), National Cancer Institute (NCI) has entered into an interagency agreement (*Y1-PC-4032*) with the Census Bureau to conduct the 2010-2011 Tobacco Use Supplement (TUS) to the Current Population Survey (CPS) (**Attachment 1**) which will provide information needed to measure progress toward tobacco control. The main CPS is funded separately by the Bureau of Labor Statistics.

The Public Health Service Act (Section 410, 42 USC § 285; Section 411, 42 USC § 285a; Section 412, 42 USC § 285a-1; and Section 413, 42 USC § 285a-2 outlines the mission of the National Cancer Institute (NCI) and authorized NCI to collect this information. 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 2010 and those in draft proposals for Year 2020. Since 1964, smoking has been responsible for over 15 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 Department of Health and Human Services (DHHS) established a goal of no more than 12 percent smoking prevalence for the nation by the year 2010.

As noted in the Plan and Budget Proposal for Fiscal Year 2009, 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 biological, genetic, behavioral, and social bases of tobacco use, addiction and cessation, and translate this knowledge into new interventions. To a great extent, NCI addresses this objective by conducting a series of tobacco use supplements (TUS) to the CPS. Two examples of continuing research highlighted in the 2009 Plan and Budget Proposal are the NCI supported Cancer Intervention and Surveillance Modeling Network (CISNET) and the Tobacco Research Network on Disparities (TReND). The former initiative 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. The latter initiative's mission is 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. The TUS-CPS has and will continue to provide the foundation for much of the research for these two initiatives.

In 2009, the National Institutes of Health (NIH), National Institute of Human Genome Research (NIHGR) "PhenX" initiative developed a Tobacco, Alcohol, and Other Substances Toolkit for measuring exposure for genetic studies. The TUS-CPS was selected as a model for measuring cigarette smoking exposure and phenotypes for future genome-wide association (GWAS) research (http://www.phenx.org or https://www.phenxtoolkit.org). As a model, the TUS-CPS will be used as a national standard for comparison to estimates from individual genetic studies.

In 2006, the NIH State-of-the-Science Conference on Tobacco Use: Prevention, Cessation, and Control (Supplement to Am J Prev Med 2007;33(65)) strongly recommended promoting surveillance programs that track tobacco use, (initiation, quitting, intensity of smoking, use of smokeless tobacco), use of motivation to quit, new products, marketing, policy and systems changes. In addition, the State-of-the –Science panel encouraged economic studies of tobacco prevention, cessation and control. The 2010-2011 TUS-CPS series addresses nearly all these areas.

Other recent statements and reports such as the Institute of Medicine's report "Ending the Tobacco Problem" (Bonnie et. al. 2007), the 2008 World Health Organization's MPOWER Report, and reports by CDC on best practices and key indicators for state tobacco control programs also emphasize the important role of tobacco use and policy surveillance. The TUS-CPS series partially fulfills such a niche.

Overall, the purpose of tobacco control and surveillance research is to comprehensively study, monitor and apply the best available strategies to prevent and control tobacco use so as to significantly accelerate the long-term downward trend in smoking and tobacco use and thereby, reduce the number and rate of tobacco-related cancers. The most recent short-term trend in such reduction has stalled. In addition, as reflected by NCI 's three new grant initiatives on reducing smoking in low socioeconomic populations, state and community policy and media research, and

research on smokeless tobacco and harm reduction product use, NCI is committed to determine which interventions are most effective in reducing and preventing tobacco use among diverse populations. Close attention must be paid to populations with smoking and other tobacco use prevalence rates which are elevated relative to the majority population, and groups which have displayed slower rates of decline (e.g., women, the medically underserved, the less educated, and several ethnic minority populations). The data from the CPS and its supplements such as the TUS cover diverse populations and are used by NCI, other Federal and state and local agencies, and non-Federal researchers to assess progress in cancer and other disease control.

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 and 04/12/2006 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) to the civilian non-institutionalized population. The Tobacco Use Supplements will continue to alternate between a standard or core tobacco use survey (such as the previous 2006-07 survey) and a special topic survey focusing on emerging tobacco control issues (such as the 2010-2011 survey and its May 2011 Follow-up).

The proposed clearance package, the 2010-2011 Tobacco Use Supplement to the CPS (TUS-CPS), 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 approximately every 3-4 years, with all of its on-going and cyclical supplements. Additionally, submitting an alternative type of information collection request (e.g., revision) prior to the end of the three year expiry date would be impossible for NCI because the survey(s) have not yet been finalized.

The TUS-CPS is conducted by the Census Bureau will collect data from the civilian non-institutionalized population on tobacco use, smoking prevalence, attempts at cessation including treatments and methods used; workplace smoking policies; health professional advice to stop smoking; and changes in smoking norms and attitudes. This survey will provide invaluable information to 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 as part of the National Cancer

Institute's (NCI's) Cancer Trends Progress Report, several Department of Health and Human Services' Health People 2010 and 2020 Goals, and evaluating trends related to Center for Disease Control and Prevention's (CDC) national tobacco programs. It is also relevant to past reports of NCI plans, National Investment in Cancer Research, and NCI's long-term strategic plans for eliminating the suffering and death due to cancer. The timing of this information is critical given the newly legislated authority to regulate tobacco use given to FDA. We expect a number of tobacco use behaviors to change as people adjust to the new changes in tobacco industry marketing and changes in their products.

Since the TUS-CPS data have been collected in a consistent and standard manner over the 1990's and the 2000's, the new data will also 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. The selected survey methodology must be capable of producing reliable new estimates and estimates of these behavioral changes for each of the fifty states and the District of Columbia as well as for the nation overall. State estimates are needed because most of the tobacco control initiatives are conducted at the state or local level, including national program initiatives. Demographics and socio-political environment vary by state.

In addition, 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 other special supplement data such as the special annual March Demographic Supplement providing additional data (on work experience, income, non-cash income benefits, health insurance, and migration) with the Tobacco Use Supplement conducted in a separate month. Likewise data for other topics including the American Time Use Survey, Internet Use, Food Security, Education and others can enrich the analyses of the TUS-CPS. 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. 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 is through the National Longitudinal Mortality Study (NLMS). The NLMS provides baseline data from the March CPS and some of its other supplements including the TUS and follow up for disease

outcome data through the National Center for Health Statistics' National Death Index and the NCI SEER cancer registries.

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. 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.

May 2011 Follow- Up Survey (**Attachment 2**)- As a novel initiative, the 2010-2011 TUS-CPS will also include the administration of a follow-up component, in which 45,000 respondents from the May 2010 data collection point (approximately 50% of that sample) will be re-administered a subset of TUS tobacco questions, as part of their regular CPS participation 12 months later, in May 2011 (specifically CPS May 2011 panels 5-8 will be derived from May 2010 panels 1-4 as part of the main 2010-2011 TUS-CPS fielding agreement). The timing of the main 2010-2011 TUS-CPS and the May 2011 Follow-Up will afford an unique, efficient, and critical opportunity to address a number of research questions that can only be answered through use of a repeated, longitudinal design.

Specific objectives of the Follow-Up Survey are as follows:

1) To examine smoking cessation and relapse among the same individuals, over a 12-month period;
2) To track potential changes in cigarette and non-cigarette tobacco product behavior over time, due to recent national legislation requiring regulation of tobacco by the FDA;
3) To determine whether potential increases in use of smokeless tobacco will lead to smoking cessation, as opposed to dual product use;
4) To investigate whether changes in policies and social norms lead to increases in tobacco quit attempts over the 12-month period;

5) To assess the impact of tobacco control interventions on low socioeconomic status population subgroups;
6) As a methodological investigation, to assess the test-retest reliability of TUS items on attitudes toward tobacco use and amount smoked.

Relative to cross-sectional studies, the longitudinal design to be incorporated into the Follow-Up will provide a strong foundation for answering these specific research questions. In particular, a repeated-measurement design has the advantages of (a) minimizing dependence on long-term (12-month) recall, as questions are asked for the current time period at each administration; (b) low cost relative to the establishment of a separate stand-alone cohort study; and (c) greatly increased generalizability to the general population than virtually all tobacco-related cohort studies, given that it is embedded in a study incorporating a large, nationally representative sample (the Follow-Up Study will by its nature retain this design advantage).

Attachment 3A and 3B describes the Interagency agreements between NCI and the Census Bureau with respect to activities related to survey planning, testing, data collection, editing, and transmission of the 2010-2011 Tobacco Use Supplement survey data.

A2. Purpose and Use of the Information

The Tobacco Use Supplement (TUS) to the CPS will be used to evaluate and monitor (1) changes in smoking and tobacco use prevalence (by specific type of tobacco product), quit attempts and successful quit rates; (2) the impact of intervention dissemination and penetration; (3) changes in and effects of exposure to secondhand smoke (SHS); and (4) changes in social norms which influence tobacco use within a community for each of the U.S. states. The CPS is the only known federal (national) survey with a sample size large enough to generate consistent individual state specific estimates of smoking and tobacco use prevalence and other relevant initial outcomes such as workplace bans. The CPS is chosen as the vehicle to accomplish these goals because of the cost efficiency and reduction in respondent burden, as well as the trend data already collected with this mechanism in the 1990's and 2000's. 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.

The survey results will be used to monitor prevalence of tobacco use, policies relevant to tobacco use, health professional advice to quit smoking, and changes in these indicators at this critical transitional period of FDA regulation since the 1990's and 2000's.

a. Prevalence and Patterns of Tobacco Use

The TUS to the 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) (OMB #0920-0214, exp. 12/31/09) for about 2-4 decades), will permit the NCI 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);
- tobacco users classified by type of last cigarette purchase, cost of the cigarettes, and where last purchase occurred;
- 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. This includes assessing emerging changes in products at a time of new FDA regulations and new federal excise taxes.

b. Intervention Dissemination

Examples tobacco control interventions include training of health care professionals to deliver counseling and cessation services, provision of targeted cessation interventions in various community (state) locations such as worksites, strengthening support for and implementation of local and state clean indoor air laws, and increasing tobacco excise taxes. Variations of similar

types of interventions as well as new ones including availability of national and state quit lines for diverse populations, and dissemination of the "Clinical Practice Guideline 2008 Update: Treating Tobacco Use and Dependence" are the subject of several of DHHS's initiatives. A number of questions are included on the TUS which permit monitoring of the extent of intervention penetration for selected approaches. These questions measure the degree to which intervention approaches that are directed toward the population are reaching their intended targets. Specifically, they address interventions directed toward specific channels for reaching smokers and potential smokers: i.e., the health care system (particularly here the physician and dentist directed interventions); worksite-based interventions, use of quit lines and other evidence-based cessation methods. These serve as the primary markers for assessing the extent of dissemination of various interventions throughout the communities and states, and the degree to which specific demographic groups are exposed to these interventions.

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

- those having been to a health professional (doctor or dentist) within the past year;
- those who have ever been advised to quit smoking, and those who have received such advice within the past 12 months and type of advice received;
- those who work under a complete smoking ban policy in their workplace and level of compliance; those work places that offer a smoking cessation program
- use of quit lines and other cessation methods

Labor force data which includes the demographic variables will be provided to NCI by the Census Bureau via the public use files.

c. Changes in 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. These include smoking practices in the home, and attitudes about allowing smoking in various public places. Where appropriate, these questions were taken from those used in previous surveys at the federal level and funded by outside agencies. These include NHIS (OMB #0920-0214, exp. 12/31/09),

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 cognitively tested (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 who support the view that various public places should be smoke-free
- those who have tried new smokeless tobacco products

d. Purposes/uses of the May 2011 Follow-Up Data

See Section A.1 for questions to be answered by the May 2011 Follow-Up.

e. Reports and Publications Using Past Tobacco Use Supplement Data

Data collected to date have yielded 120 publications, reports and book chapters (see **Attachment 4** which is a list of publications from our TUS-CPS searchable database available to the public on our website - http://riskfactor.cancer.gov/studies/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 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.

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; the foundation for many of the NCI TReND initiatives, a source of data for examining the relationship between tobacco use and congestive obstructive pulmonary disease (COPD) from the NLMS mentioned in Section A1; and a critical piece of OSH/CDC's State System and evaluation of some of its national tobacco control program objectives. Recently the Treasury Department stated interest in examining our latest data on cost of cigarettes and location of purchase which we are currently preparing for publication. This data was presented in 2009 to the joint conference of the Society for Research on Nicotine and Tobacco (SRNT) and SRNT-Europe.

We released our newest data in December 2008 as public use files. The first comprehensive report using our newest 2006-07 data as well as all the past data 1992-2003 was the RWJF publication, "Monitoring the Tobacco Epidemic: ." This report was released at the opening plenary session of the 2009 National Conference on Tobacco or Health (NCTOH) with copies for each of the 2,500 conference participants. The report findings and tables are also electronically available on the RWJF Impacteen Project website (http://www.impacteen.org/tobaccodata.htm and report url - (http://impacteen.org/statetobaccodata/chartbook_final060409.pdf). As a pre-conference to the same NCTOH, we held a TUS-CPS Users' Workshop which was enthusiastically received. This was the second of two such Workshops that we have held, the first was in October 2007. Some of the 1998-99, 2001-02, and 2003 data highlights are presented as three reports on the ARP/DCCPS/NCI Website (http://riskfactor.cancer.gov/studies/tus-cps/results.html) with the latest 2006-07 data presented in tables on the same website.

We published a Preventive Medicine Supplement in January 2009 summarizing current issues in tobacco control surveillance data and current sources of state and national tobacco control data (Preventive Medicine January 2009- volume 48, Issue 1, Supplement 1, pages S1-S44.) This Supplement highlights what measures can be obtained from the TUS-CPS.

A few examples are provided on how state tobacco control initiatives have benefited from our data and how the TUS-CPS was critical to policy-making. In the spring of 2009, North

Carolina became the first tobacco growing state to pass a complete ban on smoking in all indoor worksites. Among the efforts that lead to the state tobacco control program's success in getting a bill passed by the NC legislature was a publication using the TUS-CPS data demonstrating how in NC there were great disparities in clean indoor air policies by type of worksite. The California State Department of Health used Tobacco Use Supplement data as a component of their evaluation of state tobacco control efforts from 1992 through 2003. The American Stop Smoking Intervention Study (ASSIST) project evaluation, which resulted in several publications used the 1992-93, 1995-96, and 1998-99 data to measure project outcomes and exposure indices. A manuscript was published on smoking behavior, workplace policies and public opinion regarding smoking restrictions in Maryland. This was a timely article since the Maryland Occupational Safety and Health Advisory Board had recently proposed a complete ban on smoking in most Maryland worksites, including restaurants and bars, and the tobacco industry had legally challenged the regulation.

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. Thus, researchers, 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 and will likely appear in future NCI Monographs, Surgeon General Reports, MMWR reports and our TUS-CPS web site.

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 submitted into the Security and Privacy Online Reporting Tool (SPORT System). The name of the IT system is "NIH NCI Tobacco Use Supplement to the Current Population Survey (TUS-CPS)".

A4. Efforts to Identify Duplication and Use of Similar Information

a. Efforts to Identify Duplication

NCI has determined through several advisory committees that the Tobacco Use Supplement to the 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 National Health Interview Survey (NHIS) (OMB #0920-0214, exp. 12/31/09), the National Health and Nutrition Examination Survey (NHANES) (OMB #0920-0237, exp. 12/31/2011), the Behavioral Risk Factor Surveillance System (BRFSS), the National Household Survey on Drug Abuse (NHSDA), and the Monitoring the Future (MTF) are inadequate for NCI program evaluation and surveillance purposes mainly due to their limited coverage of tobacco content, or their restricted sample size. 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 outcomes; 2) They do not require that all states administer the same tobacco measures; 3) They have insufficient sample sizes for estimating prevalence and activity at the state-specific or sub-state level; 4) They use different definitions of tobacco use prevalence than those commonly used by NCI and its collaborators; or 5) As is the case with MTF, does not report on adult tobacco use behavior. In addition, TUS-CPS is unique in obtaining stable estimates on specific racial and ethnic populations (e.g. CPS sample size for Asian Americans is eight times larger than that of NHIS), and other important demographic subpopulations for assessing tobacco control disparities across the nation, regionally and for large states. Note that these subpopulation estimates address specific tobacco objectives from Healthy People 2010 and those proposed for 2020.

b. 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. The annual (OMB #0920-0214) NHIS Core obtains

relatively limited national tobacco information on adults which can be related to a range of health issues including utilization of services and limitations of activity. The NHANES (OMB #0920-0237, exp. 12/31/2011) assesses national tobacco use in conjunction with disease and health indicators, and in particular with biomarkers collected as part of laboratory-based health examination. The MTF measures national tobacco use, and other substance abuse, among teens ONLY. The NHSDA asks tobacco use in context with other substance use. While the NHSDA includes data on adults as well as teens, it focuses on a "teen" definition of smoking which emphasized experimentation, whereas the TUS, focuses primarily on adults and an "adult" definition of smoking. The "adult" definition of smoking from the TUS 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 is not fully comparable for several reasons: a) 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); b) across states, a number of statistical methodologies are used, which pose some challenges for purposes of comparisons between states, or aggregation to a national or regional level estimate of smoking prevalence.

Additionally, other surveys such as the NCI Health Information National Survey (HINTS; OMB#0925-0538, exp. 3/30/09) and the CDC National Adult Tobacco Survey (NATS; OMB#0920-0798, exp. 1/31/2011) collect tobacco use information. HINTS is primarily a national random digit-dialed sample conducted biennially. Its questionnaire was developed by the NCI's Health Communication and Informatics Research Branch (HCIRB) of the Division of Cancer Control Population Studies to assess 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. A very limited set of items on tobacco use is asked to assess respondents' perceptions of their cancer risk from participating in this behavior. This survey is conducted with a total sample of approximately 6,500 persons. From this, the Divisions of Cancer Control Population studies provide information

to public health and policy maker professionals about perceptions of cancer risks, the use of cancer information, and develop new theories about health communication and behavior. These risk perceptions and sources of information are not tracked by TUS. Thus there is little duplication between HINTS and TUS-CPS.

NATS is a one-time stratified, random-digit dialed sample of 103,000 non-institutionalized adults > 18 years of age telephone survey developed by the Office of Smoking and Health at CDC. This survey was designed to obtain a point-in-time "snapshot," using constructs from the Key Outcomes Indicators for Evaluating Comprehensive Tobacco Control Programs. The core indicators are to: 1) Prevent initiation of tobacco use among young people; 2) eliminate exposure to secondhand smoke; 3) promote quitting among adults and young people; and 4) identify and eliminate tobacco-related disparities. The data will be representative and comparable at both national and state levels. The primary purpose of the NATS is to determine tobacco use prevalence and the factors promoting and impeding tobacco use among adults.

The NATS uses a different sampling frame and methodology (random digit-dialing landline telephone frame) than the TUS-CPS (household address based frame). As such, a RDD frame excludes cell phone only households while the address based frame includes both landline and cell phone based households. NATS will incorporate a small cell phone frame for adjusting national estimates but will be unable to adjust for these type of households on the state-level. Also the larger TUS-CPS sample, more than twice the sample size of NATS, will allow for examination at the sub-state (local) level and for examining smaller health disparity subgroups including combining race/ethnicity and immigration status. A unique advantage of the TUS-CPS that we are taking advantage of in the 2010-2011 fielding period is that the CPS design lends itself to short term repeated measures of the same individual allowing us to conduct the May 2011 Follow-up efficiently at low cost (described more fully in A.1). In addition, the TUS-CPS can be linked to many other important measures from the CPS and its other supplements including the disease outcome data from the NLMS which will further enrich data analyses. Most importantly, as a one-time survey, the NATS will not be useful for satisfying the ongoing monitoring and surveillance needs described in Section A.1. Thus, the TUS-CPS benefits from a more robust methodology and its data can be used to examine trends in tobacco use and relationships with other relevant measures.

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, 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 obtains information on tobacco control policies and tobacco control interventions (e.g., workplace policies and physician/dentist advice, respectively). In addition, 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 (on work experience, income, non-cash income benefits, health insurance, and migration) with the Tobacco Use Supplement conducted in a separate month. Likewise data for other topics including the American Time Use Survey, Internet Use, Food Security, Education and others can enrich the analyses of the TUS-CPS. 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 (one such application is the NCI and CDC "State Profiles"). 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 is through the NLMS (described more fully in A.1).

Because of the consistency in methodology, the 2010-2011 Tobacco Use Supplement to the CPS will provide ongoing data for monitoring and evaluating initial and intermediate outcomes (e.g. workplace policies and home smoking rules, cessation services, health provider counseling) 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

The 2010-2011 Tobacco Use Supplement is primarily a single-time data collection. This round of data collection will occur in May 2010, August 2010, January 2011 and May 2011. Tobacco-related survey data will be gathered from approximately 150,000 households or 315,000 persons (270,000 unique persons). The NCI sponsored Tobacco Use Supplements to CPS will continue to alternate between a standard or core tobacco use survey (such as the previous 2006-07 survey) and a special topic survey (such as the 2010-2011 TUS with its May 2011 Follow-Up).

The timing of the main 2010-2011 TUS-CPS and the May 2011 Follow-Up afford a unique, efficient, and critical opportunity to examine tobacco control changes under FDA new unprecedented tobacco regulation. The May 2011 Follow-Up survey returns to a small subset (about 45,000 persons) of the main survey sample (specifically a subset of those in the May 2010 sample). The May 2011 Follow-Up is necessary to examine tobacco control changes and address a number of research questions that can only be answered through use of a repeated, longitudinal design. A repeated longitudinal design allows a time separation between potential causes and effects that are not present in a cross-sectional design. It affords a more rigorous interpretation which is also less prone to recall error (see A.1 for further discussion).

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

Notice of this study was published in the Federal Register on November 6, 2009 (Volume 74, Number 214 Pgs. 57496-97). Comments: One request for information was received on November 6, 2009. A copy of the 2010-2011 TUS-CPS was e-mailed to the requestor reiterating our data collection plans as stated in the 60-day Federal Register Notice. Another comment was received on December 16, 2009 by telephone and in written form on December 22, 2009 (**Attachment 13**) complimenting our inclusion in the 2010-2011 TUS-CPS of critically needed information on details about the types of cigars (especially small cigars) used by smokers and new and valuable information on menthol cigarette smoking. We thanked the requestor for the endorsement and agreed that we thought that was valuable and timely as well and that is why we have included the information in the proposed data collection.

Previous TUS-CPS submissions have worked with many influential people who have helped provide expertise on research and development. For the sake of brevity, only the most recent expert consults from outside NCI will be discussed (**Attachment 5A**). These individuals provide expertise in research and development and comment on topics and wording. Gary Giovino, John Pierce, David Burns, and Donald Shopland have been actively engaged in discussions of Tobacco Use Supplement questions since the inception of the TUS-CPS. These and most of the others mentioned below aided with the development of the new 2003 Tobacco

Use Special Cessation Supplement and determined what to incorporate from 2003 and 2006-07 into the 2010-2011 survey. The nature of the comments ranged from results of methodologic grant and contract research (Cris Delnevo, Lois Biener), the literature, emerging policy issues (Stephen Babb and Angela Trosclair) and consideration of complementing other tobacco surveys and sources of available data (Jennifer Cullen and Donna Vallone). These recommendations are reflected in the revisions to the TUS for the 2010-11 fielding. Pam Clark has helped with the development of the wording of the question on purchasing of individual cigarettes first appearing in 2006-07, a topic important for studying health disparities. Lois Biener gave general comments on the 2003 questionnaire and specifically on the 2006-2007 attitudes toward smoking in public places and the revisions of the smokeless tobacco questions in the 2010-11 survey.

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. While a given individual may be sensitive about answering tobacco questions as they could about any topic, the items are for the most part, are 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 total respondent burden is 45,000 hours over the 3 year clearance period. This results in an average annual burden of 15,000 hours/year. This estimate includes the approximately 90,000 individuals surveyed with the supplement in each of the 3 months, May 2010 (90,000), August 2010 (90,000), and January 2011 (90,000) supplements and the May 2011 Follow-Up (45,000) over a period of 3 years. This amounts to approximately 315,000 responses from 270,000 unique respondents surveyed within the 3 year period. The number of individuals to be surveyed with the 2010-2011 Tobacco Use Supplement is an approximation based on an estimate of the individuals to be surveyed by the Census Bureau in 2010-2011 and the supplement response rates from the earlier Tobacco Use Supplements.

The estimated average length of each respondent interview for the Tobacco Use Supplement is 9 minutes (.15 hours). 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 2006-07 Tobacco Use Supplement (18% current smokers, 18% former smokers and 64% never smoked) were used as weights to estimate average amount of respondent time. Table A.12-1 summarizes the number of respondents and burden hours by month of survey administration.

Table A.12-1 Estimates of Annual Burden Hours

Type of Respondent per Period	Number of Respondents (annualized)	Responses per Respondent	Average Time per response (minutes/hour)	Annual Burden Hours
May 2010 Survey: Individuals	30,000	1	9/60 (0.15)	4,500
August 2010 Survey: Individuals	30,000	1	9/60 (0.15)	4,500
January 2011 Survey: Individuals	30,000	1	9/60 (0.15)	4,500
May 2011 Follow-Up Survey: Individuals	15,000	1	6/60 (0.10)	1,500
Totals	105,000			15,000

The estimated total cost to the respondents is $855,000 over 3 years. These estimates are based on a figure of $19.00 per hour of estimated respondent burden and a total of 45,000 hours of respondent time. Annualized, this cost is $285,000.

Table A.12-2 Annualized Cost to Respondents Burden Hours

Type of Respondent per Survey Period	Number of Respondents (annualized)	Annual Burden Hours	Hourly Wage Rate	Respondent Cost
May 2010: Individuals	30,000	4,500	$19.00	$85,500

August 2010: Individuals	30,000	4,500	$19.00	$85,500
January 2011: Individuals	30,000	4,500	$19.00	$85,500
May 2011 Follow-Up: Individuals	15,000	1,500	$19.00	$28,500
Totals	105,000	15,000		$285,000

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

As background, the expected cost of developing and administering the 2010 Current Population Survey (CPS) Basic Labor Force (OMB#1220-0100, exp. 5/31/2011) conducted every month is approximately $70 million each year, prorated to a monthly figure would be about $5.8 million/month or $17.5 million for three months. The Census Bureau, Bureau of Labor Statistics, and other Government agencies (other than NCI), will bear these costs.

The cost estimate for the Interagency Agreements with the Census Bureau for the subject of this request, the 2010-2011 Tobacco Use Supplement to the CPS, is $2.8 million for the 2010-2011 main survey and $500,000 for the May 2011 Follow Up. 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). The National Cancer Institute will bear these costs.

NCI will 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. NCI will require an estimated total of 5 FTE over the 3 year clearance period (2 FTE of program staff time and 3 FTE of contracted staff time), for an average of 1.67 FTE per year. These figures correspond to a total of approximately $550,000 over 3 years or an average of $183,700 per year considering a salary range of $90,000-$130,000/year (average of $110,000 per FTE per year).

The overall government cost distribution is summarized in Table A.14-1.

Table A.14-1 Costs to the Federal Governments		
	Total	Annual Average
Interagency Agreement	$3,300,000	$1,100,000
NCI Personnel Subtotal		
Design, Planning, Monitoring	$300,000	$100,000
Analysis	$250,000	$83,700
Grand Total	**$3,850,000**	**$1,283,700**

Thus, the average cost to the government for the 2010-2011 Tobacco Use Supplement to the CPS over a 3 year period is approximately $3,850,000.

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 due to the scheduling and funding of the Tobacco Use Supplement with the Census Bureau. The Census Bureau has scheduled to collect the TUS-CPS approximately every 3-4 years during certain months of the year. Additionally, NCI is unable to submit an earlier information collection request because the survey(s) have not yet been finalized.

The annual hours requested for this project are estimated to be 15,000 burden hours per year, for a total of 45,000 hours over the 3 year clearance period. The current burden hours, since this is a reinstated request, is 0. The annual burden based on the 2006 submission was 11,106 hours. This increase in burden hours from the previous submission represents NCI's decision to field a slightly longer instrument and a May 2011 Follow-Up survey. The May 2011 Follow-Up survey will include about 1500 hours annually (Table A.12-1). The Follow-Up survey will be re-administered to a subset of respondents, as part of their regular CPS participation 12 months later.

The timing of the main 2010-2011 TUS-CPS and the May 2011 Follow-Up will afford an unique, efficient, and critical opportunity to address a number of research questions that can only be answered through use of a repeated, longitudinal design (refer to Section A.1. for objectives of the follow-up survey).

A16. Plans for Tabulation and Publication and Projected Time Schedule

NCI tobacco control goals include: Preventing initiation of tobacco use among young people, promoting quitting among adults and young people, 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 quit attempts.

Descriptive and multiple regression analyses will be conducted, as well as the modeling of trends for each of the indicators (discussed in Section A.2 and further outlined below) and the factors that predict them (using 1992-2011 data). In addition, the TUS- CPS data will allow the investigators to create a retrospective cohort to estimate smoking initiation rates, and successful quitting rates and providing some variables that can be used to create upstream tobacco control indices.

The following analyses are anticipated:

a. Cigarette Smoking Patterns

Proportions of current (some-day, everyday and combined), former, and never smokers as well as cessation activity and successful cessation, will be arrayed in tables for comparing trends over selected time points from 1992-93 through 2010-2011 (e.g., 1992-93, 2001-02, 2006-07, and 2010-2011) from the TUS –CPS data. Each table will be cross-tabulated by demographic characteristics, particularly age, sex, race/ethnicity, and geographic region of the country. Trends of consumption will be analyzed. Correlations between prevalence, initiation and quit rates with consumption rates (estimated from self report and from wholesale tax data receipts) will be investigated.

b. Secondhand Smoke (SHS) Exposure and other policy interventions

Policy approaches, including the voluntary adoption of work site restrictions, enactment of restrictive clean indoor air laws, and enforcement of restrictions are effective in reducing the number of persons exposed to SHS. Also, smoke-free workplace policies reduce exposure of nonsmokers to SHS and increase the likelihood that smokers in these settings will smoke fewer cigarettes or quit. Findings from the all of the prior TUS-CPS showed substantial differences in the proportion of workers who reported smoke-free policies among various

occupational groups. We will analyze trends for workplace smoking policies using the TUS-CPS from 1998-2011 in order to address disparities in exposure to SHS among different occupational and other socio-economic groups.

Data from 2003-04 NHANES (OMB #0920-0237, exp. 10/15/04) suggest that serum cotinine in nonsmokers declined substantially since NHANES III (1988-1994). Examining trends on rules for smoking in the home will help understand to what extent this decline can be ascribed to decreased exposure in the home. Because of the household composition data collected on the standard CPS questionnaire, exposure to passive smoking for children can be assessed. This assessment will come from a supplement question on smoking within the home. Exposure in the home will necessarily be a crude measure; nevertheless we will be able to estimate the exposure to children with this mechanism.

We will continue to track policy changes which eliminate excise tax loopholes by examining changes in cigarette costs and smoker tax avoidance behavior comparing the 2003, 2006-07 and 2010-2011 data. A big federal excise tax increase was put into effect in the spring of 2009 and is likely to have an impact on cigarette cost and tax avoidance behavior.

c. Smoking Norms

By providing interventions that are through multiple communication channels, the intent is to change the entire social milieu. That is, an effective delivery of tobacco control and intervention programs will include accelerating changes in social norms to further decrease the social acceptability of smoking. A number of questions on the "Tobacco Use" supplement will cover areas that measure process, rather than outcome (reported smoking) concepts. These include questions about social norms, i.e., acceptability of smoking (attitudes about smoking in public places), health care system activities, and worksite based interventions. Several analyses are anticipated for process measures.

d. Use of New and More Traditional Smokeless Tobacco Products, Various Types of Cigars and Pipes

Compare some of these estimates with traditional product estimates from earlier years such as 2006-07.

e. Prevalence of Menthol Smoking and Purchasing of Single Cigarettes

Most African-American smokers smoke mentholated cigarettes. In addition, recent trends have shown that the prevalence of the smoking of mentholated cigarettes has been

increasing among women and children/adolescents in the US. This survey will allow a sample-size large enough to provide stable estimates of mentholated smoking as well as provide data on US sub-populations. Purchasing of single cigarettes are more often an activity of youth, certain minorities and poorer smokers. We will describe this phenomenon both nationally and regionally and look at predictors of this behavior as well as how this behavior relates to attempts/provides barriers to quitting smoking.

f. Health Care Provider Counseling

One of the specific channels for interventions is the health care system. Substantial evidence suggests that minimal clinical interventions foster smoking cessation. This intervention is a tobacco objective of Healthy People 2010 and likely of Healthy People 2020 as well. Because health care system contacts among the general population are ubiquitous, a population survey is able to provide measures on anti-smoking interventions from health care providers such as doctors and dentists. We will analyze trends on counseling among both types of health care professionals. Key tabulations will use relevant demographic variables to contrast the health system data. We will analyze trends in health care system anti-smoking messages.

g. Evaluation of the Use of Evidence and Non-evidence based Cessation Treatments

We will compare use of quit lines from our 2003 survey with the utilization information from the 2006-07 and 2010-2011 surveys to look for changes since the initiation of the national quit line initiative and subsequent effect on successful quitting both nationally and by state. We will look at the relationship between use of quit lines and advice to other family members and friends to stop smoking, and use of the quit line by current smokers themselves.

h. Time Schedule for Information Collection and Publication

OMB APPROVAL	Time Schedule
Finalized questionnaire software	1 week after OMB approval
Field questionnaire wave #1	6 weeks after OMB approval - May 2010
Complete editing work wave #1	10 months after OMB approval
Field questionnaire wave #2	4.5 months after OMB approval - August 2010
Analyze wave #1	10-16 months after OMB approval

OMB APPROVAL	Time Schedule
Complete editing work wave #2	14 months after OMB approval
Field questionnaire wave #3	9.5 months after OMB approval - January 2011
Analyze wave #2	13 - 18 months after OMB approval
Complete editing work wave #3	15-16 months after OMB approval
Initial analysis for final survey all waves	18-24 months after OMB approval
Submit for Publication	24 months after OMB approval
May 2011 Follow Up Fielded	13.5 months after OMB approval
Complete editing May 2011 Follow Up	18 months after OMB approval
Initial analysis of Change	20 - 24 months after OMB approval
Submit for publication	26 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.