SUPPORTING STATEMENT FOR THE

NATIONAL ADULT TOBACCO SURVEY

PART A

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A. JUSTIFICATION

This statement supports a request to obtain approval to conduct the first National Adult Tobacco Survey (NATS), a telephone-based survey of adults, in 2009/2010. The NATS is a one-time data collection to determine tobacco use prevalence and the factors promoting and impeding tobacco use among adults in a nationally representative sample. Conducting the NATS will provide critical evaluation data to support CDC's National Tobacco Control Program (NTCP).

CDC's Office on Smoking and Health (OSH) created the NTCP in 1999 to encourage coordinated efforts nationwide to reduce tobacco-related diseases and deaths. The program provides funding and technical support to state and territorial health departments for comprehensive tobacco control programs. The four goals of the NTCP are to: (1) prevent initiation of tobacco use among young people; (2) eliminate nonsmokers' exposure to secondhand smoke; (3) promote quitting among adults and young people; and (4) identify and eliminate tobacco-related disparities. The four components of the NTCP are: (1) population-based community interventions; (2) counter-marketing; (3) program policy/regulation; and (4) surveillance and evaluation.

To provide a comprehensive framework for program evaluation, CDC created the ***Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs.*** The NATS questionnaire was designed using constructs from the ***Key Outcome Indicators*** report that

realistically can be assessed in interviews with adults. The framework is consistent with the central concepts in the most recent Funding Opportunity Announcement (FOA) that CDC distributed to states for support of statewide Tobacco Control Programs (TCP). All 50 states plus the District applied for TCP cooperative agreements and all received them. The first year of funding under a five-year cooperative agreement across all States comes to $64 million. The total CDC commitment to the states in support of their TCP cooperative agreements over a five-year period from 2009 through 2014 is expected to approximate $320 million. Over the previous 4.75 years, from 2004 through 2009, CDC invested $303 million in direct support of state-level TCPs.

To evaluate the effectiveness with which the NTCP is being implemented, it is essential to examine effectiveness at both state and national levels. Indeed, success cannot be examined usefully at only a national level because success is truly specific to each state. Moreover, CDC/OSH can only tailor technical support to states in achieving their tobacco control goals on a state-by-state basis. Therefore, the plan for the NATS is to conduct statewide probability surveys in each of 50 states and the District of Columbia, with a target of 1,863 completed interviews per state. Recognizing gender differences in tobacco use, separate estimates by state will be developed for males and females. In addition, estimates will be generated for minority group populations comprising a major component of a given state's population. In addition, a survey of 3,000 cell phone users who do not have a landline will be conducted nationally. The data gathered through the 51 State-level surveys and the 3,000 cell-phone completes will be integrated to produce national estimates. Nationally, estimates will be generated by gender, race/ethnicity, and age group. This will result in comparable analyses across states and the nation using the key outcome indicators for evaluating comprehensive TCPs.

The NATS is to be a one-time stratified, random-digit dialed, telephone survey of non-institutionalized adults 18 years of age and older. It is designed to yield data that are representative and comparable at both national and state levels. Conducting the NATS is public health practice intended to provide evaluation data for CDC's NTCP. This information will provide critical information on the key indicators for the NTCP early in the funding cycle of cooperative agreements in all states. NATS will collect data on all key outcome indicators that can be appropriately measured using a telephone survey of adults.

A precursor to the NATS questionnaire was developed in 2000 by several states with technical support from CDC/OSH. Historically, the state-based Adult Tobacco Survey (ATS) began as a questionnaire developed by and for a small group of state health departments for use in evaluating their tobacco prevention and control program expansions, funded largely by the Master Settlement Agreement. To facilitate state efforts to design, implement, and evaluate their tobacco use prevention and control programs, CDC provided technical assistance to states to enhance the relevance and decrease the respondent burden of the core ATS questionnaire. Since then, 25 states have independently conducted at least one round of a stated-based ATS. However, this precursor to the current NATS was not coordinated at the national level or designed within the evaluation framework provided by the recently-developed *Key Outcome*

Indicators for Evaluating Comprehensive Tobacco Control Programs The NATS will provide a comprehensive and coordinated national framework for evaluating tobacco control programs.

Analogously, as part of its ongoing efforts to evaluate the NTCP, CDC/OSH previously participated in the development and continues to provide technical assistance in fielding of a Youth Tobacco Survey (YTS). The original YTS was developed in 1998 by several states with technical support from CDC. Over the past decade, at least 46 states have conducted one or more cycles of a statewide YTS.

Five cycles of a National YTS have been completed to date. The first three cycles of the National YTS were fielded in 1999, 2000 and 2002 with financial support from the American Legacy Foundation and technical support from CDC/OSH. Starting in 2004, CDC/OSH assumed financial responsibility for the National YTS from the American Legacy Foundation as part of Legacy's planned reduction in funding under the Master Settlement Agreement with the tobacco companies. CDC/OSH supported the national YTS in 2004 (OMB No. 0920-0621; expiration: 12/31/2004) and 2006 (OMB No: 0920-0621; expiration: 12/31/2008) and is currently approved by OMB to conduct the National YTS in 2009 and 2011 (OMB No. 0920-0621; expiration: 12/31/2011).

Internationally, CDC/OSH also has played a role in promoting and providing technical support for cross-national adoption of versions of the YTS and ATS. The Global Youth Tobacco Survey (YTS) has been conducted under World Health Organization (WHO) sponsorship with technical support from CDC in nearly 120 countries. A Global Adult Tobacco Survey (ATS) is currently being planned or fielded in several large countries with relatively high rates of tobacco use through a public/private partnership involving technical support from CDC, funding from the Bloomberg and Gates Foundations via the CDC Foundation, and development of in-country capability by WHO.

The current proposal comes at a particularly opportune time. Under new leadership at HHS and CDC, there is increased emphasis on tobacco control and, in particular, on the management of TCPs through effective use of data. One of the highest priorities emanating from the prevention stimulus (*the American Recovery and Reinvestment Act of 2009*) is tobacco control programs, especially those focused on cessation, including Quitlines. In addition, the *Family Smoking Prevention and Tobacco Control Act (*signed into law on June 22, 2009), gave the Food and Drug Administration new authority to regulate tobacco products, and *the Children's Health Insurance Program Reauthorization Act of 2009 Act (*signed into law on February 4, 2009), included increases in Federal excise taxes on tobacco products. These developments reinforce the importance of conducting NATS in a timely manner.

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

A.1.a Background

The legal justification for the survey may be found in Section 301 of the Public Health Service Act (42 USC 241) in Appendix A. Further justification for a national survey of adult tobacco use is based on three factors: (1) public health implications of tobacco use among adults within the United States; (2) costs of health risk behaviors and; (3) specific mandates to monitor and/or reduce health risk behaviors and/or associated health outcomes.

A.1.a.1 Public Health Implications of Tobacco Use

The Health Consequences of Smoking: A Report of the Surgeon General states that despite the many prior reports on the topic and the high level of public knowledge in the United States of the adverse effects of smoking in general, tobacco use remains the leading preventable cause of disease, disability, and death in the United States. . ." (USDHHS, 2004). CDC reports that an estimated 443,000 people die prematurely from smoking or exposure to secondhand smoke each year. Another 8.6 million have a serious illness caused by smoking. For every person who dies from smoking, 20 more people suffer from at least one serious tobacco-related illness. Despite these risks, approximately 43.4 million U.S. adults smoke cigarettes. Smokeless tobacco, cigars, and pipes also have deadly consequences, including lung, larynx, esophageal, and oral cancers (http://www.cdc.gov/nccdphp/publications/aag/osh.htm). On average, adults who smoke die 14 years earlier than nonsmokers (CDC, 2006a).

Among U.S. adults 25 years of age or older, 59% of deaths are due to only two causes: cardiovascular disease (36%) and cancer (23%)" (CDC/NCHS, 2008). During 2000 through 2004, smoking resulted in an estimated annual average of 269,655 deaths among males and 173,940 deaths among females in the United States. The three leading specific causes of smoking-attributable death were lung cancer (128,922), ischemic heart disease (126,005), and chronic obstructive pulmonary disease (COPD) (92,915). Among adults aged ≥35 years, 160,848 (41.0%) smoking-attributable deaths were caused by cancer, 128,497 (32.7%) by cardiovascular diseases, and 103,338 (26.3%) by respiratory diseases (excluding deaths from secondhand smoking and from residential fires). Smoking during pregnancy resulted in an estimated 776 infant deaths annually during 2000 through 2004. An estimated 49,400 lung cancer and heart disease deaths annually were attributable to exposure to secondhand smoke. The average annual SAM estimates also included 736 deaths from smoking-attributable residential fires (CDC, 2008a).

The harmful effects of smoking do not end with the smoker. More than 126 million nonsmoking Americans, including children and adults, are regularly exposed to secondhand smoke. Even brief exposure can be dangerous because nonsmokers inhale many of the same carcinogens and toxins in cigarette smoke as smokers. Secondhand smoke exposure causes serious disease and death, including heart disease and lung cancer in nonsmoking adults and sudden infant death syndrome, acute respiratory infections, ear problems, and more frequent and severe asthma attacks in children. Each year, primarily because of exposure to secondhand smoke, an estimated 3,000 nonsmoking Americans die of lung cancer, more than 46,000 (range: 22,700–69,600) die of heart disease, and about 150,000–300,000 children younger than 18 months have lower respiratory tract infections (USDHHS, 2004).

In 2007, approximately 19.8% of U.S. adults currently smoked cigarettes (CDC, 2008b). Of these, approximately 77.8% smoked every day and 22.2% smoked some days. By age group,

the prevalence of smoking was lowest among those aged ≥65 years (8.3%), compared with those <65 years (persons aged 18–24 years [22.2%], aged 25–44 years [22.8%], and aged 45–64 years [21.0%]). Cigarette smoking is more common among men (22.3%) than women (17.4%). Cigarette smoking estimates are highest for adults with a General Education Development (GED) diploma (44.0%) or 9–11 years of education (33.3%), and lowest for adults with an undergraduate college degree (11.4%) or a graduate college degree (6.2%). Cigarette smoking is more common among adults who live below the poverty level (28.8%) than among those living at or above the poverty level (20.3%). (CDC, 2008b)

After 3 years during which prevalence in current cigarette smoking among adults remained virtually unchanged (20.9% in 2004, 20.9% in 2005, and 20.8% in 2006), the prevalence in 2007 (19.8%) was significantly lower than in 2006. For 5 consecutive years, the prevalence of smoking among women remained below 20% (19.2% in 2003, 18.5% in 2004, 18.2% in 2005, 18.0% in 2006, and 17.4% in 2007); 18.2% in 2005, 18.0% in 2006, and 17.4% in 2007); however, variability existed among subgroups of women based on race/ethnicity and age. Also, for 6 consecutive years, former smokers outnumbered current smokers. (CDC, 2008b)

During the past 40 years, smoking prevalence has declined overall and among each socio-demographic subpopulation. However, large disparities in smoking prevalence continue to exist by race/ethnicity and education level. The continuing higher prevalence among several populations, such as American Indians/Alaska Natives (36.4%), persons with GED diplomas (44.0%), and persons reporting family incomes below the federal poverty level (28.8%), emphasizes the need for more effective policy and environmental and individual-level interventions to reach and assist these subpopulations (CDC, 2008b).

Although the prevalence of current smoking among adults decreased significantly from 1998 to 2007 in 44 states, the District of Columbia, and Puerto Rico, only one state and one territory have met Health People 2010 targets for reducing adult smoking prevalence to 12% and six states have shown no substantial changes in prevalence from 1998 to 2007 after controlling for age, sex, and race/ethnicity (CDC, 2008c).

In addition, although smoking prevalence has declined dramatically since its peak in the 1960s, the number of smoking-attributable deaths has remained relatively unchanged, primarily because of increases in population size (particularly among older age groups). Even with declines in the rates of various smoking-related diseases (e.g., coronary heart disease), the absolute number of deaths is increasing as the total population increases. In addition, cohorts of smokers with the highest peak prevalence have now reached the ages with the highest incidence of smoking-attributable diseases (CDC, 2008a).

A.1.a.2 Costs of Tobacco Use

Average annual smoking-attributable health-care expenditures in 2000 through 2004 were approximately $96 billion. In addition to these direct health care expenditures, smoking accounted for an estimated 5.1 million years of potential life lost (YPLL) (3.1 for males and approximately 2.0 for females) annually, excluding deaths from smoking-attributable residential fires and adult deaths from secondhand smoke. Losses associated with YPLL resulted in $96.8 billion in productivity losses ($64.2 billion for males and $32.6 billion for females). Thus, the

total economic cost to society of smoking--$96 billion per year in direct health-care expenditures and nearly $97 billion in productivity losses—is $193 billion per year (CDC, 2008). By comparison, investments in comprehensive, state-based tobacco prevention and control programs in fiscal year 2007 totaled $595 million, approximately 325-times less than the smoking-attributable costs.

A.1.a.3 Mandates to Monitor and/or Reduce Tobacco Use

The justification for the NATS has strong Federal support. Sources of support include the Healthy People 2010 objectives (USDHHS, 2000), CDC's Strategic Plan for Tobacco Control for 2009 and Beyond, and CDC's National Tobacco Control Program and the *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs* report**.**

Healthy People 2010

The broadest justification for the NATS is found in Healthy People 2010 objectives, which charts the direction for public health activities for the current decade. As we rapidly approach 2010, it has become clear that some of these objectives will need to be adjusted and re-targeted toward 2020 because relatively little progress has been made toward reaching some goals while others have been reached and exceeded. Of the 21 tobacco-related Healthy People 2010 objectives, the NATS provides multiple measures and data for the following five of them (USDHHS, 2000):

27-1a Reduce cigarette smoking by adults.

The 2010 target is to reduce cigarette smoking to 12% for all population groups. Reduction of cigarette smoking by adults is central to the NTCP program. The NATS assesses cigarette smoking; asks questions related to awareness of quitlines, health professionals, and other cessation assistance; and about forces impeding and promoting cigarette smoking.

27-4b Increase the average age of first use of tobacco products by young adults aged 18 to 25 years

The 2010 target is to delay the age of first use among young adults aged 18 to 25 (from age 15 to age 17). The NTCP seeks to delay the age of first use of tobacco products. The NATS gathers data about age of initiation of tobacco use, and about a range of pro- and anti-tobacco influences including taxes, sponsorship and marketing, and tobacco-free policies, thereby enabling the identification of correlates of initiation (e.g., susceptibility, attitudes, and receptivity).

27-5 Increase smoking cessation attempts by adult smokers

The 2010 target is to increase the proportion of adult smokers who stop smoking for at least one day (from 41% to 75%). One of the main NTCP goals is to promote quit attempts and help smokers who attempt to quit to do so successfully. The NATS assess a range of factors associated with cessation intention, including number of cessation attempts, length of abstinence from tobacco use, symptoms of withdrawal and addiction, and use of cessation aids. In addition,

the NATS asks questions about tobacco-free policies in the workplace and other public places that support smokers who make quit attempts.

27-10 Reduce the proportion of nonsmokers exposed to environmental tobacco smoke

The 2010 target is to reduce the proportion of nonsmokers exposed to environmental tobacco smoke (from 65% to 45%). Reduction in exposure to environmental tobacco smoke is also another major NTCP goal. The NATS measures exposure to secondhand smoke and knowledge of tobacco-free policies at home, in the workplace, in vehicles, and in public places. NATS also asks general knowledge and attitude questions about secondhand smoke.

27-12 Increase the proportion of worksites with formal smoking policies that prohibit smoking or limit it to separately ventilated areas.

The 2010 target is that the proportion of worksites with formal smoking policies that prohibit smoking or limit it to separately ventilated areas will increase (from 79% to 100%). Increasing the proportion of worksites prohibiting smoking also is integral to the NTCP. The NATS asks specific questions about the workplace smoking policies and whether respondents have been exposed to smoking at the workplace.

In addition, tobacco use is named in Healthy People 2010 as one of the USDHHS Secretary's 10 Leading Health Indicators. The Leading Health Indicators reflect the major public health concerns in the United States and were chosen based upon their ability to motivate action, the availability of data to measure their progress, and their relevance as broad public health issues. Subsequently, the Secretary has recommended regular monitoring of national trends in current tobacco use. The Secretary is also encouraging states to take an even closer look by monitoring patterns of use and smoking cessation attempts, issues that require a survey instrument and data that go beyond basic prevalence. Many use the state ATS to collect the more-detailed data needed to do so, with the added advantage of having comparable national ATS data against which they can benchmark their findings.

CDC Strategic Plan for Tobacco Control for 2009 and Beyond

CDC's Strategic Plan (CDC, 2006) focuses on both the agency's priorities and future directions and constituent needs. The NATS generates data relevant to all four goals listed in the Strategic Plan:

- Prevent initiation of tobacco use among young adults and youth;
- Promote tobacco use cessation among adults and youth;
- Eliminate exposure to secondhand smoke;
- Identify and eliminate tobacco-related disparities among population groups

CDC's Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs Report

As part of its mission to reduce the incidence of tobacco-related disease and preventable death, CDC created the NTCP. The primary goal of the NTCP is to reduce tobacco-related

disease, disability, and death. This primary goal is subdivided into 4 goal areas: (1) Preventing Initiation of Tobacco Use Among Young People; (2) Eliminating Nonsmokers' Exposure to Secondhand Smoke; (3) Promoting Quitting Among Adults and Young People and; (4) Identifying and eliminating tobacco-related disparities. The *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs* publication was created by CDC to help state and territorial health departments plan, implement, and evaluate state TCPs. These goal areas can be used to understand the links between program activities, short, intermediate, and long term outcomes; to identify outcomes and; assist in selecting key indicators. Key outcome indicators are specific, measureable, characteristics of changes that represent achievement of an outcome.

The NATS questionnaire is built around key outcome indicators from each of three goal areas. For Goal Area 1, Preventing Initiation of Tobacco Use among Young People, the questionnaire addresses 9 key indicators. For Goal Area 2, Eliminating Nonsmokers' Exposure to Secondhand Smoke, the NAT S questionnaire addresses 17 additional key indicators. Finally, for Goal Area 3, Promoting Quitting among Adults and Young People, NATS addresses 17 additional key indicators. In total, the NATS is supported by 44 measureable key outcome indicators developed precisely to evaluate TCPs (Appendix D). Goal area 4, Identifying and Eliminating Tobacco-Related Disparities, will be examined by analyzing key indicator data in conjunction with demographic data.

A.1.b Privacy Impact Assessment Information

This study will collect information on tobacco use, environmental smoke exposure, attempts to quit tobacco use, and exposure to forces promoting and impeding tobacco use. The data are being gathered to determine nationally the proportion of adults who use tobacco products, are exposed to environmental smoke, and attempt to quit (and, if they attempt, did so successfully). It also seeks to measure exposure to forces promoting and impeding tobacco use. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Therefore, the data collection will have little or no effect on the respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected data remain private.

A.1.c Overview of the Data Collection System

Data will be collected using CATI to interview adults via landlines and cell phones. The bulk of the interviews (approximately 95,013) will be conducted via landlines. An additional 3,000 interviews will be conducted via cell phones with respondents who do not have a landline. Customary protocols will be followed based on CDC's experience with the Behavioral Risk Factor Surveillance System, as adapted in recent years for support of state-level efforts to conduct an ATS.

A.1.d Items of Information to be Collected

Respondents will be asked about their experience in using a variety of tobacco products, attempts to quit tobacco use (cigarettes and other tobacco products), cessation including awareness of quitlines and other available cessation assistance; exposure to environmental

smoke and knowledge of tobacco-free policies, existence of chronic conditions and disease, opinions and attitudes related to tobacco including excise taxes, exposure to forces promoting and impeding tobacco use, and youth issues.

A.1.e Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This information collection does not involve web-based data collection methods or refer respondents to websites.

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

NATS data will be used primarily by CDC/OSH, in managing and evaluating the NTCP, and the states and their sub-cooperative agreement holders, in planning, implementing and evaluating their State-specific TCPs. Results also will be used by several other parts of CDC, by other Federal agencies, and by the States. The information will have a broad use by state and local governments, nongovernmental organizations, and others in the private sector.

A.2.a Purpose of Information Collection

The purposes of the survey are to:

1. Estimate the extent to which adults engage in tobacco use behaviors.
2. Assess the degree to which tobacco use behaviors among adults vary as a function of gender, age, and race/ethnicity.
3. Estimate accomplishment of key short-term, intermediate, and long-term tobacco prevention and control outcome indicators found in CDC's *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs* Report.
4. Estimate the degree to which exposure to influences expected to promote or impede tobacco use has its expected effects.
5. Assess the degree to which response to influences expected to promote or impede tobacco use varies as a function of gender, age, and race/ethnicity.

A.2.b Anticipated Uses of Results by CDC

Aside from OSH, NATS data are likely to be used by several divisions within CDC's National Center on Chronic Disease Prevention and Health Promotion, including the Divisions of Adult and Community Health, Cancer Prevention and Control, Diabetes Translation, Heart Disease and Stroke Prevention, and Oral Health. Other Centers within CDC are likely data users, including the Center on Environmental Health.

Evaluation

- Provide progress measurements related to five *HP 2010* objectives.
- Evaluate CDC's Performance Plan in compliance with Government Performance Results Act.

- Assess trends in tobacco use among adults and exposure to pro- and anti-tobacco influences to determine the aggregate impact of tobacco prevention and control activities.

Research Synthesis

- Provide states conducting the ATS with a national index against which to compare their survey results on key short-term, intermediate, and long-term tobacco prevention and control outcome indicators.
- Present data in peer-reviewed publications and at scientific meetings.
- Identify research gaps in adult tobacco prevention and control.
- Provide public health and education officials and the general public with accurate information about tobacco use and exposure to pro- and anti-tobacco influences.
- Provide U.S. data for inclusion in analyses and reports based on cross-national comparisons.
- Provide data that are relevant and can be incorporated into a variety of government publications, including reports from the Surgeon General's office.

Policy and Program Development

- Provide policy makers with information about the tobacco use behaviors among adults so they can identify tobacco prevention and control interventions on which to focus resources.
- Provide state legislatures with information about the tobacco use and tobacco prevention and control interventions that should be preserved during a period of shrinking state budgets.
- Determine how public information campaigns that take into account exposure to pro- and anti-tobacco influences among adults should be devised.

Technical Assistance

- Help identify programs shown to be most effective in reducing tobacco use among adults.
- Assist states in interpreting their ATS data against a national benchmark.
- Provide evidence- and data-based technical assistance to state and local departments of health and education.
- Assess the need for new programs or modify existing programs that focus on reducing tobacco use among adults.
- Assess the cumulative effects of multiple interventions and sources of information (family, community, work, and the media) on tobacco use behaviors among adults.

A.2.c Anticipated Uses of Results by Other Federal Agencies and Departments

The survey results of the NATS are of interest not only to CDC, but also to other Federal agencies and departments. For example:

- Department of Health and Human Services will use NATS data to provide progress measures at national and state levels on five Healthy People 2010 objectives and one of the 10 Leading Health Indicators.

- Food and Drug Administration will be able to use NATS data to support its new efforts to regulate the contents and marketing of tobacco products.

- National Cancer Institute can use NATS data to help inform its research, educational efforts, and demonstration projects focused on adult tobacco use prevention and the determinants of cessation. NCI also can use NATS data to supplement and provide context for its longstanding Tobacco Use Supplement to the Current Population Survey (TUS-CPS).

- Office of National Drug Control Policy can use the NATS data to report on tobacco use rates and determine the impact of media campaigns and enforcement efforts on tobacco use to determine the relative effectiveness of anti-drug vs. anti-tobacco campaigns.

- Substance Abuse and Mental Health Services Administration potentially will use NATS data as a frame of reference when assessing the annual National Survey on Drug Use and Health (NSDUH) and its state-level counterparts. SAMHSA also potentially will direct its grantees to NATS-based publications through various clearinghouses, including The Promote Prevent Library, a searchable database of resources and materials that includes published works, peer-reviewed research, curricula, and web-based resources that aim to provide up-to-date information on topics relevant to mental health promotion and violence prevention.

A.2.d Use of Results by Those Outside Federal Agencies

NATS data are likely to be used in a variety of ways by state and local governments, researchers, voluntary health organizations, physicians, health educators, workplace wellness programs, and community outreach organizations:

- Policy makers in the legislative and executive branches of government are likely to use NATS data to understand the relationships between tobacco use behaviors and exposure to pro- and anti-tobacco influences at national, state, and local levels, to evaluate existing policies and programs, and to develop new policies and programs based on evidence regarding effective tobacco use prevention and control programs.

- The NATS will provide an index against which state and local health agencies can compare their state ATS results.

- State and local health departments will use the NATS data as a guide in developing local tobacco-related health promotion objectives for 2020.

- Family physicians, pediatricians, psychologists, and counselors will use the NATS to provide up-to-date information on tobacco use behaviors and factors that influence tobacco use for application in the patients they treat.

- Health educators will use the NATS to provide information that will bolster and provide a focus for their lesson plans and educational materials.

- Workplace wellness programs will use the NATS in their curriculum development to provide information on tobacco use behaviors and effectiveness of evidence-based tobacco prevention and control interventions.

- Employers will use the NATS results to create awareness of risk behaviors, assist in setting personal/corporate wellness goals, plan or modify existing programs, create/update staff development programs, and seek/target funding.

- Professional organizations will use NATS data to emphasize the importance of tobacco prevention efforts and monitor progress in tobacco control efforts.

A.2.e Privacy Impact Assessment Information

This study will collect information on tobacco use, environmental smoke exposure, attempts to quit tobacco use, and exposure to forces promoting and impeding tobacco use. The data are being gathered to determine nationally the proportion of adults who use tobacco products, are exposed to environmental smoke, and attempt to quit (and, if they attempt, did so successfully). It also seeks to measure exposure to forces promoting and impeding tobacco use. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Therefore, the data collection will have little or no effect on the respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected data remain private.

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

All data collection will involve computer assisted telephone interviewing (CATI). A survey verification line with interactive voice recognition (IVR) will be available to field inquiries about the authenticity of the survey, to allow prospective respondents to opt out of the survey, or to transfer to a company representative to complete the interview during operating hours (approximately 80 hours per week).

Approximately 3,000 interviews nationwide will be conducted specifically among cell phone users. This stratum attempts to include the growing population of households that are cell phone only and may be missed in traditional RDD land-line surveys. Recent studies indicate that close to 15 percent of U.S. households are cell phone only and disproportionately represent renters and younger households and low SES/poverty. By including cell phone numbers as part of our frame, we address this growing use of information technology to reach beyond the traditional bounds of RDD surveys. There are no legal barriers to the use of information technology to reduce burden.

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

CDC conducts ongoing searches of all major health-related electronic databases, reviews related literature, consults with key outside partners and other experts, and maintains continuing communications with Federal agencies with related missions through the Federal, interagency Tobacco and Nicotine Research Interest Group (TANRIG). These efforts have identified no previous, current, or planned efforts to conduct a comprehensive survey of tobacco use behaviors, exposure to pro- and anti-tobacco influences, and key short-term and intermediate outcome indicators among a national sample of adults. In particular, the opportunity did not exist previously to develop a questionnaire around CDC's *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs*.

CDC monitors and provides technical support to the implementation of the ATS by states. Substantial variation across jurisdictions in sampling techniques, questions, and survey administration procedures prohibit the calculation of national estimates from state-level results. Moreover, only 25 states have conducted one or more ATS, and some states have conducted only one ATS. For this reason, CDC proposes to conduct a national ATS (NATS) which will result in generation of comparable estimates using the same methodology across all states.

The only remotely related data collection is the NCI's TUS-CPS, referenced earlier. While the TUS-CPS does gather state-specific data about several aspects of tobacco use, it does not do so specifically in the context provided by CDC's *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs* report and, thus, does not provide direct support to states in development of TCPs.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

The planned data collection does not involve small businesses or other small entities.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

NATS is intended as a one-time data collection. As noted above, the resulting information will provide critical baseline information on the key indicators for the National Tobacco Control Program as a new five-year funding period began at the start of the third quarter of FY 2009. Though not currently planned, it is possible that CDC will want to conduct another NATS in 2014 as a progress measure to support another new funding announcement.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINE OF 5 CFR 1320.5

The data collection will be implemented in a manner consistent with 5 CFR 1320.5. No special circumstances are applicable to this proposed survey.

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY

A.8.a Federal Register Announcement

The 60-day *Federal Register* notice of the proposed data collection was published in the Federal Register on June 8, 2009; Vol. 74, Number 108, pages 27144-27145 (Appendix B). No substantive comments about the information collection instrument or methodology were received. A summary of public comments and CDC's response is provided in Appendix C.

A.8.b Consultations

CDC engaged the users of the State ATS and representatives of the scientific community and of other Federal agencies in designing the NATS questionnaire. A telephonic conference call involving representatives of 22 States on March 13, 2008 provided CDC with suggestions and feedback on the plan and design for NATS. Comments were again sought in the Fall 2008 and again in May/June 2009 in anticipation of a presentation to be made by CDC staff at the National Conference on Tobacco or Health in Phoenix, AZ, on June 11. Numerous states submitted questions and suggestions prior to that presentation.

In addition, CDC participated in a telephonic conference call on March 19, 2008 of the NIH Tobacco and Nicotine Research Interest Group (TANRIG). Formed in January 2003, TANRIG currently has 48 members from NIH and other DHHS agencies, including 6 members from CDC. TANRIG's mission is to increase collaboration, coordination, and communication of tobacco- and nicotine-related research among NIH Institutes and Centers, and among partnering DHHS agencies outside of NIH. Members of TANRIG provided feedback on the plan and design for NATS, plus FDA's representative to CDC, in design of the NATS and alignment of questionnaire content with an expanded Federal need for the data:

Appendix E contains a list of individuals who participated in these consultations.

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

Previous research by the Census Bureau and others has indicated that monetary incentives can increase participation among historically undercounted groups, for example, households in poverty (see Abreau and Winters, 2001). Additionally, the use of incentives may also reduce the time and money required to make contact with respondents (Creighton, King and Martin, 1999). While comparisons between two states in the BRFSS/ATS did not show a difference in response and/or refusal rates based on incentives, Brick et al. (2007) report that offering a $10 incentive improved participation over a $5 offering. On school-based surveys OMB has offered financial incentives to increase or at least maintain school participation rates. CDC believes that offering cell phone respondents an incentive will help maintain response rates for this difficult to reach population. To compensate for telephone charges incurred from the survey and to encourage the young/mobile/single population to participate, CDC will offer cell phone respondents a $10 gift. The RDD landline telephone respondents will not be offered any gift or payment.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

This data collection has received IRB approval from the CDC Human Research Protection Office (protocol #200-2002-00575/TBD; expiration: 8/11/2010). The current NATS IRB Approval Letter is in Appendix H. As part of interviewer training, prior to commencement of data collection, the project director will review all IRB-approved procedures for the protection of human subjects. The training will include procedures for reporting respondent complaints and unanticipated problems. In addition, interviewers will be instructed to discontinue a call if they feel someone is listening on another line. Such discontinued calls will set an unscheduled callback at a later date.

A.10.a Privacy Impact Assessment Information

This study will collect information on tobacco use, environmental smoke exposure, attempts to quit tobacco use, and exposure to forces promoting and impeding tobacco use. The data are being gathered to determine nationally the proportion of adults who use tobacco products, are exposed to environmental smoke, and attempt to quit (and, if they attempt, did so successfully). It also seeks to measure exposure to forces promoting and impeding tobacco use.

A. This submission has been reviewed by staff in CDC's Information Collection Review Office, who determined that the Privacy Act does not apply. Although information on respondents' names will be used to generate advance letters (Appendix K), response data will not be linked to respondent names or complete telephone numbers.

B. Precautions will be taken in how the data are handled to prevent a breach of confidentiality. Survey data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. To maintain security, only a sub-string of the telephone numbers associated with each completed call is included in the final data, so a respondent's answers cannot be connected to a specific person or telephone number. If reports or tabular data are submitted, the data will be reviewed to determine if the subject(s) can be identified when small cell counts occur. If there is the potential for the identification of these subject(s), (cell count fewer than 30 records), the data in these cells will be removed. Respondents will be told during the initial screener that the information they provide will be maintained in a confidential manner. All interviewers will be required to sign a statement of confidentiality on the date of hire, which will be reinforced at training (Appendix I).

C. Verbal consent will be elicited from participants. Before each interview, the interviewer will read the informed consent script to each participant. The consent script describes the interview, the types of questions that will be asked on the actual survey, the risks and benefits of participation, and participants' rights, and it provides information on whom to contact with questions about any aspect of the study. The consent script also indicates that participation is completely voluntary and that participants can refuse to answer any question or discontinue the interview at any time without penalty or loss of benefits. The interviewer will enter a code via the

keyboard to signify that the participant was read the informed consent script and agreed to participate.

D. Participation in the NATS is voluntary. Interviewers will tell respondents that "Any information you give me will be maintained kept private, to the extent permitted by law. If you have any questions about the survey, please call CDC at 1-770-488-5749. The survey takes approximately 20 minutes. This call may be monitored for quality assurance purposes." Interviewers will also tell respondents: "I will not ask for your last name, address, or other personal information that can identify you. You do not have to answer any question you do not want to, and you can end the interview at any time." A callback telephone number will be provided to anyone who wishes to speak with a supervisor or the client about this survey.

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

There are a total of 114 out of 157 specific tobacco-related questions on the NATS questionnaire (Appendix F/G). While an individual may be sensitive about answering such questions, the items are for the most part, not of a sensitive nature and are commonly found in surveys of health behavior. Data on tobacco use are generally regarded as being no greater than minimally sensitive. Therefore, the data collection will have little or no effect on the respondent's privacy. Nevertheless, safeguards will be put in place to ensure that all collected data remain private. There are no questions concerning illegal drug use or other criminal acts. There are no questions about emotionally charged experiences such as parental or sexual abuse. The one question that may be considered sensitive concerns sexual orientation.

Research on smoking and reasons for starting smoking have established some links between sexual orientation and propensity to smoke. Published literature on smoking among gay, lesbian, and bisexual individuals consistently finds higher rates of smoking compared to the general population (Ryan et al., 2001). Sexual orientation has been identified with health--related disparities in Healthy People 2010 and is part of OSH's activities to identify and eliminate tobacco-related disparities. It is for this reason that OSH recommends that states consider including a question on sexual orientation as part of the ATS.

The question on sexual orientation was tested previously in cognitive interviews in preparation of questionnaires for other OMB-approved studies (Hispanic/Latino ATS, OMB No. 0920-0726, expiration: 8/31/2008; and the American Indian/Alaskan Native ATS, OMB No. 0920-0671, expiration: 1/31/2008). Cognitive interviews revealed there was no issue of embarrassment in answering. Interviewers will be trained to ask the sexual orientation question in a neutral manner. If the interviewer senses any discomfort or reluctance to answer the question, the interviewer will be instructed to remind the respondent that he/she may choose to not answer the question.

There are fourteen questions which are demographic in nature, four of which ask about race and ethnicity. OMB considers questions about race and ethnicity to be sensitive. On October 30, 1997, the Office of Management and Budget (OMB) published "Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity" (*Federal Register*, 62 FR 58781 - 58790). The 1997 standards reflect a change in data collection policy, making it

possible for Federal agencies to collect information that reflects the increasing diversity of the U.S. population stemming from growth in interracial marriages and immigration. Under this policy, federal agencies are required to offer respondents the option of selecting one or more race responses from a list of five designated racial categories. Additionally, the standards provide for the collection of data on whether or not a person is of "Hispanic or Latino" culture or origin. Such standards also foster comparability across data collections carried out by various agencies. The race and ethnicity questions in the NATS follow all guidelines for the development of data collection questions, formats, and associated procedures to implement the 1997 standards.

A.12 ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

A.12.a Estimated Burden Hours

The estimated burden for this information collection is based on almost 8 years of experience conducting state-based Adult Tobacco Surveys and on timed tests of the burden imposed by the current NATS questionnaire. The planned information collection involves administration of the NATS questionnaire (Appendix F/G) to approximately 95,000 adults. Approximately 1,863 interviews will be conducted in each state.

The total average time to recruit, screen, and conduct the interview is 22 minutes. Approximately 2 minutes are needed to introduce the survey and screen for an eligible respondent, 1 minute is devoted to the informed consent process, and 19 minutes are required to complete the interview. A final pretest of the NATS questionnaire demonstrated that the vast majority of NATS interviews will take from 10 minutes to 30 minutes, with a mean of approximately 20 minutes. The total annual burden hours estimated for the NATS and associated support activities is 37,303.

Table A-12.a. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Adults ages 18 or older	Screener for land-line users (pp 11-18 of the NATS)	166,273	1	2/ 60	5,542
	Screener for cell phone users (pp 2-11 of the NATS)	5,400	1	1/ 60	90
	National Adult Tobacco Survey (pp 19-92 of the NATS) - landline	95,013	1	20/ 60	31,671
	National Adult Tobacco Survey (pp 19-92 of the NATS) - cell phone	3,000	1	20/ 60	1,000
				Total	38,303

A.12.b Estimated Annualized Cost to Respondents

For this information collection, there are no direct costs to the respondents themselves. However, the cost to adult respondents can be calculated in terms of their time in responding to the NATS as seen in Table A-12.a. Table A-12.b illustrates the total calculation of costs to respondents for the NATS. The estimated respondent burden hours have been multiplied by an estimated average hourly salary for persons in that category. The estimated burden cost in terms of the value of time adults spend in responding is based on information provided by the U.S. Department of Labor that estimates the mean of state, local, and private industry earnings as $23/hour. At that rate, the total annual cost burden for the time spent by participants is $880,969.

Table A-12.b. Annualized Estimated Cost to Respondents

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (in hours)	Hourly Wage Rate	Total Annualized Respondent Costs
Adults ages 18 or older	Screener for land-line users	166,273	1	2/ 60	$23	$127,466
	Screener for cell phone users	5,400	1	1/ 60	$23	$2,070
	National Adult Tobacco Survey - landline	95,013	1	20/ 60	$23	$728,433
	National Adult Tobacco Survey - cell phone	3,000	1	20/ 60	$23	$23,000
				Total		**$880,969**

A.13 ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

There will be no respondent capital and maintenance costs.

A.14 ANNUALIZED COSTS TO THE GOVERNMENT

The study is funded under Contract No 200-2002-00574, Task Order 20. The total contract award to Macro International Inc. is $4,565,129 over a 28-month period. Thus the annualized contract cost is $1,956,484. These costs cover the activities in Table A-14 below.

Additional costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of the study and in conducting data analysis. It is estimated that 4 CDC employees will be involved for approximately 10 % of their time (for federal personnel 100% time = 2,080 hours annually). Two are salaries of $45.46 per hour and two others are at salaries of $53.72 per hour. The direct annual costs in CDC staff time will be approximately $41,259 annually.

The total cost for the study over a 28-month period, including the contract cost and federal government personnel cost is $4,661,399.72 The annualized cost to the government for the study will be $1,956,484 + $41,258.88 = $1,997,742.88

Activity	**Costs**
Contract Costs	
Cognitive testing of questionnaire items	$ 77,130

Design and plan study	$ 93,400
Program CATI questionnaire	$ 30,428
Train and provide quality control over data collectors	$ 240,078
Collect data	$ 1,436,876
Process data and maintain database	$25,714
Clean and weight data	$31,429
Produce data file with documentation	$21,429
Subtotal	$1,956,484
Federal Employee Time Cost	$
10% time for two FTEs @$45.46/hour	$ 18,911.36
10% time for two FTE @ $53.72/hour	$ 22,347.52
Subtotal	$ 41,259
Total Contract Cost	$ 1,997,743

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is a new collection of information and therefore, there are no program changes or adjustments.

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

A.16.a Tabulation Plans

Data will be tabulated in ways that will address the principal research purposes outlined in A.2. The planned analyses to be conducted are described briefly below:

1. *Estimate the extent to which adults engage in tobacco use behaviors*. Percentages and confidence intervals will be calculated to address this objective.
2. *Assess the degree to which tobacco use behaviors among adults vary as a function of gender, age, and race/ethnicity*. Cross tabulations, Chi-square analyses, and regression analysis initially will be conducted to address this objective.
3. *Estimate accomplishment of key short-term, intermediate, and long-term tobacco prevention and control outcome indicators found in CDC's Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs report*. Cross tabulations, Chi-square analyses, and regression analysis initially will be conducted to address this objective.
4. *Estimate the degree to which exposure to influences expected to promote or impede tobacco use has its expected effects*. Chi-square and logistic regression analyses will be used.
5. *Assess the degree to which response to influences expected to promote or impede tobacco use varies as a function of gender, age, and race/ethnicity*. Chi-square and logistic regression analyses will be used.

Examples of the table shells that will be completed through analysis of the data are in Appendix J.

A.16.b Publication Plans

CDC plans to release NATS results through a variety of government publications, refereed journals, and annual conferences of national organizations focused on tobacco use, prevention and control, preventive medicine, health promotion, and epidemiology. CDC will publish NATS results initially through the *MMWR*, which will be distributed to other Federal agencies, state and local health agencies, national health organizations, universities, and the general public. Additionally, NATS results, and eventually a public use data set, will be released via the CDC web site.

A.16.c Time Schedule for the Project

The following represents our proposed schedule of activities for the NATS, in terms of months after receipt of OMB clearance. Data collection is currently scheduled to start on October 1, 2009 and end 5 months later on February 28, 2010. The urgency of receipt of timely clearance is driven by two sets of factors: (1) the multiple factors described early in this justification related to the focal importance of tobacco use control as part of larger efforts around health care reform; and (2) OMB's imposition of a restrictions on the initiation of new data collections during the period of the 2010 U.S. Census from March 1 through August 31, 2010. Results will be published initially in the *MMWR* and subsequently in other publications.

Key project dates will occur during the following time periods for the data collection:

Activity	Time Period
Program and test CATI instrument	Prior to OMB clearance *
Train interviewers	Prior to OMB clearance *
Conduct pre-testing	August-September 2009 (under separate pre-testing clearance)
Collect NATS data	1 to 5 months after OMB clearance, beginning approximately 10/1/2009
Process data and maintain database	2 to 7 months after OMB clearance
Clean and weight data	8 to 9 months after OMB clearance
Produce data file with documentation	10 months after OMB clearance
Analyze data	11 to 14 months after OMB clearance
Publish results	18 to 20 months after OMB clearance

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

The expiration date of OMB approval of the data collection will be displayed.

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

No exemptions from the certification statement are being sought.

REFERENCES

Abreu, D.A., and Winters, F. (1999) "Using Monetary Incentives to Reduce Attrition in the Survey of Income and Program Participation. " *Proceedings of the Survey Research Methods Section of the American Statistical Association.*

CDC (2006). *National Strategic Plan for Tobacco Control - FY2006-FY2008.* Atlanta, GA: CDC.

CDC (2007). *Best Practices for Comprehensive Tobacco Control Programs – 2007*. Atlanta, GA: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

CDC (2008a). Smoking-attributable mortality, years of potential life lost, and productivity loses – United States, 2000-2004. *MMWR*; 57(45):1226-1228.

CDC. (2008b). Cigarette Smoking Among Adults – United States, 2007. MMWR; 57(45):1221-1226.

CDC. (2008c). State-specific Prevalence and Trends in Adult Cigarette Smoking- United States, 1998-2007. *MMWR*; 58 (9): 221-226.

CDC, NCHS (2008). Public use data file and documentation: multiple causes of death for ICD-10 2005 data [CD-ROM].

Creighton, K. P., King, K. E., & Martin, E. A. (2001). *The Use of Incentives in Census Bureau Longitudinal Surveys (No. 2007-2)*. Washington: U.S. Census Bureau.

J. Michael Brick, Pat D. Brick, Sarah Dipko, Stanley Presser, Clyde Tucker, and Yangyang Yuan. *Cell Phone Survey Feasibility in The U.S.: Sampling and Calling Cell Numbers Versus Landline Numbers.* Public Opinion Quarterly 2007 71: 23-39

Ryan, H., Wortley, P.M., Easton, A., Pederson, L., Greenwood, G. (2001). Smoking among lesbians, gays, and bisexuals: A review of the literature. American Journal of Preventative Medicine, 21, 142-149.

Starr, G, T Rogers, M Schooley, S Porter, E Wiesen & N Jamison (2005*). Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs*. Atlanta, GA: CDC.

USDHHS (2000). With understanding and improving health and objectives for improving health. In: *Healthy People 2010.* Washington, DC: U.S. Department of Health and Human Services.

USDHHS (2004). *The Health Consequences of Smoking: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Service, Public Health Service, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.