NATIONAL YOUTH TOBACCO SURVEY
2012-2014

SUPPORTING STATEMENT: PART A

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A. JUSTIFICATION

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

This statement supports a request to obtain approval for the revision of a currently approved information collection to conduct the school-based National Youth Tobacco Survey (NYTS) (OMB No. 0920-0621; exp. 1/31/2012. The term of this request is for three years (2012-2014). The NYTS is a survey of students in grades 6-12 that assesses tobacco use behaviors and behavioral determinants. The proposed information collection includes the following changes to the currently approved information: change from biennial to annual data collection and modifications to the survey instrument to include new items to measure progress toward meeting the strategic goals of FDAs Family Smoking Prevention and Tobacco Control Act. The proposed information collection will use the current OMB-approved sampling strategy, recruitment methods, and data collection procedures to conduct the NYTS among nationally representative samples of students in public and private schools, enrolled in grades 6-12, during January through March of 2012.

Prior to 2004 the NYTS was conducted and privately funded by the American Legacy Foundation (Legacy), a 501(c)(3) organization established in 1999 as a result of the 1998 Master Settlement Agreement (MSA) between a coalition of 46 state attorneys general and five U.S. territories and the tobacco industry. Payments designated by the settlement were Legacy's main source of funding. Legacy conducted the NYTS in 1999, 2000, and 2002, each time receiving technical support (e.g., in establishing contact with states and in publishing NYTS data in *Morbidity and Mortality Weekly Report)* from the Centers for Disease Control and Prevention (CDC). Following the 2002 NYTS, Legacy ceased funding of the NYTS because of a scheduled reduction in their budget. Beginning in 2003, CDC assumed responsibility for funding and conducting the NYTS. CDC received a one-year approval from OMB to conduct the 2004 NYTS (OMB No. 0920-0621; exp.12/31/04) and a three-year approval to conduct the 2006 and 2008 NYTS (OMB No. 0920-0621; exp.12/31/08). To improve the coordination and efficiency of school-based surveillance activities within CDC, implementation of the 2008 NYTS was delayed until 2009 to coordinate survey implementation with the national Youth Risk Behavior Survey (YRBS). CDC received a three-year approval to conduct the 2009 and 2011 NYTS (OMB No. 0920-0621; exp. 1/31/2012). CDC plans to conduct the NYTS annually while continuing to coordinate survey implementation with the national YRBS during odd years. Shifting to annual data collection is critical in order to provide data necessary to measure progress toward meeting the strategic goals of FDAs Family Smoking and Tobacco Prevention Act. Thus, CDC requests OMB approval to conduct the NYTS in 2012, 2013, and 2014.

A.1.a Background

CDC is responsible for leading and coordinating strategic efforts aimed at preventing tobacco use among youth and, among all age groups, promoting tobacco cessation, protecting nonsmokers from secondhand smoke, and eliminating tobacco-related health disparities. A comprehensive tobacco control program must have surveillance and evaluation systems that can track and document a wide range of short-term, intermediate, and long-term intervention outcomes in the population, the data from which can inform program and policy direction, as

well as demonstrate programmatic and fiscal accountability (CDC, 2007). The NYTS assesses short-term (such as increased knowledge about the negative health consequences of tobacco use), intermediate (such as reduced access to tobacco products), and long-term (such as reduced cigarette smoking prevalence) outcomes (Starr et al., 2005). As such, NYTS data are instrumental in expanding the science base of tobacco control; building stakeholder capacity to design, implement, and evaluate comprehensive tobacco control programs; and facilitating coordinated efforts among partners.

The NYTS is the national component of CDC's comprehensive youth tobacco surveillance system. This system also is comprised of the Youth Tobacco Survey (YTS), which provides state-level tobacco use data, and the Global Youth Tobacco Survey (GYTS), which provides international tobacco use data. Since the NYTS is comparable to the YTS in methodology and content, states can measure their program's progress relative to national trends. Similarly, the NYTS provides data to represent the United States in the international community having conducted or now planning to conduct the GYTS. CDC collaborates with the World Health Organization (WHO) in providing training and technical assistance to countries around the world in conducting the GYTS, which contains core questions found on both the YTS and the NYTS. Collectively, the YTS, NYTS, and GYTS are critical to CDC's responsibility to provide technical assistance to global, national, state, and local tobacco prevention and control activities.

The NYTS comprehensively assesses use of many tobacco products (cigarettes, cigars, smokeless tobacco, pipe tobacco, bidis, and kreteks), some of which appeal especially to youth, and also includes questions on knowledge of and attitudes toward tobacco; exposure to secondhand smoke; and, exposure to pro- and anti-tobacco influences such as portrayals of tobacco in advertising and mass media, provision of school- and community-based interventions, and enforcement of minors' access laws. These data are essential to a variety of Federal, state, and local to the design, implementation, and evaluation of comprehensive youth tobacco prevention and control programs by a variety of Federal, State, and local stakeholders .

The justification for implementation of the NYTS is based on three factors: (1) public health implications of tobacco use; (2) economic costs of tobacco use; and (3) mandates to monitor, reduce, and alter attitudes toward tobacco use and reduce exposure to pro-tobacco influences found in Section 301 of the Public Health Service Act (42 USC 241) (Attachment A).

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

The United States has made great strides in the fight against tobacco related illnesses and death since the landmark 1964 Surgeon General's Report on the health effects of cigarette smoking. Since then, adult smoking rates in the United States have been reduced by half from 42.4% in 1965 to 20.6% in 2008 (CDC, 2010a). However, despite this progress and the high level of public knowledge in the United States on the adverse effects of smoking, tobacco use remains the single leading preventable cause of disease and death in the United States, causing an estimated 443,000 deaths each year, with secondhand smoke responsible for 49,400 of those deaths (CDC, 2008). In 2009, approximately 20.6% (46.6 million) of U.S. adults currently smoked cigarettes (CDC, 2010b). Of these, approximately 78.1% (36.4 million) smoked every day and 21.9% (10.2 million) smoked some days. Despite significant declines during the past 30

years, the prevalence of cigarette smoking in the United States has plateaued in recent years, with no significant changes in prevalence from 2005 (20.9%) to 2009 (20.6%) (CDC, 2010b).

A limited number of health risk behaviors established during adolescence, including tobacco use, account for the overwhelming majority of immediate and long-term sources of morbidity and mortality. There are 8.6 million people in the United States who suffer from at least one serious illness caused by smoking (CDC, 2003). For every person who dies of a smoking-attributable disease, there are 20 more people who are suffering from a serious illness related to smoking (CDC, 2003). Historically, smoking has attributed to a wide variety of conditions, such as lung, throat, oral, bladder, esophageal, and laryngeal cancers; coronary heart and cardiovascular diseases; reproductive effects, and sudden infant death syndrome (SIDS). This list has been expanded to include abdominal aortic aneurysm, acute myeloid leukemia, cervical cancer, kidney cancer, pancreatic cancer, pneumonia, periodontitis, and stomach cancer (USDHHS, 2004).

Among U.S. adults 35 years of age and older, approximately 41% of deaths were attributable to cancer, approximately 32.7% to cardiovascular disease and approximately 26.3% to respiratory disease. The three leading specific causes of smoking-attributable deaths were lung cancer, chronic obstructive pulmonary disease (COPD), and ischemic heart disease (CDC, 2008).

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 die of heart disease, and about 150,000–300,000 children younger than 18 months have lower respiratory tract infections (CDC, 2011)

From 2000-2004, an estimated 49,400 lung cancer and heart disease deaths were attributable to secondhand smoke exposure (excluding deaths from residential fires); an estimated 735 deaths resulted from smoking-attributable fires; and, smoking during pregnancy resulted in an estimated 776 infant deaths (CDC, 2008) During this time period (2000-2004) smoking accounted for an estimated average 5.1 million Years of Potential Life Lost (YPLL) per year,(3.1 million YPLL for men and 2.0 million YPLL for women, not including fire- and adult SHS-related deaths) and an estimated annual average of $96.8 billion lost in productivity (CDC, 2010b).

The immediate health effects of tobacco use among children and adolescents include coughing, decreased lung growth and function, reduced cardio-respiratory endurance, increased susceptibility to respiratory infections, and decreased ability to participate in physical activities (USDHHS, 1994). In addition, smoking by children and adolescents is associated with an increased risk of early atherosclerotic lesions and increased risk factors for cardiovascular diseases, such as increased levels of low-density lipoprotein cholesterol, increased very-low-density lipoprotein cholesterol, increased triglycerides, and reduced levels of high-density lipoprotein cholesterol (USDHHS, 1994). Two follow-up studies in the United Kingdom and Hong Kong have confirmed and built upon the findings from the 1994 Surgeon General's report

on the health consequences of smoking. Lam et al. (1998) found that adolescents (age 12-15) who smoked more than six cigarettes per week had a higher prevalence of coughing and wheezing compared to their non-smoking counterparts. Similarly, Withers et al. (1998) found that children (ages 6-8) and adolescents (ages 14-16) who smoked at least 1 cigarette per week for a year had a higher prevalence of coughing and wheezing compared to their non-smoking counterparts. Tobacco use also may serve as an antecedent to depression among adolescents (Goodman & Capitman, 2000).

More than 80% of adult smokers begin smoking before 18 years of age (SAMHSA, 2009). In 2008, more than 3,500 kids under 18 attempted smoking on any given day for the first time, and nearly 1,000 other kids became established smokers, on a daily basis (SAMHSA, 2009). Age at initiation of smoking is an important indicator of future smoking behavior. Persons who start smoking when they are young are more likely to become strongly addicted to nicotine (USDHHS, 1994). Young people who try to quit using tobacco experience the same nicotine withdrawal symptoms as adults who try to quit (USDHHS, 1994). According to the 2009 NYTS data, 8.2% of middle school students and 23.9% of high school students reported currently using any type of tobacco (CDC, 2010a). Cigarette smoking was the most prevalent form of tobacco use, with 5.2% of middle school students and 17.2% of high school students reporting they currently smoke cigarettes (CDC, 2010a).

Tobacco use is also highly correlated with alcohol and other drug use and other health risk behaviors, and may help perpetuate them (Upadhyaya et al., 2002). Research conducted by NIDA revealed that individuals who smoked cigarettes were more like to use illegal drugs (NIDA, 2003). For all age groups combined, the 65.8 percent of participants who had ever smoked were: seven times more likely to have tried marijuana; seven times more likely to have tried cocaine; 14 times more likely to have tried crack; and 16 times more likely to have tried heroin (NIDA, 2003). When data were broken down by age groups, the associations between smoking and other drug use were striking:

- Teens between ages 12 to 15 who smoked cigarettes were 44 times more likely to use crack, compared with only a twofold risk in those 50 or older.
- 95% of high school seniors who smoke, tried illicit drugs, while only 27% of non-smokers tried illicit drugs;
- 94% of smoking seniors tried marijuana compared to 20% of non-smoking seniors;
- 49% of smoking seniors tried cocaine, while 5% of non-smoking seniors tried it;
- 18.4% of smoking seniors drank daily compared to 1.7% of non-smoking seniors; and
- 67.9% of smoking seniors did some heavy drinking, while only 17.2% of non-smoking seniors did some heavy drinking (NIDA, 2003)

These data demonstrate the clear public health dangers that begin with tobacco use and further support the need for continued rigorous, scientific research and surveillance.

A.1.a.2 Costs of Tobacco Use

The economic impact of smoking and exposure to secondhand smoke is enormous in terms of increased medical costs, lost productivity, and other factors.

Average annual smoking-related productivity losses from 2000-2004 are estimated at $96.8 billion ($64.2 billion for males and $32.6 billion for females) (CDC, 2008). This figure does not include costs associated with smoking-attributable health-care expenditures, smoking-related disability, employee absenteeism, or secondhand smoke-attributable morbidity and mortality. From 2000-2004, average annual smoking-attributable health-care expenditures were estimated at $96 billion (CDC, 2008). When taken together, these expenditures plus the $96.8 billion in lost productivity exceeded $192 billion per year. With the evidence that tobacco use may lead to other drug and alcohol use, health costs associated with tobacco use could increase.

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

The justification for tobacco use surveillance among middle and high school students has strong Federal support. The NYTS provides data to support several strategic planning priorities with CDC and HSS. Sources of support include the Healthy People 2020 objectives (USDHHS, 2010), CDC's Performance Plan for FY 2012 (CDC, 2011) on selected Government Performance and Results Act (GPRA) measures, the U.S. Department of Health and Human Service's Tobacco Control Strategic Action Plan (USDHHS, 2010), CDC's National Strategic Plan in Tobacco Control (CDC, 2006a), and FDA's Family Smoking Prevention and Tobacco Control Act. In addition to these strategic initiatives, CDC has identified tobacco use as one of its ten winnable battle areas in public health (CDC, 2011),

The broadest justification for the NYTS is found in Healthy People 2020 objectives, which provides a framework and direction for public health activities to reduce tobacco use for the current decade. Of the 20 tobacco-related Healthy People 2020 objectives, the NYTS provides multiple measures and data for six of them (USDHHS, 2010):

- Objective TU-2—Reduce tobacco use by adolescents

  The NYTS assesses use of a range of tobacco products, including those that have shown increasing popularity among youth in recent years and are significant health hazards to the user, including bidis and kreteks.

- Objective TU-3—Reduce the initiation of tobacco use among children, adolescents, and young adults

  The NYTS assesses not only initiation of tobacco use, but also a range of pro- and anti-tobacco influences; thereby enabling the identification of correlates of initiation (e.g., susceptibility, attitudes, and receptivity).

- Objective TU-7—Increase cessation attempts by adolescent smokers

  One goal of comprehensive tobacco prevention programs is to help people quit smoking. The NYTS assess a range of factors associated with cessation intention, including number of cessation attempts, length of abstinence from tobacco use, symptoms of withdraw and addiction, and use of cessation aids.

- Objective TU-11— Reduce the proportion of nonsmokers exposed to secondhand smoke

  NYTS assesses exposure to secondhand smoke in a variety of settings including home, school, work, vehicle, and indoor/outdoor public venues.

- Objective TU-18— Reduce the proportion of adolescents and young adults grades 6 through 12 who are exposed to tobacco advertising and promotion.

  NYTS assesses exposure to multiple types of tobacco advertising and promotions (i.e., outdoor billboards, internet ads, social media).

- Objective TU-19— Reduce the illegal sales rate to minors through enforcement of laws prohibiting the sale of tobacco products to minors.

  The NYTS assesses a range of factors related to access to tobacco products by minors including point of purchase and requests for proof of age.

Tobacco use among youth also is named in Healthy People 2020 as one of the USDHHS Secretary's 12 Leading Health Indicators (IOM, 2011). 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 YTS to collect the more-detailed data needed to do so, with the added advantage of having comparable NYTS data against which they can benchmark their findings.

In compliance with GPRA, CDC's Online Performance Appendix focuses the agency's priorities and directions for the future and assesses constituents' requirements (CDC, 2011). One of the focal areas in CDC's Performance Appendix is to reduce the proportion of adolescents (grade 9 through 12) who are current cigarette smokers. The associated GPRA measure is the reduction of cigarette smoking among youth. CDC's strategy for preventing tobacco use is a crosscutting approach that includes support for state programs, surveillance, prevention, research, evaluation, and health promotion. Only the NYTS gathers comprehensive national surveillance data among middle and high school students on tobacco use, including cigarette smoking, and on the influences promoting or discouraging tobacco use. Trend data underscore the importance of CDC's focus on efforts related to the reduction of tobacco use among adolescents. From 2000 to 2009, prevalence of current tobacco and cigarette use and experimentation with smoking cigarettes declined for middle school and high school students,

but no overall declines were noted for the 2006--2009 period (CDC, 2010a). Declines were seen only for a few measures within a few population subgroups (CDC, 2010a). NYTS data are essential for creating historical context around these finding and determining whether progress toward meeting the Healthy People 2020 objectives has resumed or plateaued. The NYTS is an important tool used by CDC to provide support and technical assistance to state and national partners for comprehensive Tobacco Control Programs (TCP). NYTS data enable comprehensive evaluation of key state TCP short-term, intermediate, and long-term outcome indicators.

One of the U.S. Department of Health and Human Service's Tobacco Control Strategic Action Plan includes as one of its four strategic actions: Advance Knowledge: Accelerate Research to Expand Science Base and Monitor Progress (USDHHS, 2010). The annual conduct of the NYTS will facilitate the provision of timely updates to tobacco-use behaviors among middle and high school students.

CDC's Strategic Plan for Tobacco Control focuses on both the agency's priorities and future directions and constituent needs. The NYTS generates data relevant to four of the seven Strategic Plan goals: 1) prevention of tobacco use among youths and young adults 2) elimination of secondhand exposures 3) promotion of tobacco use cessation and 4) identification and elimination of tobacco-related health disparities (CDC, 2006).

Passage of the Family Smoking Prevention and Tobacco Control Act, H.R. 1256 gave the FDA the power to regulate the tobacco industry. A signature element of the law imposes new warnings and labels on tobacco packaging and their advertisements, with the goal of discouraging minors and young adults from smoking. The seven provisions of the law focus on (1) regulation of content, marketing, and sale of tobacco products; (2) requirements for disclosure of all product ingredients; (3) FDAs ability to change tobacco content such as banning flavoring in cigarettes; (4) prevention of sales that do not involve face-to-face exchanges; (5) limiting advertising that may target youth; (6) larger warning labels on cigarette packs; and (7) regulation of the use of terms like "light," "mild," or "low" that give the impression tobacco products pose less of a health risk. Recent revisions of the NYTS instrument will enable FDA to monitor data related to four of the seven provisions including: youth access/direct sales to minors; access to and use of tobacco products targeting youth including flavored tobacco products, electronic cigarettes and dissolvable tobacco products; exposure to tobacco advertising; and knowledge of new warning labels on tobacco products.

In addition to the strategic initiatives mandating the reduction of tobacco use by youth, CDC, in an effort to keep a close eye on emerging public health issues, established a list of ten Winnable Battle areas.

- Food Safety
- Global Immunization
- Healthcare-associated Infections
- HIV in the U.S.
- Lymphatic Filariasis in the Americas
- Motor Vehicle Injuries
- Nutrition, Physical Activity and Obesity
- Mother-to-Child Transmission of HIV/AIDS Globally
- Teen Pregnancy
- Tobacco

These areas have been chosen based on the magnitude of the health problems and our ability to make significant progress in improving outcomes. Each area is a leading cause of illness, injury, disability, or death, and/or represents enormous societal costs (CDC, 2011). In addition, there are evidence-based, scalable interventions already in place for each area and can be broadly implemented (CDC, 2011).

Data collected through the NYTS will (1) allow states to develop strong policies that protect nonsmokers from second-hand smoke, (2) help researchers and policy makers to better understand the use of media among youth to graphically show the human impact of smoking, (3) provide comprehensive tobacco use data to support well-funded tobacco control programs and implement other key evidence-based policies will decrease the number of smokers and save lives. Completion of these steps will move CDC and the public health community in the right direction to make the area of tobacco use a winnable battle.

A.1.b Privacy Impact Assessment Information

The primary purpose of the NYTS is to provide nationally representative data on behaviors and behavioral determinants related to tobacco use of middle and high school students. It represents the only national data on tobacco use by middle school students. 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

The NYTS will be administered to a national probability sample of middle and high school students. The NYTS instrument will be a self-administered, paper-and-pencil questionnaire consisting of 81 questions on a variety of tobacco related topics. (Attachment I1). The questions include prevalence of tobacco product use, knowledge and attitudes, media and advertising, minors' access and enforcement, school curriculum, environmental tobacco smoke (ETS) exposure, and cessation.

A.1.d Items of Information to be Collected

Students who have obtained parental permission to participate and are in classrooms selected to participate will be asked to report about their tobacco use behaviors and behavioral determinants on a paper-and-pencil questionnaire.

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

The primary purpose of the NYTS is to collect information on the use of many tobacco products; knowledge of and attitudes toward tobacco; exposure to secondhand smoke; and, exposure to pro- and anti-tobacco influences such as portrayals of tobacco in advertising and mass media, provision of school- and community-based interventions, and enforcement of minors' access laws and exposure to new/expanding warning labels. NYTS data will be used by several Federal agencies, including CDC. The information will have a broad use by state and local governments, nongovernmental organizations, and others in the private sector.

A.2.a Survey Purposes

The purposes of the survey are to:

1. Provide data for short-term, intermediate, and long-term key indicators to the design, implementation, and evaluation of comprehensive tobacco prevention and control programs.
2. Estimate the extent to which middle and high school students engage in tobacco use behaviors and their exposure to influences promoting or discouraging tobacco use.
3. Assess the degree to which engaging in tobacco use behaviors and exposures to influences promoting or discouraging tobacco use varies by student as a function of gender, age, grade in school, and race/ethnicity.
4. Describe the trends in tobacco use behaviors and pro- and anti-tobacco use influences. Assess the degree to which these trends vary as a function of gender, age, grade in school, and race/ethnicity.
5. Determine the interrelationships among tobacco use behaviors and exposure to pro- and anti-tobacco influences and the degree to which these inter-relationships vary as a function of gender, age, grade in school, and race/ethnicity.
6. Provide data related to theory driven constructs that can be useful for explaining tobacco use behavior, designing interventions, and evaluating intervention efficacy and effectiveness.

A.2.b Anticipated Uses of Results by CDC

NYTS data will be used by several divisions *within* the CDC, including the Office on Smoking and Health, the Division of Adolescent and School Health, the Division of Cancer Prevention and Control, and the Division of Oral Health.

Evaluation

- Provide progress measurements related to six *HP 2020* objectives and one Leading Health Indicator.
- Evaluate CDC's Performance Plan in compliance with GPRA.

- Assess trends in tobacco use among middle and high school students and exposure to pro- and anti-tobacco influences to determine the aggregate impact of tobacco prevention and control activities.
- Provide data to evaluate the impact of comprehensive tobacco control programs on tobacco use by youth in the context of Dr. Tom Frieden's Framework for Public Health Action: the Health Impact Pyramid (Frieden, 2010).

Research Synthesis

- Provide states conducting the YTS 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 youth tobacco prevention and control.
- Provide public health and education officials, youth, parents, 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 WHO sponsored international reports based on administration of the GYTS around the world.
- 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 middle school and high school students so they can identify tobacco prevention and control interventions on which to focus resources.
- Provide state legislatures with information about the youth 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 youth should be devised.

Technical Assistance

- Help identify programs shown to be most effective in reducing tobacco use among youth.
- Assist states in interpreting their YTS 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 youth.
- Assess the cumulative effects of multiple interventions and sources of information (school, family, community, and the media) on tobacco use behaviors among youth.

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

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

- Food and Drug Administration plans to use the NYTS data over time to track important baseline and progress measurement data related to the Family Smoking Prevention and Tobacco Control Act. This will include data related to youth access/direct sales to minors; use of tobacco products targeting youth including flavored tobacco products, electronic cigarettes and dissolvable tobacco products; exposure to tobacco advertising; and knowledge of new warning labels on tobacco products.

- Department of Health and Human Services uses NYTS data to track progress on six Healthy People 2020 objectives and one of the 12 Leading Health Indicators. USDHHS cited the NYTS data in their November 2010 strategic action plan: *Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services* (USDHHS, 2010).

- Health Resources and Services Administration identifies NYTS data as a source for credible and reliable quantitative youth data that provide a strong scientific aspect to MCHB needs assessments in their *Promising Practices in MCH Needs Assessment: A Guide Based on a National Study* (USDHHS, HRSA, 2004) report. In addition, NYTS data support HRSA, MCHB, and the American Academy of Pediatrics' *Bright Futures Health Supervision Guidelines* formulate specific risk-reduction recommendations to prevent and assess tobacco use and exposure for infants, children, and adolescents. http://mchb.hrsa.gov/programs/training/brightfutures.htm

- National Institute on Drug Abuse (NIDA) uses NYTS data as a frame of reference when assessing the annual Monitoring the Future survey of drug use. NIDA included an NYTS-based journal publication among its key findings in basic behavioral research in its February, 2007 Director's Report to the National Advisory Council on Drug Abuse (USDHHS, NIH & NIDA, 2007), one of NIDA's mechanisms for ensuring rapid and effective dissemination and use of data for the improvement of prevention, treatment and policy as it relates to drug abuse and addiction.

- National Cancer Institute can use NYTS data to help inform its research, educational efforts, and demonstration projects focused on youth tobacco use prevention and the determinants of cessation. NYTS data are cited in NCI's President's Cancer Panel 2006-2007 Annual Report titled *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk* (USDHHS, NIH & NCI, 2007)

- Office of the Surgeon General can use the NYTS results to assess the need for focused use of resources for tobacco prevention and control efforts targeting youth that was articulated in *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (USDHHS, 1994) and disease prevention documented in *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease* (USDHHS, 2010).

- Department of Education can use the NYTS to report on minors' access to tobacco, enforcement of tobacco laws, use of tobacco products on school property, and exposure to secondhand smoke on school property.

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

- The Substance Abuse and Mental Health Services Administration supports a variety of tobacco prevention and treatment activities. SAMHSA can use NYTS data to support the continued enforcement of the Synar Amendment, which focuses on reducing the sale of tobacco products to minors and creating partnerships to implement or enhance current tobacco cessation programs.

- The Administration on Children and Families integrates tobacco control and prevention into its programs that promote the economic and social well being of families, children, individuals, and communities. The ACF can use NYTS data to support its campaign to deliver health risk-reduction messages related to secondhand smoke.

- The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) can use NYTS data to support its tobacco-related research activities that include basic, clinical, and epidemiological studies of the reproductive, neurobiological, developmental, and behavioral processes that determine and maintain the health of children, adolescents, and adults affected by tobacco use and or exposure.

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

Findings from the NYTS will also be used in a variety of ways by state and local governments, researchers, voluntary health organizations, physicians, teacher training institutions, educational administrators, health educators, teachers, and parents:

- Policy analysts and policy researchers in the legislative and executive branches of government will use NYTS and YTS 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 to develop new policies based on evidence regarding effective tobacco use prevention and control programs.

- Policy makers may evaluate findings from the study of these data in considering policy approaches at national, state, and local levels.

- The NYTS will provide an index against which state and local health and education agencies can compare their state YTS results. See Attachment C for a list state tobacco control reports that cite NYTS data.

- Findings are used by state and local health and education agencies to assess disparities in tobacco use among racial/ethnic groups at the national level and how that compares to what's occurring locally.

- The NYTS provides data to help states evaluate age group targets for tobacco prevention media campaigns.

- State Coordinated School Health programs use NYTS data to gauge the success of their prevention efforts and work to identify areas of focus and ways to integrate prevention efforts.

- State and local law enforcement officials will use findings from the NYTS to determine national compliance with the Synar Amendment, which bans the sale of tobacco products to youth aged <18 years.

- Institutes of higher education will use findings from the NYTS in their teacher training programs to provide information on tobacco use behaviors and effectiveness of evidence-based tobacco prevention and control interventions.

- State and local health departments will use the findings from the NYTS as a guide in developing local tobacco-related health promotion programs to measure progress toward meeting Healthy People 2020 objectives.

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

- School administrators will use findings from the NYTS to provide information to assist them in justifying and planning educational programs to prevent tobacco use and capitalize on extant interventions that curtail use.

- Health educators and other teachers will use findings from the NYTS to provide information that will bolster and provide a focus for their lesson plans and educational materials.

- State and local education agencies already have used NYTS results in creating awareness of risk behaviors, setting program goals, planning or modifying programs, developing staff development programs for teachers, and seeking/targeting funding.

- Nongovernmental organizations and foundations have used NYTS data to characterize the problem of youth tobacco use and to evaluate interventions to decrease tobacco use. Examples include:

    - For example, NYTS data were used in the American Cancer Society (2002) report *Cancer Prevention & Early Detection: Facts and Figures 2003*.
    - The Robert Wood Johnson Foundation funded a report that used NYTS data to highlight the need for tobacco prevention and control efforts among Asian American and Pacific Islander youth in their report Critical Policy Issues on Tobacco Prevention and Control for the Asian American and Pacific Islander Community (Asian Pacific Partners for Empowerment and Leadership, 2000).
    - The American Legacy Foundation (2000a-2000e, 2001a, 2001b, 2002, 2003a, 2003b, 2004, 2005) has used NYTS data in a series of First Look reports that address youth tobacco use and comprehensive tobacco control efforts.

- Professional organizations have used NYTS data to emphasize the importance of tobacco prevention efforts and monitor progress in tobacco control efforts. For example, the American Medical Association, a collaborative partner with the *SmokeLess States*®: *National Tobacco Policy Initiative* used NYTS data in their 2006 Annual Tobacco Report (American Medical Association, 2006).

- Parents and students will use findings from the NYTS posted through popular media including social networking sites, news outlets, and print media to better understand tobacco use behaviors and exposure to pro- and anti-tobacco influences among their children.

A.2.e Privacy Impact Assessment Information

The primary purpose of the NYTS is to provide nationally representative data on behaviors and behavioral determinants related to tobacco use of middle and high school students. It represents the only national data on tobacco use by middle school students. 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.

Data collected from school administrators during recruitment is information available in the public domain and school administrators will not provide personal information. The data collected on the NYTS are not identifiable. Even though teachers will be required to enter student names on a Data Collection Checklist (Attachment H1) to monitor parental permission form returns and make sure that questionnaires are completed only by students for whom permission has been obtained, the Data Collection Checklist is destroyed after the questionnaire has been administered. At no point in time is there any way to connect students' names to their response data.

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

To reduce burden, data are to be collected on optically scannable questionnaire booklets. The data cannot be accessed from currently existing automated databases. During questionnaire design, every effort has been made to limit respondent burden. This proposed data collection is not compliant with the Government Paperwork Elimination Act. However, scannable questionnaire booklets are currently generally regarded as the least burdensome for a school-based data collection

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

CDC conducts ongoing searches of all major educational and 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. 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 nationally representative sample of students in grades 6 through12. The NYTS is the sole national comprehensive youth tobacco survey specifically designed to monitor and evaluate key short term (attitudes and intentions) and intermediate (behaviors) outcome indicators of comprehensive tobacco control programs and policies.

Other surveys that ask tobacco-related questions include the YRBS (OMB No. 0920-0493, exp. 11/30/2011, and the NSDUH, OMB No. 0930-0110). However, this should in no way suggest that other national or smaller-area surveys represent duplications. Unlike the YRBS, the NYTS gathers data on not only high school (grades 9th to 12th) student but also on middle school (grades 6th to 8th) students and is the ***only*** source of such data. In addition, all other national surveys (YRBS, NSDUH, MTF) are multi-risk factor surveys that can ask only a limited number of questions about any one behavior. Tobacco use behavior is related to a wide spectrum of other health behaviors and health outcomes, and is thus a critical measure to include in surveys of many topics among youth and adults. However, those questions cannot meet the needs specific to the evaluation of tobacco prevention and control activities. Smaller-area surveys help to inform programmatic activities at state and local levels. CDC assists states with the implementation of their own state Youth Tobacco Survey. Substantial variation across jurisdictions in sampling techniques, questions, and survey administration procedures prohibit the calculation of national estimates from state-level results. So, while smaller area surveys are essential tools for informing programmatic activities at the state level, they are insufficient to meet national data needs. Surveys for youth and adults are addressed with differing questions and survey modes by design. For NYTS, survey forms are administered at schools because that provides the most confidentiality for their responses; it is also where most youth are during weekdays. Clearly, this mode would not be suitable for adults. Similarly, some tobacco-use questions asked of youth, for whom tobacco use is an officially proscribed behavior, and for whom tobacco use may be a recently-acquired behavior, would not be appropriate for adults and vice versa. Thus, CDC concluded that the NYTS is not duplicative of other surveys.

Currently, the NYTS is only collected every other year. Yet the rapid rise in youth prevalence in the early 1990s demonstrates the need for more frequent assessments in order to identify such patterns in a timely manner in order to mitigate the damage. With the new FDA authorities, many changes are occurring in the tobacco control environment, making it important to monitor closely their impacts on youth. Finally, given the recent passage of the Family Smoking Prevention and Tobacco Control Act, no existing surveys include measures of particular relevance to FDA's regulatory authorities and actions.

In order to meet the needs of both CDC and FDA, the NYTS will be conducted annually, with questions of particular relevance to FDA being asked in even years, and questions relevant to CDC's non-regulatory public health approaches being asked in the odd years. Thus, the survey is specifically being designed to avoid duplication while meeting the needs of both sister agencies. A summary of new questions that were developed by FDA, and approved by both agencies is provided in Attachment I8.

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 IF COLLECTING THE INFORMATION LESS FREQUENTLY

The CDC NYTS was initially designed as a biennial survey. However, as witnessed during the past decade, youth tobacco use can increase or decrease rapidly, making biennial collection less than optimal. On June 22, 2009 the Family Smoking Prevention and Tobacco Control Act was enacted, which gave FDA the authority to regulate tobacco products. Under this new authority, a number of regulatory and enforcement actions are underway or will be commencing soon, including the prohibition of certain types of tobacco advertising and promotion, prohibition of the sale of single cigarettes, elimination of flavors in cigarettes (other than menthol), enforcement of youth access restrictions, and the introduction of graphic warning labels on cigarette packs. In order to ensure that FDA's goal of protecting young people from tobacco use is met, annual data collection is needed to monitor the impact of FDA's actions on public health as well as to measure potential unintended consequences (such as increased use of currently unregulated tobacco products such as e-cigarettes and little cigars). The collection of annual data is particularly important in the first few years following FDA's regulatory authority as many regulations are being implemented in a short time frame. Rather than develop a completely new surveillance system to monitor measures critical to FDA regarding youth tobacco use, thereby increasing burden to the population, the FDA has partnered with CDC to leverage the existing NYTS system to collect annual data that will be useful to both FDA and CDC. The annual NYTS will monitor tobacco product usage among the nation's youth and collect key information which will assist the FDA in ensuring that its efforts are protecting the public's health. The collaboration between CDC and FDA in administering the NYTS annually will not only help CDC and FDA but other stakeholders whose mission it is to reduce tobacco use.

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 1320.6. 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 Notice of the proposed data collection was published in the *Federal Register* on June 15, 2011: Volume 76, Number 115, pages 33497-33498 (Attachment B1). Three public comments were received and acknowledged (Attachment B-2). The NYTS information collection request has been modified to address these comments and includes more information about the roles and strengths of NYTS.

A.8.b Consultations

A.8.b1 Consultations with Various User Communities and Experts

Historically, the state YTS 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 YTS questionnaire. Thus, periodically, CDC met with representatives from a growing number of states to review their perceptions of the utility of data produced by the YTS, identify and remove redundancies, and identify the most relevant indicators. What was the core state YTS questionnaire in the summer of 1999 became the core for the first NYTS conducted in the fall of 1999. In February, 2005 CDC met with state and U.S. Territories representatives of the State and territories to again solicit stakeholder input on the core YTS instrument.

Although Legacy was responsible for the design, instrumentation, products, and statistical aspects of the first three cycles of NYTS, Legacy actively consulted with CDC and other partners during each survey cycle. The purposes of such consultations were to ensure the technical soundness and user relevance of survey results; to verify the importance, relevance, and accessibility of the information sought in the survey; to assess the clarity of instructions; and to minimize respondent burden.

In numerous respects, the NYTS explicitly drew on a long tradition of consultations that occurred to support other CDC school-based data collections in that the NYTS inherited the lessons derived especially to: (1) developing and implementing a sampling plan that efficiently oversamples racial and ethnic minority groups; (2) optimizing institutional receptiveness toward the survey and (3) effectively fielding an anonymous classroom-based survey that can be understood readily by respondents.

In anticipation of the 2004 NYTS, the first NYTS to be conducted by CDC, CDC consulted with members of the Youth Substance Use Working Group of the DHHS Data Council to obtain guidance and suggestions on the overall design of the study and questionnaire. In addition, an appropriate representative of the U.S. Department of Education was invited to participate in the process of review. Those involved in the 2004 consultations on NYTS are listed below.

2004 NYTS Consultants	
Peggy Barker Survey Statistician SAMHSA 5600 Fishers Lane, Room 16C-06 Rockville, MD 20857 Phone: 240-276-1258 E-mail: pbarker@samhsa.gov	Stephen Marcus, Ph.D. Epidemiologist Tobacco Research Branch National Cancer Institute 6130 Executive Boulevard, MSC 7337 Rockville, MD 20892 Phone: 301-594-7934 E-mail: marcusst@mail.nih.gov
Jim Colliver, Ph.D. Acting Chief, Epidemiology Research Branch National Institute on Drug Abuse (NIDA) 6001 Executive Boulevard, Suite 5153 MSC 9589 Bethesda, MD 20852-9589 Phone: 301-402-1846 Email: jcollive@nida.nih.gov	William Modzeleski, MPA Associate Deputy Under Secretary U.S. Department of Education 400 Maryland Ave SW Washington DC 20202 Phone: 202-260-3954 Email: Bill.Modzeleski@ed.gov
Joe Gfroerer Director, Division of Population Surveys Substance Abuse and Mental Health Services Administration (SAMHSA) 5600 Fishers Lane, Room 16-105 Rockville, MD 20857 Phone: 301-443-7977 Email: jgfroere@samhsa.gov	Howard Riddick, Ph.D. Chief, Survey Planning and Development Branch National Center for Health Statistics Centers for Disease Control and Prevention 3311 Toledo Rd. Hyattsville, MD 20782 Phone: 301-458-4459 Email: hcr8@cdc.gov
Kevin Hennessy, Ph.D. Senior Policy Analyst Office of the Assistant Secretary for Planning and Evaluation Department of Health and Human Services H.H. Humphrey Building 200 Independence Avenue, S.W. Washington, DC 20201 Phone: 202-690-7272 Email: khenness@osaspe.dhhs.gov	

For the most recent cycle of the NYTS, several experts within CDC's Office on Smoking and Health, Epidemiology Branch, were consulted to review and provide recommendations on the current design of the study and questionnaire. These included:

2012 NYTS Consultants	
Shanta Dube, Ph.D.	Ralph S. Caraballo

Lead Health Scientist Centers for Disease Control and Prevention Office on Smoking and Health Epidemiology Branch 4770 Buford Highway NE, MS-K50 Atlanta, GA 30341 Phone: 770.488.6287 Fax: 770-488-5848 E-mail: SDube@cdc.gov	Branch Chief Centers for Disease Control and Prevention Office on Smoking and Health Epidemiology Branch 4770 Buford Highway NE, MS-K50 Atlanta, GA 30341 Phone: 770.488.5732 Fax: 770-488-5848 E-mail: RCaraballo@cdc.gov
Martha Engstrom, Ph.D. Lead Health Scientist Centers for Disease Control and Prevention Office on Smoking and Health Epidemiology Branch 4770 Buford Highway NE, MS-K50 Atlanta, GA 30341 Phone: 770.488.5749 Fax: 770-488-5848 E-mail: MEngstrom@cdc.gov	Stacy Thorne Health Scientist Centers for Disease Control and Prevention Office on Smoking and Health Epidemiology Branch 4770 Buford Highway NE, MS-K50 Atlanta, GA 30341 Phone: 770.488.5366 Fax: 770-488-5848 E-mail: SThorne@cdc.gov
Erika Fulmer, Associate Service Fellow Centers for Disease Control and Prevention Office on Smoking and Health Epidemiology Branch 4770 Buford Highway NE, MS-K50 Atlanta, GA 30341 Phone: 770.488.5334 Fax: 770-488-5848 E-mail: EFulmer@cdc.gov	René Arrazola, MPH Epidemiologist Centers for Disease Control and Prevention Office on Smoking and Health Epidemiology Branch 4770 Buford Highway NE, MS-K50 Atlanta, GA 30341 Phone: 770-488-2414 Fax: 770-488-5848 E-mail: RArrazola@cdc.gov

Additional expert consultations were conducted with individuals from the Roswell Park Cancer Institute and the University of California San Diego.

Andrew Hyland, PhD; Research Scientist; Department of Health Behavior, Division of Cancer Prevention & Population Sciences, Roswell Park Cancer Institute; Elm and Carlton Streets Buffalo, New York 14263 716.696.2985 andrew.hyland@roswellpark.org	**John Pierce, PhD;** Professor, Moores UCSD Cancer Center / Family & Preventive Medicine, Cancer Prevention & Control Program, University of California San Diego; 9500 Gilman Drive, Dept. 0901 La Jolla, California 92093-0901 United States 858.822.2380 jppierce@ucsd.edu

The FDA established a working group to obtain guidance and suggestions for new items on the questionnaire that would facilitate the measurement of key data needed to address the Family Smoking and Tobacco Prevention Act. Working group members included:

Allison Hoffman, PhD; Health Scientist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.9203 Allison.Hoffman@fda.hhs.gov	**April Brubach, MA;** Supervisory health Communication Specialist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.3214 April.Brubach@fda.hhs.gov
Benjamin Aperlberg, PhD, MHS; Epidemiologist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.8869 Benjamin.Aperlberg@fda.hhs.gov	**Conrad Choiniere, PhD;** Social Scientist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.9228 Conrad.Choiniere@fda.hhs.gov
Corinne Husten, MD, MPH; Senior Medical Advisor; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.9201 Corinne.Husten@fda.hhd.gov	**Diana Finegold;** Paralegal Specialist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.9227 Diana.Finegold@fda.hhs.gov

Kathleen Quinn, MPH; Deputy Director; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.9213 Kathleen.Quinn@fda.hhs.gov	**Laura Shay, RN, PhD;** Social Scientist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.795.9374 Laura.Shay@fda.hhs.gov
Shawn Fultz, MD; Director; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.795.9374 Shawn.Fultz@fda.hhs.gov	**Tesfa Alexander, PhD;** Health Communication Specialist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.9335 Tesfa.Alexander@fda.hhs.gov
Greta Tessman, MA; Social Scientist; Center for Tobacco Products, Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850 301.796.6722 Greta.Tessman@fda.hhs.gov	

In addition to expert consultations, in anticipation of the 2004 NYTS, cognitive testing interviews were conducted to investigate potential sources of response error. In general, the results indicated that most terms and language used in the survey were easily understood. In instances where questions were considered vague, ambiguous, or confusing, appropriate revisions were made to clarify the question. Specific individuals who were consulted during these revisions included:

Michael Schwerin, Ph.D. Survey Research Methodologist Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709 Phone: 919-541-6000 Email: schwerin@rti.org	Paul D. Mowery, Ph.D. Senior Statistician Biostatistics, Inc. 228 East Wesley Road NE Atlanta, GA 30305 Phone: 404-261-0825 Email: pmowery@cdc.gov
Laura Flicker, Ph.D. Survey Methodologist Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709 Phone: 919-316-3510 Email: lflicker@rti.org	

Another round of cognitive testing was undertaken prior to the 2006 NYTS. Specifically, testing evaluated revisions to certain existing core survey questions and additional new items subsequently under consideration. This round of cognitive testing identified a few questions that participants had difficulty understanding, and appropriate revisions were made. Specific individuals who were consulted during these revisions included:

Emily McFarlane Survey Methodologist Survey Research Division Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709 Phone: 919-541-6566 Email: emcfarlane@rti.org	Donald Smith Senior Survey Director Survey Research Division Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709 Phone: 919-541-7087 Email: dgs@rti.org

Most recently in anticipation of the 2012 NYTS, the FDA conducted several rounds of cognitive review to evaluate new items being added to the questionnaire. Cognitive interviews were conducted with 9 students on July 12, 2011 on new questions recently added to the 2012 NYTS, as well as a handful of older questions for which response categories may need to be refreshed over time (e.g., those that mention popular websites). Interviews were not conducted based on errors or item non-response from previous iterations of NYTS. In summary, the cognitive interviewing participants found the survey instrument clear and easy to complete. The new questions that were tested, changes made if any, and final question wording are provided in Attachment I-8. This attachment also provides a list of questions that were removed to maintain the previous length of 81 items; thus, not increasing the burden on students who will receive the questionnaire. The final 2012 NYTS questionnaire can be found in Attachment I1.

Specific individuals involved in this testing and subsequent consultation and questionnaire revisions include:

Carol L. Schmitt, Ph.D. Public Health Policy Research Program RTI International 701 13th St., NW, Suite 750 Washington, DC 20005-3967 Phone: 202-728-2046 Mobile: 443-254-3146 E-mail: cschmitt@rti.org FAX: 202-728-2095	Jennifer Alexander MSW, MPH Health Communication Program RTI International 701 13th St., NW, Suite 750 Washington, DC 20005-3967 Phone: (301) 891-6787 E-mail: jalexander@rti.org

A.8.b.2 Consultations with Sampling Experts

Consultations conducted previously with sampling experts to develop the sampling design for the national YRBS remain relevant because the fundamental YRBS sampling design was adopted for the NYTS in 2009 and is being maintained for the 2012 NYTS. These consultations date back to August 9, 1989, when CDC and contractor staff met in Washington, D.C. with OMB and several sampling experts and Federal agency representatives to discuss the sampling plan for the YRBS. The results of these consultations are reflected in the sampling

plan in Part B of the clearance package. Specifically, school districts and schools deciding *not* to participate in the survey would not be replaced on the assumption that refusing schools would be systematically different from cooperative schools so that replacement of refusing schools would introduce bias into the results. Also, Common Core Data (CCD) provided by the National Center for Educational Statistics would be used to ensure adequate oversampling of African-American and Hispanic students. The 2009 cycle marked a change in sampling design as the NYTS moved to a design incorporating features of the YRBS in order to support a more efficient coordinated implementation. A minimal set of changes were developed to the design of the NYTS that would preserve comparability with past cycles and align the studies in a way that supported coordinated implementation. The sampling experts who have contributed to the project design over time include:

Dr. Ronaldo Iachan, Ph.D. Senior Statistician ICF Macro, Inc. 11785 Beltsville Drive Calverton, MD 20705 Phone: 301- 572-0538 Email: rIachan@icfi.com	Jim Scanlon, Ph.D. (YRBS panel) ASPE 200 Independence Avenue, SW Washington, DC 20201 Phone: (202) 690-7100 Email: jim.scanlon@hhs.gov
Joe Fred Gonzales, Jr., Ph.D. (YRBS panel) Mathematical Statistician National Center for Health Statistics Office of Research and Methodology 3311 Toledo Road, Room 3121 Hyattsville, MD 20782 Phone: 301-458-4239 Email: jfg2@cdc.gov	Joshua T. Brown, M.S. Statistician ICF Macro, Inc. 126 College Street Burlington, VT 05401 Phone: 802-863-9600 Email: jBrown3@icfi.com
William H. Robb, M.S. Statistician ICF Macro, Inc. 126 College Street Burlington, VT 05401 Phone: 802-863-9600 Email: wRobb@icfi.com	Mirna Moloney, Ph.D. (ABD) Statistician ICF Macro, Inc. 11785 Beltsville Drive Calverton, MD 20705 Phone: 301- 572-0943 Email: mmoloney@icfi.com

A detailed Sampling and Weighting Plan for the NYTS can be found in Attachment L.

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

Schools will be given educational materials and $500 in appreciation for their participation in NYTS. No payments will be offered or made to student respondents. OMB first suggested that CDC offer school incentives on school-based surveys as a means of improving school response rates and, thereby, improving the generalizability of results. Increasingly in recent years, school-based data collections, most of which do not fall under OMB scrutiny, have offered financial incentives to increase or at least maintain school participation rates. CDC believes that offering school incentives helps maintain or slightly increase school participation rates despite the growing number of competing, non-instructional demands placed on schools, including standardized testing.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

This data collection has received IRB approval from the CDC Human Research Protection Office (protocol #4118, exp.:12/18/2011). The current NYTS IRB Approval Letter is in Attachment J.

Staff in the CDC Information Collection Review Office have reviewed this proposal and have determined that the Privacy Act is not applicable. All selected schools, students, and their parents will be informed that anonymity will be maintained throughout data collection, that all data will be safeguarded closely, and that no institutional or individual identifiers will be used in study reports. Anonymity will be promised to students and their parents on parental permission forms. Students will be reminded that their responses are anonymous at the start of the survey administration session by the survey administrator, who will be a professional data collector trained to conduct this survey.

Several actions will be taken to help ensure anonymity. The survey will be administered in a classroom setting, with adequate space between respondents. No personal identifiers will appear on survey questionnaires. Each student will submit the completed questionnaire in a sealed envelope, which will be deposited directly into a "ballot box." After administration of the survey to a class section, all questionnaires for that class will be removed from the box, deposited in an envelope, and labeled with a school identification number (for weighting purposes only). Throughout data collection, all completed questionnaires will be stored in locked files at the contractor's offices and will be accessible only to staff directly involved in the project. Questionnaires will be retained by the contractor for a period of three years and then destroyed.

Privacy Impact Assessment Information

a. Privacy Act Determination. In review of this application, it has been determined that the Privacy Act does not apply to information collected through the NYTS survey. No identifying information will be retained in the data record that would enable an individual survey to be tracked back to a particular student.

b. Information Security. The data collection contractor has several security procedures in place to safeguard data. Data that are collected at school remain under the exclusive control of the contractor's field staff until they are shipped to the contractor's headquarters. School personnel are not responsible for collecting and storing any data. The paper data will be stored in locked files, accessible only to staff directly involved in the project, retained for three years after completion of the data collection, and then destroyed. In addition, all electronic data will be stored on secured servers and will be accessible only to staff directly involved in the project. All contractor staff involved with the project are required to sign a confidentiality, intellectual property, non-competition, and non-solicitation agreement which is a statement of personal commitment to guard the confidentiality of data.

c. Consent. Every student selected to participate in the NYTS survey will receive a parental consent form (Attachment I3 and I4). All students and their parents will be

informed that information will be maintained in an anonymous manner throughout the student data collection, that all data will be safeguarded closely, and that no institutional or individual identifiers will be used in study reports. The notification is included in the NYTS parental permission form distribution script (Attachment I2), the NYTS parental permission form and fact sheet – English and Spanish (Attachment I3 and I4), and in the instructions on the front page of the NYTS questionnaire (Attachment I1). All data collectors will be professionally trained to administer the NYTS. When introducing the questionnaire, data collectors will remind students that their responses will be treated in an anonymous manner (Questionnaire Administration Guides, Attachment I7).

d. Voluntary Nature of Participation. For the NYTS, participation is voluntary and respondents will be assured that there is no penalty if they decide not to respond, either to the information collection as a whole or to any particular question.

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

Seventy-six of the 81 questions on the NYTS are specific to tobacco-related issues (Attachment I1). Those pertaining to actual tobacco use, especially when asked of underage children, may be considered sensitive by at least a portion of parents, students, or the school community. However, because getting accurate information on this topic is critical, the NYTS questionnaire must contain these sensitive questions. During the past 20 years, one of the primary responsibilities of CDC has been to monitor priority risk behaviors among youth. To monitor such behaviors, CDC must ask youth about them. Students are told in the instructions to the NYTS (Attachment I7) that “In order to help develop better education programs, educators and health officials must collect comprehensive data on the attitudes, knowledge, and behaviors of middle and high school students (grades 6 through 12) with respect to tobacco, and on other influences that might make a youth susceptible to tobacco use in the future.” Students also are instructed to read the front cover of the questionnaire booklet which states, “This survey is about tobacco. We would like to know about you and the things you do that may affect your health. Your answers will be used for programs for young people like yourself.”

The remaining five questions are demographic in nature, two 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 NYTS follow all guidelines for the development of data collection questions, formats, and associated procedures to implement the 1997 standards.

The questions were developed in close cooperation with representatives from school systems across the nation and are presented in a straightforward and sensitive manner. Parental permission to participate in the NYTS will be obtained. Attachment I3 and I4 contains the parental permission form and fact sheet in English and Spanish, respectively. The parental permission form reminder notice in English and Spanish can be found in Attachment I5 and I6, respectively. At each school, local procedures for sending home parental permission forms will be followed. Schools will be asked to ensure permission forms are distributed at least 7 days before the survey administration. Teachers track the return of parental permission forms on the Data Collection Checklist to ensure that only students with parental permission participate. A waiver of written student assent was obtained for the participation of children because this research presents no more than minimal risk to subjects, parental permission is required for participation, the waiver will not adversely affect the rights and welfare of the students because they are free to decline to take part, and it is thought that some students may perceive they are not anonymous if they are required to provide stated assent and sign a consent/assent document. Students are told "Participating in this survey is voluntary and your grade in this class will not be affected, whether or not you answer the questions." Completion of the survey implies student assent.

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 over 10 years of experience conducting the NYTS. The planned information collection involves administration of the NYTS questionnaire (Attachment I1) to independent samples of students in the spring of 2012. Respondents include state-level, district-level, and school-level administrators who provide information in the Recruitment Script for the NYTS (Appendices E1, F1, and G1), teachers who complete the Data Collection Checklist for the NYTS (Attachment H1), and students who receive instructions for and complete the NYTS questionnaire (Attachment I7). More information about the Data Collection Checklist is detailed in section B.2.f.

The NYTS will be conducted in 2012 among nationally representative samples of students attending public and private schools in grades 6 through12. At state, school district, and school levels, the cooperation of educational administrators will be sought in recruitment of sampled schools. Burden estimates are based on expected sample sizes and budget under the current contract for the 2012 NYTS cycle. These figures may be adjusted slightly when a new contract is put in place for the 2013 and 2014 NYTS cycles. For this cycle of data collection, the total number of respondents, by type, will include: state-level administrators (n=35), district-level administrators (n=150), and school-level administrators (n=244) who provide information in the Recruitment Script for the NYTS; teachers (n=816) who complete the Data Collection Checklist for the NYTS; and students (n=24,591) who receive instructions for and complete the NYTS questionnaire. There are no costs to respondents except their time. The total burden hours estimated for the NYTS and associated support activities is 18,862. These totals for this cycle are provided in Table 1.

A.12.b Estimated Cost to Respondents

As noted above, for this information collection, there are no direct costs to the respondents themselves or to participating schools. However, the cost for administrators, teachers, and students can be calculated in terms of their time in responding to the 2012 NYTS as seen in Table A-12a and A12b. These tables illustrate the total calculation of burden costs for the 2012 NYTS. In each category, the estimated respondent burden hours have been multiplied by an estimated average hourly salary for persons in that category. The Bureau of Labor Statistics is the source for hourly wages (http://www.bls.gov/bls/blswage.htm). The estimated burden cost in terms of the value of time students spend in responding are based on a minimum wage for students aged less than 20 years of $4.25/hour. The total estimated respondent burden cost for conducting the 2012 NYTS is $92,946. Again, it should be noted that estimated costs to respondents are based on expected sample sizes for the 2012 NYTS cycle. These figures may be adjusted slightly when a new contract is put in place for the 2013 and 2014 NYTS cycles.

Table A12a - 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)
State Administrators	State-level Recruitment Script for the National Youth Tobacco Survey	35	1	30/60	18
District Administrators	District-level Recruitment Script for the National Youth Tobacco Survey	150	1	30/60	75
School Administrators	School-level Recruitment Script for the National Youth Tobacco Survey	244	1	30/60	122
Teachers	Data Collection Checklist for the National Youth Tobacco Survey	816	1	15/60	204
Students	National Youth Tobacco Survey	24,591	1	45/60	18,443
				Total	**18,862**

Table A12b - 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 Respondent Costs
State Administrators	State-level Recruitment Script for the National Youth Tobacco Survey	35	1	30/60	$38.17	$668
District Administrators	District-level Recruitment Script for the National Youth Tobacco Survey	150	1	30/60	$47.25	$3,544
School Administrators	School-level Recruitment Script for the National Youth Tobacco Survey	244	1	30/60	$42.08	$5,134
Teachers	Data Collection Checklist for the National Youth Tobacco Survey	816	1	15/60	$25.57	$5,216
Students	National Youth Tobacco Survey	24,591	1	45/60	$4.25	$78,384
					Total	**$92,946**

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 2011 27957. The total contract award to Macro International Inc. is $1,699,716. The cost of the contract, annualized over the three years of this clearance request, is $566,572. These costs cover the activities in Table 3 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 two CDC employees will be involved for approximately 20% and 35% of their time (for federal personnel 100% time = 2,080 hours annually) at salaries of $40.90 and $43.70 per hour, respectively. The direct annual costs in CDC staff time will be approximately $17,014 + $31,814 = $48,828 annually. The total estimated annualized cost for the study, including the contract cost and federal government personnel cost, is $615,400.

Table A14 - Annualized Study Cost

Activity	**Cost**
Contract Costs	
Design and plan	$58,224
Programming and developing	$50,991
Recruitment and preparation	$65,255
Printing and distribution	$15,742
Recruiting and training	$42,997
Collection of data	$253,238
Processing, cleaning, weighing and developing data files	$54,960
Dissemination and reporting of results	$25,144
Subtotal	$566,572 *
Federal Employee Time Cost	
20% time for one FTE	$17,014
35% time for one FTE	$31,814
Subtotal	$48,828
Total Estimated Annualized Cost to the Federal Government	$615,400

**Components may not sum to this figure due to rounding*.

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

NYTS is a school-based survey that has been conducted biennially since 2000 (OMB No. 0920-0621, exp 1/13/2012). CDC seeks to continue the information collection for a period of three years to conduct the NYTS in 2012, 2013, and 2014. The proposed information collection includes the following changes to the currently approved information collection: change from biennial to annual data collection; changes to the survey instrument to include new items. The CDC NYTS was initially designed as a biennial survey. However, as witnessed during the past decade, youth tobacco use can increase or decrease rapidly, making biennial collection less than optimal. The passage of the Family Smoking Prevention and Tobacco Control Act requires annual monitoring of the positive and possible negative impact of FDAs regulatory authority. Changes to the NYTS will enable FDA to measure specific information relevant to the new law.

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 prevalence of tobacco use behaviors and behavioral determinants among middle and high school students overall and by gender, grade in school, and race/ethnicity*--Descriptive statistics (percentages and confidence intervals) will be calculated to address this objective.

2. *Assess whether tobacco use behaviors and behavioral determinants vary by gender, grade in school, and race/ethnicity*--Cross tabulations, Chi-square analyses, and regression analysis initially will be conducted to address this objective.

3. *Determine the associations between tobacco use behaviors and behavioral determinants* –Chi-square and logistic regression analyses will be used.

4. *Describe trends in tobacco use behaviors and behavioral determinants among middle and high school students overall and by gender, grade in school, and race/ethnicity*-- Multiple regression analyses that controls for gender, grade in school, and race/ethnicity and that simultaneously assesses linear and higher order time effects will be used.

5. *Examine the effects of schools and local areas (school districts or PSUs) in estimating the prevalence of tobacco use*-- multilevel models will be used.

Examples of the table shells that will be completed through analysis of the data are in Attachment K.

A.16.b Publication Plans

CDC's publication of data from prior cycles of NYTS was largely limited to the *MMWR*. CDC is in the process of releasing NYTS 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, adolescent health, and epidemiology. The 2000 YTS and NYTS (CDC, 2001) data and 2001-2002 YTS and NYTS data (CDC, 2006c) were published as *MMWR Surveillance Summaries*. Selected results from the 2004 NYTS were reported in an *MMWR* weekly article (CDC, 2005b). Another weekly *MMWR* article published in 2009 presented NYTS data on cigarette brand preference among middle and high school students who are established smokers also were published. Most recently, trend analyses on the use of tobacco by middle and high schools students from 2000-2009 was cited in a special *MMWR* published in August of 2010.

CDC will continue to publish NYTS results initially through the *MMWR*, which will be distributed to other Federal agencies, state and local health and education agencies, national health and education organizations, universities, and the general public. Additionally, NYTS results and a public use data set are available on the CDC web site at: http://www.cdc.gov/tobacco/data_statistics/surveys/NYTS/index.htm.

A.16.c Time Schedule for the Project

The following represents our proposed schedule of activities for the NYTS, in terms of months after receipt of OMB clearance. The end date for data collection is constrained by the dates on which schools close for the summer. In addition, given that some twelfth grade students may be absent during the final weeks of the school year, it is highly desirable to complete data collection two months before schools close for the summer; i.e., by the end of March.

Key project dates will occur during the following time periods for the 2012 data collection:

Activity	**Time Period**
Recruit and schedule schools	1 to 3 months after OMB clearance
Print scannable questionnaires	1 to 2 months after OMB clearance
Train field data collectors	2 months after OMB clearance
Collect data	2 to 5 months after OMB clearance
Process data	3 to 6 months after OMB clearance
Weight/clean data	7 to 8 months after OMB clearance
Produce data file with documentation	9 months after OMB clearance
Analyze data	10 to 11 months after OMB clearance
Publish results	15 to 17 months after OMB clearance

Data collection is currently scheduled to occur during January through March, 2012. The time schedule for the 2013 and 2014 data collection will be analogous to that of the 2012 data collection. Results will be published in early 2014 initially in the *MMWR*, and subsequently in other publications.

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.

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