NATIONAL YOUTH TOBACCO SURVEY
2015 - 2017

OMB No. 0920-0612

Revision

SUPPORTING STATEMENT: **PART A**

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TABLE OF CONTENTS

A.10. Assurance of Confidentiality Provided to Respondents

A.10.1 Privacy Impact Assessment Information

1. Overview of the Data Collection System
2. Information to be Collected
3. How Information will be Shared and for What Purpose
4. Impact of Proposed Collection on Respondent's Privacy
5. Voluntary or Mandatory Nature of Participation
6. Opportunity to Consent to Sharing and Submission of Information
7. Information Security
8. Privacy Determination

A.11. Justification for Sensitive Questions

A.12. Estimates of Annualized Burden Hours and Costs

A.12.a Estimated Burden Hours

A.12.b Estimated Annualized Cost to Respondents

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

A.14. Annualized Cost to the Government

A.15. Explanation for Program Changes or Adjustments

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

A.16.a Tabulation Plans

A.16.b Publication Plans

A.16.c Time Schedule for the Project

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

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

REFERENCES

LIST OF ATTACHMENTS

A. Authorizing Legislation

B1. 60-Day Federal Register Notice

B2. Public Comment on the 60-Day Federal Register Notice and CDC Response

C. State Tobacco Control Reports that Cite National Youth Tobacco Survey Data

D. Publications from Prior Cycles of the National Youth Tobacco Survey

E1. State-level Recruitment Script for the National Youth Tobacco Survey

E2. State-level Recruitment Script for the National Youth Tobacco Survey Supplemental Document – State Letter of Invitation

F1. District-level Recruitment Script for the National Youth Tobacco Survey

F2. District-level Recruitment Script for the National Youth Tobacco Survey Supplemental Document – District Letter of Invitation

G1. School-level Recruitment Script for the National Youth Tobacco Survey

G2. School-level Recruitment Script for the National Youth Tobacco Survey Supplemental Documents – School Letter of Invitation and NYTS Fact Sheet for Schools

G3. School-level Recruitment Script for the National Youth Tobacco Survey Supplemental Documents – Letter to Agreeing Schools

H1. Data Collection Checklist for the National Youth Tobacco Survey

H2. Data Collection Checklist for the National Youth Tobacco Survey Supplemental Documents – Letter to Teachers in Participating Schools

I1. National Youth Tobacco Survey Questionnaire

I2. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form Distribution Script

I3. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form and Fact Sheet (English Version)

I4. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form and Fact Sheet (Spanish Version)

I5. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form Reminder Notice (English Version)

I6. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form Reminder Notice (Spanish Version)

I7. National Youth Tobacco Survey Questionnaire Supplemental Documents – Questionnaire Administration Script

I8. Summary of Changes in the NYTS Questionnaire from 2014 to 2015

I9. Example: Instrument Testing Activity

J. IRB Approval Letter

K. Sample Table Shells

L. Detailed Sampling and Weighting Plan

LIST OF TABLES

- **Goal of the study:** The National Youth Tobacco Study (NYTS) is designed to assess the distribution and determinants of tobacco use behaviors among youth enrolled in grades 6-12.

- **Intended use of the resulting data:** These data have been used to inform and evaluate the National Comprehensive Tobacco Control Program; inform progress towards achieving Healthy People 2020 objectives related to tobacco and youth; provide data to inform the Department of Health and Human Service's Tobacco Control Strategic Action Plan, and provide national benchmark data.

- **Methods to be used**: A random sample of approximately 250 schools will be asked to participate in the 2015 NYTS. One or two classes (about 25 to 50 students) from each grade 6 through 12 will be selected randomly to take part in each school. Approximately 100 to 200 students are asked to participate in a school containing grades 9 through 12. In a school with grades 6 through 8, approximately 75 to 150 students are asked to participate in the survey. The survey is estimated to take 35-45 minutes to complete, or one class period.

- **The subpopulation to be studied**: The population studied will consist of nationally representative samples of students in public and private schools, enrolled in grades 6-12.

- **How data will be analyzed:** : The NYTS employs a repeat cross-sectional design to develop national estimates of tobacco use behaviors and exposure to pro- and anti-tobacco influences among students enrolled in grades 6-12.

OVERVIEW

The Centers for Disease Control and Prevention (CDC) requests OMB approval for three years to continue annual information collection for the National Youth Tobacco Survey (NYTS). The NYTS was previously conducted by CDC in 2004, 2006, 2009, 2011, 2012, 2013, and 2014. The most recent OMB approval was for NYTS information collection in 2012, 2013, and 2014 ("2012 - 2014 National Youth Tobacco Survey (NYTS)," OMB no. 0920-0621, exp. 1/31/2015). The NYTS employs a repeat cross-sectional design to develop national estimates of tobacco use behaviors and exposure to pro- and anti-tobacco influences among students enrolled in grades 6-12. This Revision includes an update to the title of the information collection reflecting plans to conduct NYTS surveys annually in 2015, 2016, and 2017. Because NYTS content varies from year to year, this revision also includes (i) a summary of updates to the NYTS questionnaire specifically for the 2015 cycle of information collection, and (ii) a burden allocation for instrument development and testing. The estimated burden per response has not changed. This revision reflects a net decrease in total burden due to a reduction in the estimated number of responses.

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 request to conduct the school-based National Youth Tobacco Survey (NYTS) (OMB No. 0920-0621; exp. 1/31/2015). The NYTS is designed to assess the distribution and determinants of tobacco use behaviors among youth enrolled in grades 6-12. The information collection proposed in this request 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 May of 2015, 2016, and 2017. The survey instrument will be revised to add items that are relevant to the present circumstances in tobacco prevention and control efforts among youth upon approval of this information collection request. The term of this request is to collect information annually for three years (2015-2017).

The NYTS is the only nationally representative survey of middle and high school students that focuses exclusively on tobacco use patterns and associated factors. The Centers for Disease Control and Prevention (CDC), the lead agency for public health surveillance in the U.S., is responsible for administering the NYTS. These data have been used to inform and evaluate the National Comprehensive Tobacco Control Program; inform progress towards achieving Healthy People 2020 objectives related to tobacco and youth; provide data to inform the Department of Health and Human Service's Tobacco Control Strategic Action Plan, and provide national benchmark data for state-level Youth Tobacco Surveys and for comparison with the international community through the Global Youth Tobacco Survey.

In addition, the Food and Drug Administration (FDA) recognized that routine national data on tobacco use behaviors in youth were important for informing and evaluating the impact of FDA tobacco regulatory activities. In order to minimize duplication of data collection and the burden on survey participants, the CDC and FDA have collaborated to leverage the NYTS as a single data source to inform national objectives for tobacco use prevention and control among youth. The annual administration of NYTS has helped in the rapid identification of emerging trends, such as the increased use of electronic cigarettes (e-cigarettes) observed between 2011 and 2012 (CDC, 2013a; CDC, 2013b), and allows for the development and inclusion of specific measures relevant to national objectives for tobacco prevention and control among youth.

CDC requests OMB approval to continue conducting the NYTS in 2015, 2016, and 2017. Survey methods remain the same as in past cycles of NYTS administration. A random sample of approximately 250 schools will be asked to participate in the 2015 NYTS. The probability of a school being selected is based on enrollment in grades 6 through 12. One or two classes (about 25 to 50 students) from each grade 6 through 12 will be selected randomly to take part in each school. Approximately 100 to 200 students are asked to participate in a school containing grades 9 through 12. In a school with grades 6 through 8, approximately 75 to 150 students are asked to participate.

The 2015 NYTS instrument (Attachment I1) has 81 questions and is estimated to take 35-45 minutes to complete, or one class period. Changes from the 2014 instrument are summarized in Attachment I8. Given the dynamic nature of the tobacco product environment and use of the NYTS to serve the information needs of multiple agencies, CDC anticipates the need to update NYTS content from year to year, and may process Change Requests to modify both terminology and questions. Instrument pre-testing will be conducted to maintain the survey at its current length, which is compatible with administration in one class period in the school-based setting. This feature is considered important for maintaining an adequate school participation rate.

A.1.a Background

CDC is responsible for leading and coordinating national strategic efforts aimed at preventing tobacco initiation, promoting tobacco cessation, protecting nonsmokers from secondhand smoke, and eliminating tobacco-related health disparities. Additionally, in recognition of the fact that preventing the initiation of tobacco use is a key public health objective. NYTS includes questions designed to estimate the number of youth who may be more likely to use tobacco products in the future. A comprehensive tobacco control program must have surveillance and evaluation systems that can monitor and document a wide range of short-term, intermediate, and long-term intervention outcomes in the population (USDHHS, NIH, & NIDA, 2013), the data from which can inform public health program and policy efforts, as well as demonstrate programmatic and fiscal accountability (CDC, 2014a). The NYTS is a multifactorial survey that measures short-term outcomes (such as increased knowledge about the negative health consequences of tobacco use and exposure to secondhand smoke), intermediate-term outcomes (such as reduced access to tobacco products), and long-term outcomes (such as reduced tobacco use prevalence) (CDC, 2012b; CDC, 2014a; Starr, et al., 2005). As such, NYTS data are instrumental in providing the science base to inform evidenced-based approaches to public health interventions; stakeholder capacity to design, implement, and evaluate comprehensive tobacco control programs; and the facilitation of coordinated efforts among national and state partners.

The NYTS produces national estimates for the entire U.S. and provides important comparison data for other surveillance efforts. For example, many states conduct a Youth Tobacco Survey (YTS) to collect state-level tobacco use data, and a number of countries participate in the Global Youth Tobacco Survey (GYTS), which provides international tobacco use data. Since these surveys are comparable to the NYTS in methodology and content, states can measure their program's progress relative to national trends. Similarly, 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 NYTS, YTS, and GYTS are critical to CDC's ongoing, comprehensive efforts to provide technical assistance to international, national, state, and local tobacco prevention and control efforts.

The NYTS is a comprehensive assessment of knowledge, attitudes, perceptions and behaviors related to multiple tobacco products (cigarettes, cigars, smokeless tobacco,

pipe tobacco, e-cigarettes, hookahs, snus, dissolvable tobacco, and bidis) and also includes items about exposure to secondhand smoke, 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 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 the continued 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

Tobacco use remains the single leading preventable cause of disease and death in the United States. Age at initiation of smoking is an important indicator of future smoking behavior, as more than 86% of adult smokers report that they tried their first cigarette by the time they were 18 years of age (USDHHS, 2014). Additionally, people who start smoking when young are more likely to become strongly addicted to nicotine (USDHHS, 2014), and young people who try to quit using tobacco, experience the same nicotine withdrawal symptoms as adults who try to quit (USDHHS, 2012b). Also, nicotine exposure during adolescence may have lasting adverse consequences for brain development (USDHHS, 2014).

The immediate health effects of tobacco use among adolescents and children include coughing spells, shortness of breath, wheezing or gasping, more frequent headaches, increased phlegm (mucus), respiratory illnesses that are worse and happen more often, reduced physical fitness, poor lung growth and function, worse overall health, and addiction to nicotine (ACS, 2013b). 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. This list has been expanded to include gum disease and tooth loss, infertility and impotence, chronic lung diseases, hearing loss, vision problems, and blood vessel disease (ACS, 2013b). Independent research has confirmed the health effects of tobacco use among adolescents, as Martin-Pujol et al. (2013) found a significant association between adolescents who smoked tobacco and wheezing. The 2014 Surgeon General's Report on Smoking documented new evidence that links active smoking to an increased risk of developing adolescent asthma (USDHHS, 2014).

One of the newest nicotine-containing products on the U.S. market is electronic nicotine delivery systems (ENDS). ENDS include electronic cigarettes, vape pens, electronic hookahs and other similar devices. ENDS are battery-powered devices that provide doses of nicotine and other additives to the user in an aerosol and can contain flavorings that are

particularly appealing to youth (e.g., fruit, mint, or chocolate). ENDS, including electronic cigarettes (e-cigarettes), that are not marketed for therapeutic purposes are currently unregulated by the FDA. Moreover, in half the U.S. states, there are no restrictions on the sale of ENDS to minors (CDC, 2013a). However, on April 24th, 2014, the FDA proposed to regulate ENDS, cigars, pipe tobacco, nicotine gels, hookah (or water pipe) tobacco, and other products that are not currently regulated (FDA, 2014), including youth access restrictions. The 2012 NYTS revealed that e-cigarette use among youths in grades 6 through 12 more than doubled between 2011 and 2012, from 3.3% to 6.8%. Moreover, concurrent use of both e-cigarettes and conventional cigarettes was also high, with over 76% of current e-cigarette users reporting concurrent use of conventional cigarettes in 2012 (CDC, 2012b). Additionally, hookah (water pipe) is an increasing medium through which adolescents are consuming tobacco. The prevalence of hookah smoking among adolescents in 2013 was 21.4%, which is a significant increase, from 17.1% in 2010 and 18.3% in 2012 (NIDA, 2014). Past 30 day use of hookah among high school students also increased from 4.1% to 5.4% during 2011-2012 (CDC, 2013b).

Taken as a whole, these data demonstrate the clear public health importance of monitoring tobacco use and related behaviors among adolescents, 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 2005-2009 are estimated at $107.6 billion ($69.6 billion for males and $38 billion for females) (USDHHS, 2014). 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. In 2006 alone, deaths from coronary heart disease and lung cancer in nonsmokers due to exposure to secondhand smoke resulted in 532,580 years of productive life lost, and $5.68 billion lost in productivity (USDHHS, 2014). In 2009, an estimated $132.5 billion of health care expenditures in adults 19 years of age and older were attributable to smoking, an approximate 38% increase from 2004 (USDHHS, 2014). In total, smoking-attributable health care expenditures and productivity losses exceeded $240 billion 2009. Considering 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 for the U.S. Department of Health and Human Services (DHHS), including the Healthy People 2020 objectives (USDHHS, 2010b), CDC's Budget Request Summary for FY 2015 (CDC, 2014b) on selected Government Performance and Results Act (GPRA) measures, DHHS's Tobacco Control Strategic Action Plan (USDHHS, 2012a), and the Family Smoking Prevention and Tobacco Control Act. In addition to these strategic initiatives, CDC has identified tobacco use as one of its ten 'winnable battles' for public health (CDC, 2013c). Further information on these priorities follows below.

The Tobacco Use Chapter of Healthy People 2020 provides a framework and direction for public health activities to reduce tobacco use for the current decade. The NYTS is the established data source for Healthy People 2020 objective 18, which is to reduce the proportion of adolescents and young adults in grades 6 through 12 who are exposed to tobacco marketing; this objective has 4 sub-objectives pertaining to exposure to tobacco marketing through the following media and settings (USDHHS, 2010b):

- Objective 18.1 — Internet;
- Objective 18.2 — magazines and newspapers;
- Objective 18.3 — movies and television;
- Objective 18.4 — point of purchase.

The NYTS data are essential for creating historical context around Healthy People objectives and whether progress toward meeting these objectives has resumed or plateaued. In addition, the NYTS provides data that is complementary and supportive to other Healthy People Tobacco Use objectives as follows:

- Objective 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, including hookah and e-cigarettes.

- Objective 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 7—Increase cessation attempts by adolescent smokers

  One goal of comprehensive tobacco prevention programs is to help people quit smoking. The NYTS assesses 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 11— Reduce the proportion of nonsmokers exposed to secondhand smoke

  NYTS assesses exposure to secondhand smoke in a variety of settings.

- Objective 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.

The Healthy People 2020 youth tobacco use objectives are also one of the DHHS 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 monitor patterns of use and smoking cessation attempts, issues that require a survey instrument and data that go beyond basic prevalence. Many state's use YTS to collect these detailed data, 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, 2014d). 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 2011 to 2012, prevalence of current tobacco and cigarette use declined among middle school (4.3% to 3.5%) and high school (15.8% to 14%) students; however a substantial proportion of youth tobacco use is comprised of products other than cigarettes, stressing the importance of monitoring and preventing new and emerging product use among youth (CDC, 2013b). 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.

The annual administration of the NYTS will provide timely estimates of tobacco-use behaviors; exposure to tobacco marketing and advertising; compliance with tobacco-use policies, including minor's access law to prevent underage tobacco purchases; exposure to new/expanding warning labels; levels of exposure to secondhand smoke; and social norms related to tobacco-use. It will address each of the four U.S. Department of Health and Human Service's Tobacco Control Strategic Action Plan major action areas: 1) Leading by Example: Leveraging HHS Systems and Resources to Create a Society Free From Tobacco-Related Death and Disease; 2) Improving the Public's Health: Strengthening the Implementation of Evidence-Based Interventions and Policies in States and Communities; 3) Engaging the Public: Changing Social Norms Around Tobacco Use, and; 4) Advancing Knowledge: Accelerating Research to Expand the Science Base and Monitor Progress (USDHHS, 2012a).

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law. The Act amended Section 201 of the Food, Drug, and Cosmetic Act (FD&C)

(21 U.S.C. 321) by inserting Chapter 9 ("Tobacco Products"), Section 901, which provided FDA with regulatory authority over the manufacture, distribution, and marketing of tobacco products, including the authority to promulgate tobacco product standards; regulate the labeling of tobacco products, including health warnings on tobacco product packages and in ads and removal of misleading descriptors such as "light", "low", and "mild"; require the testing and reporting of harmful or potentially harmful constituents (HPHC) by tobacco product brand and sub-brand; and restrict access to tobacco products, advertising, and promotions among youth. CDC and FDA have collaborated in recent revisions to the NYTS instrument to prevent data duplication, enabling the leveraging of the CDC-initiated NYTS to collect information relevant to FDA's regulatory authority, including awareness of tobacco product health warnings, perceptions about the harms of tobacco products, use of flavored tobacco products, symptoms of tobacco dependence, and ease of minor's access to tobacco.

In addition to the strategic initiatives mandating the reduction of tobacco use by youth, CDC established a list of ten "Winnable Battles" in an effort to closely monitor emerging public health issues.

- 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 the nation's 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. In addition, there are evidence-based, scalable interventions already in place for each area that can be broadly implemented (CDC, 2014c).

Data collected through the NYTS can: (1) inform the development of health policy and guidelines that protect nonsmokers from secondhand smoke; (2) help researchers and policy makers to better understand youth exposure to pro-tobacco influences; (3) provide comprehensive tobacco use data to support well-funded tobacco control programs; (4) inform the implementation of other key evidence-based policies that will decrease the number of smokers and save lives. Completion of these steps will move CDC and the public health community one step closer toward eliminating tobacco use and achieving this winnable battle.

CDC requests OMB approval to conduct the NYTS in 2015, 2016, and 2017. The NYTS is conducted in a school-based setting. Respondents are students in grades 6-12. The survey instrument is updated annually to reflect changes in the relevant product environment and emerging standards in terminology and classification of these products.

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

The primary purpose of the NYTS is to collect information on the use of 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, enforcement of minors' access laws. NYTS data will be used not only by CDC, but by several other Federal agencies, including FDA. Additionally, 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 specific aims of the survey are to:

1. Provide data for short-term, intermediate, and long-term key indicators related 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, as well as 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 as a function of sex, age, grade in school, and race/ethnicity.
4. Describe trends in tobacco use behaviors and pro- and anti-tobacco use influences. Assess the degree to which these trends vary as a function of sex, age, grade in school, and race/ethnicity.
5. Determine the interrelationships between tobacco use behaviors and exposure to pro- and anti-tobacco influences, and the degree to which these associations vary as a function of sex, age, grade in school, and race/ethnicity.
6. Provide data related to theory-driven constructs, including curiosity and susceptibility to using tobacco products in the future among never users of tobacco, that can be useful for prediction of future tobacco experimentation and progression to established use among never users, explaining tobacco use behavior, designing interventions, and evaluating intervention effectiveness. Curiosity and susceptibility are high-risk cognitions that are independent predictors of future tobacco experimentation and progression to established use among never users (Choi et al, 2001 Pierce et al, 1996, 2005; Jackson, 1998; Loewenstein, 1994). Curiosity temporally precedes susceptibility and indicates interest, even in the absence of intentions to use (Loewenstein, 1994). Susceptibility signals likelihood of tobacco experimentation and established use through developing beliefs about future smoking (Pierce et al, 1996, 2005). Both curiosity and susceptibility precede

direct intentions to use and are psycho-social measures of future tobacco experimentation and use. While curiosity and susceptibility may be useful measures to identify those at future risk of smoking experimentation and established use, they have distinct differences. As described in Pierce et al. 2005, curiosity is less explored as a predictive construct for future smoking behaviors and "can arise quickly, change focus, and end abruptly. At its peak, it can be a powerful motivational force, often leading to impulsive behavior and eliciting attempts at self-control [Loewenstein, 1994]." In comparison, susceptibility measures are intended to capture intentions and expectations regarding future behaviors, i.e., the preexperimentation phase preceding a specific behavior (Pierce et al. 1996).

Both curiosity and susceptibility are critical to identify those at different stages of risk for future experimentation and use to best target with public education campaigns, for use as inclusion criteria for experiments targeting those at risk, as well as for surveillance and evaluation of tobacco control and regulatory efforts (Duke et al, 2015). These constructs have been included in various data collections and continue to be a key part of these efforts and key indicators of their effects. In addition to using susceptibility to monitor youth at risk for tobacco use, as inclusion criteria for experimental an evaluations studies, and to identify target audiences for public educations campaigns, FDA will use curiosity to monitor early interest in both cigarette and non-cigarette tobacco products. Current efforts to validate the longitudinal power of these instruments both among other populations and for tobacco products other than cigarettes are ongoing. A brief description of the predictive performance of these indexes is provided below separately for curiosity and susceptibility:

Curiosity

Using a single-item measure of curiosity in 2015, Strong et al. found that "compared to those who were definitely not curious about smoking, teens who were probably not curious had a 1.90 (95% CI = 1.28–2.81, $p < .001$) increase in the odds of becoming a young adult smoker and teens who indicated that they were either probably or definitely curious indicated a 2.38 (95% CI = 1.49–3.79) increase in the odds of becoming a young adult smoker (Strong et al, 2015). Adding the curiosity measure to the original susceptibility to smoking index (a three-question construct), increased the sensitivity of the combined index to 78.9% compared to 62.2% identified by the susceptibility index. However, investigators observed a loss of specificity—indicating no observable improvement in the positive predictive value of the combined (curiosity + susceptibility) index (Strong et al. 2015). Thus, while addition of a curiosity measure increases the ability of investigators to predict the proportion of individuals who become future smokers, the decrease in specificity due to introduction of the curiosity measure demonstrates that the proportion of individuals incorrectly identified as future smokers also increases.

Strong et al.'s findings are similar to earlier findings by Pierce et al. (2005), which found that those who reported being probably or definitely curious had a 2.12 (95% CI = 1.53-2.93) odds ratio for future smoking experimentation. While Pierce also observed that inclusion of the curiosity measure to the susceptibility measures resulted in classification of a much higher percentage of the baseline population as susceptible to smoking, resulting in increased sensitivity, Pierce et al. also observed a marked decline in

specificity---producing a higher overall misclassification rate.

Similarly, Nodora et al found that those who reported being probably or definitely curious had 2.43 (95% CI = 1.37-4.32) times the odds of future smoking behavior (Nodora et al, 2014; Pierce et al, 1996). While the sensitivity for the combined susceptibility index increased due to inclusion of the curiosity measure, investigators also noted that both the specificity and positive predictive value decreased.

Susceptibility

For the three-item measure of susceptibility, Pierce found that those at the highest level of susceptibility has 3.15 times the odds (95% CI = 2.37-4.17) of experimenting with smoking four years later compared to those not susceptible, echoing similar findings from Choi et al and Nodora et al (Choi et al, 2001; Pierce et al, 1996; Nodora et al, 2014). More recently, Strong et al. found that even after accounting for other relevant factors, those with the highest level of susceptibility had 2.42 times the odds of established smoking compared to those "committed never users" (Strong et al, 2015). In this study, the three-item measure of susceptibility had a sensitivity of 62.2%, specificity of 49.6% and positive predictive value of 18.9%. The four-item measure of "enhanced" susceptibility which incorporates the three items plus curiosity had a sensitivity of 78.9%, specificity of 35.9% and positive predictive value of 19.0% (Strong et al, 2015). The enhanced measure identifies more youth at risk for future tobacco use compared to the original measure of susceptibility (66.5% vs. 47.7%).

Plans to report outcomes collected on curiosity and susceptibility

Collection of data on the above constructs is important to both CDC and FDA. CDC will be able to monitor susceptibility as an intermediate outcome associated with initiation of tobacco use (Outcome 2 within Goal Area 1 of *Key Outcome Indicators for Evaluating Comprehensive Tobacco Control Programs - 2014*). In addition, these measures are intended to help FDA = identify youth who may be a target audience for public education efforts at a developmental stage when such interventions may be most impactful. Monitoring curiosity will allow CDC and FDA to look for early signals of increasing risk in populations or for specific products as the tobacco landscape continues to evolve.

The analytical plan for use of these indicators involves a denominator of respondents who have never smoked cigarettes (or the tobacco product assessed). Respondents will be categorized as being susceptible to using tobacco products if they indicate a lack of a firm resolve not to use tobacco in the near future or if offered by a friend. For the three-item construct for example, susceptibility to cigarette smoking will be defined as any response other than "definitively not" to questions assessing whether respondents will smoke soon, whether they will smoke in the next one year, or whether they will smoke if offered a cigarette by a friend. Susceptibility and curiosity will be analyzed as percentages with 95% confidence intervals; and their association with other risk factors or behaviors will be explored. Data will be weighted to account for the complex survey design.

7. Inform and monitor the impact of FDA's policies, programs, and regulatory activities and assess progress towards achieving one of its core public health goals: preventing youth tobacco use.

A.2.b Anticipated Uses of Results by CDC

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

Evaluation

- Direct progress measurement related to one *HP 2020* objective (which contains 4 sub-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.
- Both curiosity and susceptibility are useful measures to estimate the level of potential future use for cigarette and other tobacco products among youth.
- Provide data to evaluate the impact of comprehensive tobacco control programs on tobacco use by youth in the context of the CDC Director, Dr. Thomas Frieden's, "Framework for Public Health Action: the Health Impact Pyramid" (Frieden, 2010).

Research Synthesis

- Provide states conducting the YTS with a national index that can be compared to state-specific short-term, intermediate, and long-term tobacco prevention and control outcome indicators.
- Publish data in peer-reviewed publications and present at scientific meetings.
- Identify research gaps in youth tobacco prevention and control.
- Identify those at different stages of risk for future experimentation and use of tobacco products in terms of curiosity and susceptibility, and publish findings in peer-reviewed publications and present at scientific meetings.
- 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 WHO-sponsored international reports based on administration of the GYTS.
- Provide data that are relevant and can be incorporated into a variety of government publications, including Surgeon General's reports.

Policy and Program Development

- Provide stakeholders with information about tobacco use behaviors among middle school and high school students to help inform the identification and implementation of tobacco prevention and control interventions.
- Determine how to best devise public information campaigns that take into account exposure to pro- and anti-tobacco influences among youth.

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-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 preventing and 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:

- DHHS uses NYTS data directly to monitor progress on one of the Healthy People 2020 objectives and one of the 12 Leading Health Indicators. USDHHS cited the NYTS in their August 2012 tobacco epidemic progress report: (USDHHS, 2012a) *Ending the Tobacco Epidemic: Progress toward a Healthier Nation. Washington, DC: US Department of Health and Human Services.* USDHHS also cited NYTS data in their 2014 Surgeon General's Report: (USDHHS, 2014) *The Health Consequences of Smoking- 50 years of Progress: A Report of the Surgeon General.*

  FDA plans to use the NYTS data over time to inform its regulatory authority over the manufacture, distribution, and marketing of tobacco products. This includes the generation of national estimates of tobacco use and key tobacco-related measures among middle and high school students, such as tobacco product harm perceptions, exposure to marketing, and symptoms of tobacco dependence. In addition, data will be used to help monitor the impact of FDA regulatory activities, such as enforcement of youth tobacco product sales restrictions, restrictions on marketing and promotion, and changes to health warnings on cigarette and smokeless tobacco packages. In order to further identify target audiences for public educations campaigns, FDA could use curiosity information to track early interest in both cigarette and non-cigarette tobacco products. This will allow FDA to assess the effects of its regulatory activities on its public health goal of reducing initiation among youth, and identify youth who may be a target audience for public education efforts at a developmental stage when such interventions may be most impactful.
- Health Resources and Services Administration (HRSA) identifies NYTS data as a source for credible and reliable youth data that provide a strong scientific aspect to Maternal and Child Health Bureau (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.

- National Institute on Drug Abuse (NIDA), in collaboration with FDA, is coordinating with CDC to harmonize tobacco-related measures in NYTS and the Population Assessment of Tobacco and Health study. These efforts are complementary to the missions of each agency while helping to prevent data duplication.

- National Cancer Institute (NCI) uses 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 were articulated in *The Health Consequences of Smoking- 50 years of Progress: A Report of the Surgeon General* (USDHHS, 2014) and in *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General.* (USDHHS, 2012b).

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

Findings from the NYTS can 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 researchers in the legislative and executive branches of government can 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 to inform decisions related to policy approaches at national, state, and local levels.

- The NYTS can 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 can be used by state and local health and education agencies to assess disparities in tobacco use among racial/ethnic groups at the national level and make comparisons to the state and local levels.

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

- State Coordinated School Health programs can 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 can 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 can 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 can 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 can 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 can 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 can 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 have previously 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 previously used NYTS data to characterize the problem of youth tobacco use and to evaluate interventions to decrease tobacco use. Examples include:

    - NYTS data were used in the American Cancer Society (ACS) 2013 report *Cancer Prevention & Early Detection: Facts and Figures 2013* (ACS, 2013a). Likewise, the ACS cites NYTS data on their website on the page discussing who uses smokeless tobacco (ACS, 2013c).

    - The Robert Wood Johnson Foundation (RWJF) 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). RWJF also cited the NYTS in a 2002 report concerning making tobacco relevant

for Asian American and Pacific Island communities (Asian Pacific Partners for Empowerment and Leadership, 2002).

- The California Cancer Research Fund for the University of California funded a report that cites NYTS data used to address tobacco use among Asian American, Native Hawaiian, and Pacific Island communities in California (The University of California, 2012).

- American Legacy Foundation, or Legacy, (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. The ALF also used NYTS data in the 2005 study, Physician and dentist tobacco use counseling and adolescent smoking behavior: results from the 2000 National Youth Tobacco Survey (Shelley et al., 2005). Smoking among Asian American and Hawaiian/Pacific Islander youth: new data from the 2000 National Youth Tobacco Survey also cites the NYTS (Appleyard, Messeri, & Haviland, 2001), along with Tobacco Fact Sheet: Cigars, Cigarillos, and Little Cigars. (American Legacy Foundation, 2012).

- Professional organizations have previously 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 can 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.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.

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 through 12. The NYTS is inherently distinct

from other existing population-level surveys that are conducted with different areas of emphasis and/or with different populations.

Other surveys that ask tobacco-related questions include the Youth Risk Behavior Survey (YRBS) (OMB No. 0920-0493, exp. 9/30/2015, and the NSDUH, OMB No. 0930-0110). However, the YRBS is not duplicative of the NYTS. Unlike the YRBS, the NYTS gathers data among high school (grades 9th to 12th) students, as well as among middle school (grades 6th to 8th) students; NYTS is currently the ***only*** source of such extensive data on tobacco use among both middle and high school students in the United States. In addition, all other national surveys (YRBS, National Survey on Drug Use and Health (NSDUH), and Monitoring The Future (MTF)) are multi-risk factor surveys that can ask only a limited number of questions about specific risk behaviors. Tobacco use is related to a wide spectrum of other health behaviors and health outcomes, and thus, is a critical measure to include in surveys of many topics among youth and adults. However, the tobacco-related questions in those multi-purpose surveys cannot meet the needs specific to the evaluation of tobacco prevention and control activities at the national level.

Smaller-area surveys help to inform programmatic activities at state and local levels but are not designed to produce national estimates. CDC assists states with the implementation of their own state youth tobacco surveys (YTS), however, substantial variation across jurisdictions in sampling techniques, questions, and survey administration procedures prohibit the calculation of national estimates from state-level results. Therefore, 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 include differing questions and survey modes by design. For NYTS, the survey is administered at schools because that provides the most secure setting for youth and it is also where most youth are during weekdays. Additionally, NYTS has been specifically designed and adjusted to limit the administration of the survey to a single class period for to best accommodate respondents. This mode would not be suitable for adults. Similarly, some tobacco-use questions asked of youth, who are legally prohibited from purchasing tobacco and for whom tobacco use may be a recently acquired behavior, would not be appropriate for adults.

In the early 1990s the rapid rise in youth prevalence of tobacco use demonstrated the need for frequent assessments in order to identify such patterns in a timely manner in order to mitigate the damage. In addition, many changes are occurring in the tobacco control and tobacco product landscape, making it important to closely monitor their impacts on youth. In 2012, OMB approved the administration of the NYTS on an annual basis, and CDC and FDA began collaborating on ways to use the NYTS to help FDA inform its regulatory authority. Typically, NYTS instrument content in odd years will reflect an emphasis on information needed to inform CDC's non-regulatory public health approaches, and NYTS instrument content in even years will reflect an emphasis on information needed to inform FDA's regulatory activities. Thus, the survey is specifically being designed to avoid duplication while meeting the needs of both agencies. Beginning

in 2012, questions were added to the survey specifically related to FDA's regulatory authority, including awareness of tobacco product health warnings, perceptions about the harms of tobacco products, use of flavored tobacco products, symptoms of tobacco dependence, and ease of minors' access to tobacco.

For the 2015 NYTS, the CDC and FDA established a working group to obtain guidance and suggestions for new items on the questionnaire that would help facilitate the measurement of key data needed to address the missions of both agencies. Working group members include:

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Ahmed Jamal, MBBS Epidemiologist Phone: 770-488-5077 E-mail: AJamal@cdc.gov	Linda J. Neff, Ph.D., M.S.P.H. Branch Chief Phone: 770-488-8647 E-mail: LNeff@cdc.gov
David M Homa, Ph.D., M.P.H. Senior Scientific Advisor Phone: 770-488- 3626 E-mail: DHoma@cdc.gov	Brian A. King, Ph.D., M.P.H. Deputy Director For Research Phone: 770-488- 5107 E-mail: BaKing@cdc.gov
Shaohua S (Sean) Hu, DrPH, MD, MS Senior Epidemiologist Phone: 770-488- 5845 E-mail: FIK4 @cdc.gov	
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Karen A. Cullen, Ph.D., M.P.H. Epidemiologist Phone: 240-402-4513 E-mail: Karen.Cullen @fda.hhs.gov	Benjamin Apelberg, Ph.D., M.H.S. Branch Chief Phone: 301-796-8869 E-mail: Benjamin.Apelberg@fda.hhs.gov

In addition to CDC-FDA collaboration specific to the NYTS, enhanced review procedures were instituted in 2013 to promote overall efficiency and quality in federally-sponsored data collection relating to tobacco use and control. These efforts are coordinated through the HHS/Assistant Secretary for Planning and Evaluation (ASPE). An inter-agency workgroup was established under the HHS Data Council with representatives from HHS OPDIVS and programs collecting tobacco related data. The role of the group is to build infrastructure and connections to facilitate coordination and communication during the developmental stage of survey design to reduce duplication, improve response rates, reduce respondent burden, and promote standardization of estimates, where feasible. Representatives of the inter-agency workgroup have been consulted in the development of this ICR. Additional federal agencies consulted through this process include NCHS, NIH/NCI, NIH/NIDA, and SAMSHA.

The NYTS is the sole national comprehensive youth tobacco survey specifically designed to monitor and evaluate key short-term (knowledge and attitudes), intermediate (intentions), and long-term (behaviors) outcome indicators of comprehensive tobacco control programs and policies among a nationally representative sample of students in grades 6-12.

HHS/ASPE has approved submission of this Revision ICR for the NYTS.

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

The NYTS was initiated as a biennial survey in 1999. However, as witnessed during the past decade, youth tobacco use can increase or decrease rapidly, making biennial collection less optimal. On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act was enacted, which gave FDA the authority to regulate the manufacturing, distribution, and marketing of tobacco products. Under this new authority, a number of regulatory and enforcement actions are underway, 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), and enforcement of youth access restrictions. In order to ensure that FDA's goal of protecting young people from tobacco use is achieved, annual data collection is necessary to monitor the impact of FDA's actions on public health, as well as to measure emerging public health issues (such as increased use of currently unregulated tobacco products, like the doubling of ever use of e-cigarettes between 2011and 2012 among all 6^{th} to 12^{th} grade students (CDC, 2013a)). The collection of annual data has been particularly important in the early 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, CDC and FDA partnered to leverage the existing NYTS system to collect annual data that will be useful to both federal agencies. The annual NYTS monitors tobacco product use among the nation’s youth and collects key information which will assist both CDC and FDA in ensuring that both agencies are protecting the public’s health. The collaboration between CDC and FDA in administering the NYTS annually will help both federal agencies, as well as 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 1320.5. 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 Notice of the proposed data collection was published in the *Federal Register* on 06/25/2014: Volume 79, Number 122, pages 36067-8 (Attachment B1). Two public comments were received and acknowledged (Attachment B2). One comment was an expression of opinion about the value of the NYTS. The NYTS information collection request has been modified to address these comments and includes more information about the roles and strengths of NYTS. The other comment included specific suggestions regarding product terminology and the overall organization of questions on the survey instrument. Given the proliferation of relevant products, identifying terminology that is both broadly useful and sensitive to emerging trends will continue to be a challenge for surveillance. The 2015 NYTS reflects the results of instrument pre-testing and the most appropriate terminology at this time for key federal partners, given the constraints on survey length. OSH anticipates that the NYTS instrument will be updated for future cycles of survey administration, incorporating findings from a variety of research and surveillance efforts.

A.8.b Consultations

Consultations on the design, instrumentation, products, and statistical aspects of the NYTS have occurred at critical junctures during its original design and have continued since it originally received OMB clearance. 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.

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. 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. territory representatives to again solicit stakeholder input on the core YTS instrument.

Although Legacy was responsible for the design, instrumentation, education products, and statistical aspects of the first three cycles of NYTS, Legacy actively consulted with CDC and other partners during each survey cycle. The purpose of these consultations was to ensure the technical soundness; 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.

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) develop and implement a sampling plan that efficiently oversamples racial and ethnic minority groups; (2) optimize institutional receptiveness toward the survey and (3) effectively field an anonymous classroom-based survey that can be understood readily by respondents.

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

Schools will be given $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 review, have offered financial incentives to increase or 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

During recruitment, districts and schools 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 the parental permission forms. Additionally, at the start of the survey administration sessions, professionally trained NYTS data collectors will instruct students to not put their names anywhere on the survey instrument and remind them that their responses will be treated in an anonymous manner (Questionnaire Administration Script, Attachment I7). At the conclusion of the survey administration session, students will be instructed to place their completed surveys in an envelope and seal it. The sealed individual student envelopes will then be deposited into a classroom-specific envelope.

This data collection has received IRB approval from the CDC Human Research Protection Office. This approval is noted on the parental permission forms. The current NYTS IRB Approval Letter is in Attachment J.

A.10.1 PRIVACY IMPACT ASSESSMENT INFORMATION

1. Overview of the Data Collection System

The NYTS will be conducted with a nationally representative sample of 6-12 grade students in public and private schools, during January through May of 2015, 2016, and 2017. Gaining access to and support for the survey involves a tiered approach. We begin by contacting State Education Agencies and State Departments of Health to notify them

of the survey and request general guidance on working with the selected school districts and schools. We then contact selected districts to invite them to participate and obtain local approval to conduct the survey in selected schools. Once cleared at the school district level, selected schools will be invited to participate. After a school agrees to participate, a tailor-made plan for collection of data in the school will be developed (e.g., select classes, determine whether the survey will be administered to selected class sections simultaneously or in serial).

The NYTS takes about 35 minutes to complete. No individually identifiable information is collected on the survey (e.g., student name, class, school, etc.).

On the day of the survey, the data collector will bring all materials needed to conduct the survey. The data collector will work with the respective classroom teacher to determine which students have completed the necessary parental permission form process (using the Data Collection Checklist), and consequently are eligible to take the survey.

After the survey is completed, students will be instructed to place their completed survey in an envelope and seal it. The sealed individual student envelopes will then be deposited into a classroom-specific envelope. As the NYTS administration is completed in each selected class, the classroom-specific envelope will be deposited in a school-specific envelope labeled with a school identification number (for weighting purposes only). Sealed school packets will be transmitted by the NYTS trained data collector to the data collection contractor's survey processing center.

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

2. Information to be Collected

The 2015 NYTS 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, exposure to secondhand smoke, minors' access and enforcement, school curriculum, and cessation.

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 the paper-and-pencil questionnaire.

3. How Information will be Shared and for What Purpose

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 a professionally trained NYTS data collector.

All contractor staff involved with the project are required to sign a non-disclosure, intellectual property, non-competition and non-solicitation agreement which is a statement of personal commitment to safeguard data obtained.

4. Impact of Proposed Collection on Respondent's Privacy

Data collected from school administrators during recruitment is information that is already available in the public domain; school administrators will not provide personal information. The data collected on the NYTS are not identifiable.

As a means to monitor the parental permission form process and to ensure questionnaires are completed only by students for whom permission has been obtained, teachers are asked to enter student names on the Data Collection Checklist (similar to a class roll) (Appendix H1). Teachers can substitute any other information in place of student names (such as student ID numbers or letters) on the Data Collection Checklist as long as it will allow them to individually determine which students received parental permission to participate. This information will be conveyed to the data collector on the survey administration day.

The Data Collection Checklist is an optional tool to assist in managing the parental permission and student assent process. It will be destroyed at the end of the study. No individually identifiable information is collected on the NYTS survey (e.g., student name, class, school, etc.), therefore there is no way to connect students' names to their response data.

Participation in the NYTS should pose little or no effect on the respondent's privacy.

No individually identifiable information is collected on the NYTS survey (e.g., student name, class, school, etc.), therefore there is no way to connect students' names to their response data.

5. Voluntary or Mandatory 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.

6. Opportunity to Consent to Sharing and Submission of Information

Although teachers are asked to record student names or another identifier on the Data Collection Checklist (Attachment H1), this information is only used to manage the parental permission and student assent process. Consent to record and provide this information to the CDC or data collection contractor will not be sought. The Data Collection Checklist will be destroyed at the end of the study.

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.

7. Information Security

CDC's authorized 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 survey processing center. School personnel are not responsible for collecting and storing any data. The paper data will be stored in a locked file room (within a secured facility), 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.

8. Privacy Act Determination

Staff in the CDC Information Collection Review Office have reviewed this application and have determined that the Privacy Act does not apply. No identifying information will be retained in the data record that would enable an individual survey to be tracked back to a particular student.

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

Seventy-four 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 some 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 25 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 6-12) 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 seven questions are demographic factors, two of which ask about race and ethnicity, and two of which are mandatory questions from Department of Health and Human Services Office on Minority Health. 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.

A.12 ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

Federal tobacco control and surveillance activities must adapt to a dynamic product environment. From time to time, CDC may modify instrument content to reflect changes in the federal government's need for information to inform public health and regulatory activities. These modifications will be submitted to OMB through the Change Request mechanism.

Before requesting OMB approval of changes to the NYTS questionnaire, CDC may also conduct (i) cognitive testing of new questions, (ii) cognitive testing of proposed changes in the wording of, or response options associated with individual questions, and/or (iii) pre-testing of the NYTS instrument as a whole, to ensure that burden per response remains compatible with administration in one class period. Detailed descriptions of these information collections will also be submitted to OMB under the Change Request mechanism.

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 2015. Respondents include state-level, district-level, and school-level administrators who provide information in the Recruitment Scripts for the NYTS (Attachments E1, F1, and G1), teachers who complete the Data Collection Checklist for the NYTS (Attachment H1).

The NYTS will be conducted each year among a nationally representative sample of students attending public and private schools in grades 6 through 12. 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 2015 NYTS cycle. These figures may be adjusted slightly when a new contract is put in place for the 2016 and 2017 NYTS cycles.

For the 2015 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=220) who provide information in the Recruitment Script for the NYTS; teachers (n=973) who complete the Data Collection Checklist for the NYTS; and students (n=20,077) who receive instructions for and complete the NYTS questionnaire. There are no costs to respondents except their time.

The burden table also includes a new allocation of 78 annualized burden hours for instrument testing activities. Due to changes in the relevant product environment, patterns of use of tobacco and relevant products, or other factors, testing may be needed to assess new questions, changes in the wording of existing questions, or the response options associated with individual questions. The estimate of 78 burden hours per year was developed as follows. Cognitive testing of questionnaire content will typically be conducted in semi-structured interviews of one hour or less (30 interviews per year @ one hour per interview = 30 burden hours). In addition, CDC may conduct pre-tests to ensure that each year's NYTS questionnaire can be completed within one class period (30 tests per year @ 45 minutes/test = 23 hours). Finally, the allocation for testing includes screening of up to 150 youth prior to participation in testing activities (150 youth @ 10 minutes/response = 25 hours). Respondent screening may be needed to ensure that testing is conducted with individuals whose characteristics are similar to the NYTS target population of youth in grades 6-12. The configuration of testing activities may vary from year to year. For purposes of burden estimation, the total estimated number of respondents involved in testing is 150 and the adjusted average burden per response is 31 minutes/response. Each testing activity will be submitted to OMB as a Change Request. A partial example is provided in Attachment I9.

The total burden estimated for the NYTS and associated support activities is 15,582 hours. The totals for this cycle are provided in Table 1.

A.12.b Estimated Cost to Respondents

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 each category, the estimated respondent burden hours have been multiplied by an estimated average hourly salary for persons in that category. The U.S. Bureau of Labor Statistics is the source for hourly wages (http://www.bls.gov/oes/current/oes_nat.htm) (U.S. Bureau of Labor Statistics, 2014). 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 2015 NYTS is $80,944.

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	220	1	30/60	110
Teachers	Data Collection Checklist for the National Youth Tobacco Survey	973	1	15/60	243
Students	National Youth Tobacco Survey	20,077	1	45/60	15,058
	Testing Activities	150	1	31/60	78
				Total	**15,582**

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	$43.36	$759
District Administrators	District-level Recruitment Script for the National Youth Tobacco Survey	150	1	30/60	$58.18	$4,364
School Administrators	School-level Recruitment Script for the National Youth Tobacco Survey	220	1	30/60	$43.59	$4,795
Teachers	Data Collection Checklist for the National Youth Tobacco Survey	973	1	15/60	$27.55	$6,702
Students	National Youth Tobacco Survey	20,077	1	45/60	$4.25	$63,995
	Testing Activities	150	1	31/60	$4.25	$329
	Total					**$80,944**

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. GS-23F-9777H. The total contract award to ICF to conduct the 2015, 2016, and 2017 NYTS is $4,510,913. The cost of the contract, annualized over the three years of this clearance request, is $1,503,637. These costs cover the activities in

Table 3 below. Some activities will be conducted during the pre-clearance period and others will occur post-clearance.

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 $58.09 and $46.43 per hour, respectively. The direct annual costs in CDC staff time will be approximately $24,248 + $33,915 = $58,163 annually. The total estimated annualized cost for the study, including the contract cost and federal government personnel cost, is $1,561,800.

Table A14 - Annualized Study Cost

Activity	**Cost**
Contract Costs	
Design and plan	$154,522
Programming and developing	$135,326
Recruitment and preparation	$173,182
Printing and distribution	$41,778
Recruiting and training	$114,111
Collection of data	$672,073
Processing, cleaning, weighing and developing data files	$145,859
Dissemination and reporting of results	$66,730
Subtotal	$1,503,637
Federal Employee Time Cost	
20% time for one FTE	$24,248
35% time for one FTE	$33,915
Subtotal	$58,163
Total Estimated Annualized Cost to the Federal Government	$1,561,800

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

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

The 2015 NYTS instrument will be updated to observe patterns of use for both traditional tobacco products and emerging products, however, there are no changes to the estimated burden per response or frequency of data collection for the survey instrument, the recruitment scripts, or the checklist used by teachers. For the 2015-2017 approval period we are including a new allocation of 78 burden hours per year to allow for instrument testing activities.

There is a net reduction in the total estimated burden hours due to an expected overall reduction in the number of respondents for 2015-2017, when compared to the previous OMB approval period 2012-2014. The 2012-2014 NYTS approval was based on 25,836 annualized responses and 18,862 annualized burden hours. Current estimates for the 2015-2017 cycles of survey administration are based on estimates of 21,455 annualized responses and 15,582

annualized burden hours for 2015. The estimates for 2015 are used as annualized estimates for 2015-2017, although minor adjustments may be needed for 2016 and 2017, as explained below.

The actual number of NYTS respondents varies from year to year for two reasons:

1) The NYTS sample is typically smaller in odd-numbered years, which is when CDC administers the national Youth Risk Behavior Survey (YRBS, OMB No. 0920-0493, exp. 9/30/2015). On odd years, CDC coordinates the sampling draw for the NYTS and the YRBS to minimize the chance that the same school is recruited for participation in both surveys. Coordinated sampling and recruitment have a number of benefits, which include promoting positive interactions with school systems and maintaining adequate response rates for both NYTS and the national YRBS.

2) CDC uses an iterative sampling process to adapt to changes in the composition of the population of interest. Each year's NYTS dataset is analyzed in terms of school response rate, student response rate, and the characteristics of both schools and students. Prior to the selection of each annual sample, the adaptive sampling design is updated with a modified sampling frame which reflects the coordination with the national YRBS, population composition changes, as well as all the information gained during the most recent NYTS cycles (e.g., response rates and other sampling parameters). This iterative process results in a sampling plan unique for each year of NYTS administration that reflects the most current characteristics of the dynamic student population.

   Specifically, estimates for the 2015 NYTS also reflect a change in the sampling design for 2015 which reduces the number of respondents. The NYTS sampling design has been modified to reduce oversampling and the negative precision impact, i.e., the associated variance-inflating effects due to unequal weighting. With the lower design effects due to unequal weighting in the revised design, we expect to attain the same effective sample sizes with smaller total sample sizes.

Table A15 –
Annualized Estimates for the 2015 NYTS, with changes since previous OMB approval

Type of Respondent	Form Name	No. of Respondents	Change	No. of Responses per Respondent	Average Burden Per Response (In Hours)	Total Burden (In Hours)	Change
State Administrators	State-level Recruitment Script for the National Youth Tobacco Survey	35	0	1	30/60	18	0
District Administrators	District-level Recruitment Script for the National Youth Tobacco Survey	150	0	1	30/60	75	0
School Administrators	School-level Recruitment Script for the National Youth Tobacco Survey	220	-24	1	30/60	110	-12
Teachers	Data Collection Checklist for the National Youth Tobacco Survey	973	+157	1	15/60	243	+39
Students	National Youth Tobacco Survey	20,077	-4,514	1	45/60	15,058	-3,385
	Testing Activities	150	+150	1	31/60	78	+78
	Total	21,605	-4,231			15,582	-3,280

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 sex, 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 sex, grade in school, and race/ethnicity*--Cross tabulations, Chi-squared analyses, and regression analysis initially will be conducted to address this objective.

3. *Determine the associations between tobacco use behaviors and behavioral determinants* –Chi-squared 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 sex, grade in school, and race/ethnicity*-- Multiple regression analyses that controls for *sex,* 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*. The 2000 YTS and NYTS data and 2001-2002 YTS and NYTS data were published as *MMWR Surveillance Summaries* (CDC, 2001). Selected results from the 2004 NYTS were reported in an *MMWR* weekly article (CDC, 2005). 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 (CDC, 2009). 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, 2010). Updated data on current tobacco use among middle and high school students was published in a weekly *MMWR* summary in 2012 (CDC, 2012a). Two weekly *MMWRs* were published in 2013 describing e-cigarette use among middle and high school students (CDC, 2013a) and another report provided an overview of all tobacco product use among this population (CDC, 2013b). 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.

CDC and FDA also have released NYTS results through a variety of government publications, websites, peer-reviewed scientific journals, and annual conferences of national organizations focused on tobacco use, prevention and control, preventive medicine, public health, adolescent health, and epidemiology. A recent supplement was published in the American Journal of Preventive Medicine, with eight research articles co-authored by CDC and FDA describing new findings from the 2012 NYTS. An article was published in *JAMA Pediatrics* (Dutra & Glantz, 2014) to examine e-cigarette use and conventional cigarette smoking. In addition, data from the NYTS from 2000 through 2012 were used to assess patterns and trends of current tobacco use (cigarettes, cigars, and other tobacco products) among U.S. high school students (Arrazola et al., 2013). CDC hosted a podcast summarizing data on the popularity of emerging tobacco products, including e-cigarettes, among middle and high school students (Arrazola, R.A., 2013).

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 2015 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, 2015. The time schedule for the 2016 and 2017 data collection will be analogous to that of the 2015 data collection. Results will be published in early 2016 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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