**Information Collection Request**

Revision

# NATIONAL YOUTH TOBACCO SURVEY, 2021 - 2023

OMB No. 0920-0621, expires 04/30/2021

## SUPPORTING STATEMENT: PART A

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## TABLE OF CONTENTS

## LIST OF ATTACHMENTS

H5. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form (Active) and Fact Sheet (Spanish Version)

H6. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form (Active) and Fact Sheet (Spanish Version)

H7. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form Reminder Notice (English Version)

H8. National Youth Tobacco Survey Questionnaire Supplemental Documents – Parental Permission Form Reminder Notice (Spanish Version)

H9. National Youth Tobacco Survey Questionnaire Supplemental Documents – Questionnaire

- **Goal of the study**

The study is to design, conduct, and report on the school-based National Youth Tobacco Survey (NYTS) among 6th through 12th grade students in 2021, 2022, and 2023. The purpose of the survey is to assess student use of tobacco in a variety of forms; their knowledge of and attitudes toward tobacco; their exposure to secondhand tobacco smoke; and their exposure to influences that promote or discourage tobacco use, such as portrayals of tobacco in advertising and mass media, enforcement of age restrictions in the sales of tobacco to minors, provision of school- and community-based interventions, and access to supports in attempting to stop using tobacco.

- **Intended use of the resulting data**

The NYTS data will be used to inform the National Comprehensive Tobacco Control Program; inform progress towards achieving Healthy People 2030 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.

- **Methods to be used to collect**

Data for the NYTS shall be collected on a tablet via a digitally based self-administered questionnaire. For the NYTS, it is expected that an estimated 24,000 students attending approximately 320 schools will participate.

- **The subpopulation to be studied**

Contingent upon final analytic sample size, NYTS will provide data among subpopulations of youth, by race/ethnicity, sexual orientation, gender identity, mental health (depression/anxiety), and socio-economic status.

- **How data will be analyzed**

The NYTS data will be weighted to provide nationally representative estimates. Data sets and documentation for the NYTS available online. National trends and patterns of the distribution and determinants of tobacco use behaviors among youth enrolled in grades 6-12 can be compared by demographics and across years.

## OVERVIEW

CDC requests OMB approval to conduct the NYTS in 2021, 2022, and 2023 (OMB No. 0920-0621; exp. 4/30/2021). The survey instrument has been developed to include items that are relevant to the present circumstances in tobacco prevention and control efforts among youth. Burden allocation for instrument development and testing has been calculated to allow for cognitive testing related to potential questionnaire revisions that might occur after 2021. However, the estimated burden per response to complete the actual survey has not changed.

## A. JUSTIFICATION

### A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

Collection of data on tobacco use among youth reflects a critical public health priority. Tobacco prevention and control remains one of the strategic goals of the U.S. Department of Health and Human Services for advancing the health, safety, and well-being of the American People. Given that most tobacco initiation begins in adolescence, monitoring of tobacco use among youth is important. 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 NYTS measures short-term outcomes (such as increased knowledge about the negative health consequences of tobacco product 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, 2012; CDC, 2014). The justification for the implementation of the NYTS is based on three factors: (1) public health implications of tobacco use; (2) economic burden 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 A1). Specifically, the following factors make it necessary for the CDC to conduct the NYTS:

- The NYTS provides data to support several strategic planning priorities for the U.S. Department of Health and Human Services (DHHS), including CDC's Budget Request Summary for FY 2019-2021 (CDC, 2018b) on selected Government Performance and Results Act (GPRA) measures; DHHS's Tobacco Control Strategic Action Plan (USDHHS, 2012), and activities mandated by the Family Smoking Prevention and Tobacco Control Act. The NYTS is also the data source for 7 Healthy People 2030 objectives related to reducing adolescent prevalence of: current use of any tobacco products; current use of e-cigarettes; current use of cigarettes; current use of cigars, cigarillos, and little cigars; current use of flavored tobacco products; current use of smokeless tobacco products; and exposure to tobacco product marketing.

- The annual administration of NYTS has helped in the identification of emerging trends, such as the increased use of electronic cigarettes (e-cigarettes) from 2011 through 2018 (CDC, 2013; CDC, 2015; CDC, 2019), and allows for the development and inclusion of specific measures relevant to national objectives for tobacco prevention and control

among youth. The 2018 NYTS showed a dramatic increase in current e-cigarette use among both middle school and high school students; notably, prevalence increased by 78% among high school students during 2017-2018 (from 11.7 % to 20.8%) (FDA, 2018; CDC, 2019a). Driven by the increase in e-cigarette prevalence, the prevalence of any tobacco product use increased among both middle school and high school students, erasing the decline in youth tobacco product use that had occurred in previous years (CDC, 2019). More recently, the 2019 NYTS showed the prevalence of e-cigarette use further increased, with 1 in 10 middle school students and over 1 in 4 high school students having used e-cigarettes in the past 30 days (FDA-CDC, 2019; CDC. 2019b). Publications based on past cycles of the NYTS are listed in Attachment C.

- The NYTS serves as a national benchmark against which states can measure their progress in tobacco control and prevention. Many states conduct a Youth Tobacco Survey (YTS) whose methodology is comparable to the NYTS. States therefore 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 Global Youth Tobacco Survey (GYTS), which contains core questions found on both the YTS and the NYTS.

## A.2 PURPOSE AND USE OF INFORMATION COLLECTION

NYTS collects 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, and enforcement of minors' access laws. 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 tobacco control programs; and (4) inform the implementation of other key evidence-based policies that will prevent youth initiation, decrease the number of tobacco product users, and save lives.

NYTS data will be used, not only by CDC, but also by several other Federal agencies, including FDA. Additionally, the NYTS data can be used by state and local governments, nongovernmental organizations, academic institutions, and others in the private sector.

- CDC: uses NYTS data for evaluation of comprehensive tobacco control policies; measuring progress made in reaching national objectives (e.g., Healthy People 2030 objectives); policy and program development; research synthesis; and technical assistance to state, local, and other partners.

- FDA: uses the NYTS data over time to inform and monitor its regulatory authority over the manufacture, distribution, and marketing of tobacco products.

- Health Resources and Services Administration (HRSA): uses NYTS data to support HRSA, Maternal and Child Health Bureau (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 children, and adolescents.

- 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.

- Office of the Surgeon General: uses and references the NYTS results to assess the need for focused use of resources for tobacco prevention and control efforts targeting youth. NYTS data have figured prominently in recently released reports. Based on findings from the 2018 NYTS (FDA, 2018; CDC, 2019), the U.S. Surgeon General issued an advisory on e-cigarette use among youth, declaring the increased use as epidemic. (OSG, 2018).

- State and local governments: use NYTS data as an index against which state and local health and education agencies can compare their state YTS results. Attachment B lists state tobacco control reports that cite NYTS data. State and local law enforcement officials also 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.

- Nongovernmental organizations, foundations, and academic institutions (e.g. American Cancer Society; The Robert Wood Johnson Foundation; The California Cancer Research Fund for the University of California; the Truth Initiative; the American Medical Association; and The Institute of Medicine): have extensively used NYTS data in official reports, white papers, and fact sheets. Additionally, academic researchers use data from NYTS for research and surveillance.

## A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

From 1999-2018, the NYTS was administered via a paper-and-pencil questionnaire. However, after successfully completing a pilot survey in 2018 to assess the feasibility of conducting the NYTS using an electronic mode of administration, the NYTS fully transitioned to a digital-based survey mode in 2019. Participants were provided with a tablet to complete the survey in schools; data were collected offline using a programmed survey application. Students absent on the day of survey administration could complete a make-up survey using a web-based version of the survey programmed to mimic the tablet-based application.

This transition allowed for the programming of skip instructions to tailor the questionnaire to the individual tobacco product use status of respondents. In addition to improving both the overall detail and validity of responses, the transition was expected to result in reduced burden time, as individuals are not asked to read through and answer questions that are not applicable to their current tobacco product use behaviors. Preliminary estimates of response time burden from administration of the 2019 survey suggested that the average time to complete the survey (104 questions, with programmed skip instructions) was about 12.5 minutes (after exclusion of outliers). However, the allotted burden time for the 2019 digital-based survey remained the same as when the NYTS was administered by paper-and-pencil, allowing for one class period (up to

45 minutes) for survey completion. Time to complete the 2020 survey is not expected to exceed the burden level from past administrations of NYTS, and this is expected to remain the same for the 2021-2023 surveys; all respondents will be allowed up to one 45-minute class period to complete the survey. Thus, overall respondent burden has been kept at the same level for the current 2021-2023 cycle.

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

In order to minimize duplication of data collection and the burden on survey participants, the CDC and the Food and Drug Administration (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 target population of NYTS (grades 6-12) makes it inherently distinct from other school-based surveys such as the national Youth Risk Behavior Survey (grades 9-12); and Monitoring The Future (grades 8, 10, and 12). While other multi-purpose household surveys also sample youth (such as the National Survey on Drug Use and Health (NSDUH) and the National Health and Nutrition Examination Survey (NHANES)) and contain some tobacco-related content, the scope of these tobacco-specific questions cannot meet the needs specific to the evaluation of tobacco prevention and control activities at the national level.

In addition to the 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. 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. Federal agencies consulted through this process include NCHS, NIH/NCI, NIH/NIDA, and SAMSHA.

## 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

NYTS currently is conducted annually. Conducting it less than annually will adversely impact the ability to assess emerging trends. This will be particularly important for assessing progress toward reaching Healthy People 2030 national targets for tobacco control. Furthermore, the tobacco product environment is rapidly evolving; CDC and other public health agencies need annual data to identify and track emerging products and issues and to inform public health

policies and actions. For example, after increasing from 2011-2015, youth e-cigarette use declined during 2016 and 2017, followed by a rapid 1-year increase from 2017 to 2018, from 11.7% to 20.8% among high school students (FDA, 2018; CDC, 2019). The prevalence of e-cigarette use among both middle school and high school students increased further in 2019, with 27.5% of high school students and 10.5% of middle school students reporting past 30 day use (FDA-CDC, JAMA, 2019). A less frequent NYTS administration would not have been able to track these nuanced changes in e-cigarette use and resulting changes in overall tobacco product use among youth. Furthermore, FDA also requires annual monitoring of youth tobacco use behavior to inform and evaluate tobacco regulatory policies. 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. The annual NYTS monitors tobacco product use among the nation's youth and collects key information that 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

### Federal Register Announcement

A 60-day Federal Register Notice (Attachment A2) was published in the Federal Register on January 23, 2020, Docket no. CDC-2019-0117, volume 85, no 15, document no. 2020-01042, pages 3916-3918.

Six comments were received through the 60-day FRN. CDC's responses to these comments are provided in Attachment A3.

### Consultations

Since 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.
Consultations on the design, instrumentation, products, and statistical aspects of the NYTS have been made with these experts 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. Some of these experts are shown in in Table A.8 below.

**Table A.8: Consultants for 2021-2023 NYTS**

| **Office on Smoking and Health,<br>Centers for Disease Control and Prevention<br>4770 Buford Highway NE, Atlanta GA 30341** | |
|---|---|
| Linda J. Neff, Ph.D., M.S.P.H.<br>Chief, Epidemiology Branch<br>Phone: 770-488-8647<br>E-mail: LNeff@cdc.gov | David Homa, Ph.D., M.P.H.<br>Senior Science Advisor, Epidemiology Branch<br>Phone: 770-488-3626<br>E-mail: DHoma@cdc.gov |
| Brian A. King, Ph.D., M.P.H.<br>Deputy Director for Research Translation, Office of the Director<br>Phone: 770-488-5107<br>E-mail: BaKing@cdc.gov | Ahmed Jamal, MBBS, M.P.H.<br>Surveillance Team Lead, Epidemiology Branch<br>Phone: 770-488-5077<br>E-mail: AJamal@cdc.gov |
| Katrina Trivers, Ph.D., M.S.P.H<br>Research Team Lead, Epidemiology Branch<br>Phone: 404-498-6861<br>Email: KTrivers@cdc.gov | Sean Hu, MD, Dr.P.H.<br>Senior Epidemiologist, Epidemiology Branch<br>Phone: 770-488-5845<br>E-mail:SHu@cdc.gov |
| Andrea Gentzke, Ph.D., M.S.<br>Health Scientist, Epidemiology Branch<br>Phone: 404-498-1795<br>Email: AGentzke@cdc.gov | Teresa Wang, Ph.D., M.S.<br>Epidemiologist, Epidemiology Branch<br>Phone: 404-498-1502<br>E-mail: TWWang@cdc.gov |
| | |
| **Center for Tobacco Products,<br>Food and Drug Administration<br>10903 New Hampshire Avenue, Silver Spring, MD 20993** | |
| Bridget Ambrose, Ph.D., M.P.H.<br>Deputy Director, Division of Population Health Science<br>Phone: 301-796-4235<br>E-mail: Bridget.Ambrose@fda.hhs.gov | Benjamin Apelberg, Ph.D., M.H.S.<br>Director, Division of Population Health Science<br>Phone: 301-796-8869<br>E-mail: Benjamin.Apelberg@fda.hhs.gov |
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| Michael Sawdey, Ph.D., M.P.H.<br>Epidemiologist, Epidemiology Branch 2<br>Phone: 301-796-3452<br>Email: Michael.Sawdey@fda.hhs.gov | Kimberly Snyder, M.P.H.<br>Social Scientist, Evaluation Branch<br>Phone: 240-402-2216<br>E-mail: Kimberly.Snyder@fda.hhs.gov |

## A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

Schools will be given $500 in appreciation for their participation in NYTS, which is consistent with previous years of NYTS implementation (2011-2020). 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 PROTECTION OF THE PRIVACY AND CONFIDENTIALITY OF INFORMATION PROVIDED BY RESPONDENTS

The CIO's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. This determination is based on the fact that the information that will be collected within NYTS is not considered a "record" as defined by the Privacy Act: it will not include individuals' financial transactions, medical history, criminal or employment history, name, or the identifying number, symbol, or other identifier assigned to any individual, such as a finger or voice print or a photograph. 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. 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. Participants can choose to leave the study at any point. Participants also can choose to skip any questions they find uncomfortable.

The NYTS does not collect any student-level personal identifiers. Furthermore, school-level identifiers and sub-national level identifiers (e.g., state code) are not included in the final analytic dataset to protect the privacy and confidentiality of individual respondents. The sampling variables in the dataset, required for use in analysis using complex sampling procedures, have been modified so that users cannot identify locations based on these variables. The Primary Sampling Unit (PSU) ID is created using an algorithm seeded by a random number. SAS is used to create the new PSU ID as a function of the Original PSU. A PSU crosswalk, not available in the public use data release, is provided by the contractor to CDC OSH.

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 and protection of privacy are promised to students on parental permission forms (Attachments H3, H4, H5, H6). Students will be reminded that their responses are anonymous at the start of the survey administration session by a professionally trained NYTS data collector. Access controls used to secure and protect collected data are listed in Table A.10.

**Table A.10: Access Controls**

| Technical Controls | Physical Controls | Administrative Controls |
|---|---|---|
| • User identification<br>• Passwords<br>• Firewall<br>• Virtual Private Network (VPN) | • Guards/Security Officers<br>• 24-hour maintenance of Video/Audio of all data centers and all offices<br>• Identification badges<br>• Key Cards | 1. No directly identifying information will be collected (thus, the Privacy Act does not apply).<br>2. Methods will be in place to ensure least privilege. Data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study.<br>3. 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.<br>4. NYTS data are currently stored on the CDC network in an access-restricted CDC shared directory folder (\\cdc.gov\project\NCCD_OSH_NYTS). Two versions of this shared directory have been created, one version providing read-only access to files and the other version providing full access. The NYTS project leader, Dr. Ahmed Jamal, manages access to the shared directory. Currently, these files containing the raw and final data for each year of the NYTS is only accessible to OSH Epidemiology branch leadership and the NYTS implementation team members. |

## A.11 INSTITUTIONAL REVIEW BOARD (IRB) AND JUSTIFICATION FOR SENSITIVE QUESTIONS

All procedures have been developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. This data collection has received IRB approval from the CDC Human Research Protection Office. This approval is noted on the parental permission forms. Current NYTS IRB Approval Letters are in Attachments J1 and J2.

### Sensitive Questions

Although unlikely, certain questions asked during the survey about tobacco use could be considered by some individuals to be sensitive, although tobacco product use behaviors would not generally be considered highly sensitive. Of note, the 2020 NYTS survey was approved to begin collecting information related to sexual orientation. The data collection instrument for 2021 also has proposed asking questions related to gender identity, depression and anxiety, and socio-economic status, all of which are associated with higher tobacco product use. As with other questions on the NYTS, participants may choose to skip any question they are not comfortable answering. Furthermore, no protected personal information is being collected in this study that could trace responses back to individual students.

## 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 also may conduct (i) cognitive testing of new questions or proposed changes in the wording of, or response options associated with individual questions, and/or (ii) 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 also will be submitted to OMB under the Change Request mechanism.

### Estimated Burden Hours

The estimated burden for this information collection is based on over 20 years of experience conducting the NYTS. The planned information collection involves administration of the NYTS questionnaire (Attachment H1) to independent samples of students in the spring of 2021. Respondents include state-level, district-level, and school-level administrators who provide information in the Recruitment Scripts for the NYTS (Attachments D1, E1, and F1), teachers who complete the Data Collection Checklist for the NYTS (Attachment G1). For the 2021 cycle of data collection, the total estimated number of respondents, by type, will include: state-level administrators (n=33), district-level administrators (n=253), and school-level administrators (n=281) who provide information in the Recruitment Script for the NYTS; teachers (n=1,177)

who complete the Data Collection Checklist for the NYTS; and students (n=24,000) who receive instructions for and complete the NYTS questionnaire. There are no costs to respondents except their time.

Burden estimates are based on expected sample sizes and budget under the current contract for conducting the 2018-2020 NYTS cycle. Due to changes in the relevant product environment, patterns of tobacco product use, 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 burden table includes an additional allocation of 75 annualized burden hours for instrument testing activities, resulting in 153 total annualized burden hours for these testing activities (up from 78 in previous package). The estimate of 153 burden hours per year was developed as follows. Cognitive testing of questionnaire content will typically be conducted in semi-structured interviews of two hours or less (40 interviews per year @ two hours per interview = 80 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 300 youth prior to participation in these testing activities (300 youth @ 10 minutes/response = 50 hours). Such respondent screening is 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, no more than 300 respondents will be included in screening activities (10 minutes a response). Of those 300 respondents, no more than 40 may participate in cognitive testing (120 minutes a response) and no more than 30 may participate in survey pretesting activities (45 minutes a response). Each testing activity will be submitted to OMB as a Change Request.

The total burden estimated for the NYTS and associated support activities is 18,733 hours. These totals for this cycle are provided in Table A.12a.

**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. Wages are based on May 2018 national data on occupational employment and wages published by the U.S. Bureau of Labor Statistics (USBLS 2019). 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 2021 NYTS is $105,864 (Table A.12b).

**Table A.12a: 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 | 33 | 1 | 30/60 | 17 |
| District Administrators | District-level Recruitment Script for the National Youth Tobacco Survey | 253 | 1 | 30/60 | 127 |
| School Administrators | School-level Recruitment Script for the National Youth Tobacco Survey | 281 | 1 | 30/60 | 141 |
| Teachers | Data Collection Checklist for the National Youth Tobacco Survey | 1,177 | 1 | 15/60 | 295 |
| Students | National Youth Tobacco Survey | 24,000 | 1 | 45/60 | 18,000 |
| | Cognitive Testing | 40 | 1 | 120/60 | 80 |
| | Survey Pre-tests | 30 | 1 | 45/60 | 23 |
| | Testing Activities | 300 | 1 | 10/60 | 50 |
| | | | | **Total** | **18,733** |

**Table A.12b: 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 | 33 | 1 | 30/60 | $60.23 | $994 |
| District Administrators | District-level Recruitment Script for the National Youth Tobacco Survey | 253 | 1 | 30/60 | $70.23 | $8,885 |
| School Administrators | School-level Recruitment Script for the National Youth Tobacco Survey | 281 | 1 | 30/60 | $63.38 | $8,905 |
| Teachers | Data Collection Checklist for the National Youth Tobacco Survey | 1,177 | 1 | 15/60 | $33.75 | $9,931 |
| Students | National Youth Tobacco Survey | 24,000 | 1 | 45/60 | $4.25 | $76,500 |
| | Cognitive Testing | 40 | 1 | 120/60 | $4.25 | $340 |
| | Survey Pre-tests | 30 | 1 | 45/60 | $4.25 | $96 |
| | Testing Activities | 300 | 1 | 10/60 | $4.25 | $213 |
| | **Total** | | | | | **$105,864** |

## 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 NYTS currently is funded through 2022 under Contract No. 200-2017-F-96232. The total contract award to ICF (Rockville, MD) to conduct the 2021 and 2022 NYTS is $5,777,520. The estimated cost of the contract, annualized over two of the three years of this clearance request, is $2,888,762. These costs cover the activities in Table A.14 below. Some activities will be conducted during the pre-clearance period and others will occur post-clearance. The contract will be up for rebid for 2023 and forward; study costs are expected to be comparable.

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 three CDC employees will be involved for approximately 40% of time (one at a salary of $59.86 per hour and two at salaries of $42.60 per hour) and one CDC employee 70% of time at a salary of $50.66 (based on 2019 General Schedule Locality Pay Tables for Atlanta, GA; for federal personnel 100% time = 2,080 hours annually). The direct annual costs in CDC staff time will be approximately $120,690 + $73,761 = $194,451 annually. The total estimated annualized cost for the study, including the contract cost and federal government personnel cost, is $3,083,213.

**Table A.14: Estimated Annualized Study Cost**

| **Activity** | **Cost** |
|---|---|
| *Contract Costs* | |
| Design and plan | $186,415 |
| Programming and developing | $53,783 |
| Recruitment and preparation | $936,952 |
| Printing and distribution | $42,076 |
| Recruiting and training | $142,701 |
| Collection of data | $1,331,590 |
| Processing, cleaning, weighing and developing data files | $135,086 |
| Dissemination and reporting of results | $60,159 |
| Subtotal | $2,888,762 |
| *Federal Employee Time Cost* | |
| 40% time for three FTEs | $120,690 |
| 70% time for one FTE | $73,761 |
| Subtotal | $194,451 |
| Total Estimated Annualized Cost to the Federal Government | $3,083,213 |

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

## A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

The 2018-2020 NYTS instruments were revised through non-substantive change requests to maintain valid surveillance of both traditional and emerging tobacco products as well as obtain other data relevant to the youth tobacco use environment. The content of the 2021 instrument remains largely consistent with the past NYTS surveys. For 2021-2023, there are no changes to

the estimated burden per response, the frequency of data collection for the survey instrument, the recruitment scripts, or the checklist used by teachers. For this approval period, we are including an allocation of 55 new burden hours per year to allow for instrument testing activities (133 burden hours, total).

We have increased the number of school districts contacted, and thus the number of schools in the sample, in an effort to adjust further for nonresponse and to achieve a sample of approximately 24,000 middle school and high school students. This therefore increases the overall burden estimate slightly relative to the previous cycle. The 2018-2020 NYTS approval was based on 25,614 annualized responses and 18,537 annualized burden hours. Current estimates for the 2021-2023 cycles of survey administration are based on estimates of 26,114 annualized responses and 18,733 annualized burden hours for 2021.

**Table A.15: Annualized Estimates of Respondents and Burden, 2021-23 NYTS**

| Type of Respondent | Form Name | No. of Respondents | Change from 2018-20 | No. of Responses per Respondent | Average Burden Per Response (In Hours) | Total Burden (In Hours) | Change from 2018-20 |
|---|---|---|---|---|---|---|---|
| State Administrators | State-level Recruitment Script for the National Youth Tobacco Survey | 33 | -5 | 1 | 30/60 | 17 | -2 |
| District Administrators | District-level Recruitment Script for the National Youth Tobacco Survey | 253 | +100 | 1 | 30/60 | 127 | +50 |
| School Administrators | School-level Recruitment Script for the National Youth Tobacco Survey | 281 | +41 | 1 | 30/60 | 141 | +21 |
| Teachers | Data Collection Checklist for the National Youth Tobacco Survey | 1,177 | +204 | 1 | 15/60 | 295 | +52 |
| Students | National Youth Tobacco Survey | 24,000 | 0 | 1 | 45/60 | 18,000 | 0 |
| | Cognitive Testing | 40 | +10 | 1 | 120/60 | 80 | +50 |
| | Survey Pre-tests | 30 | 0 | 1 | 45/60 | 23 | 0 |
| | Testing Activities | 300 | +150 | 1 | 10/60 | 50 | +25 |
| | Total | 26,114 | +500 | | | 18,733 | +196 |

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

### Tabulation Plans

Data will be tabulated in ways that will address the principal research purposes outlined in A.2. Some of the planned analyses and the sample table shells are shown in Attachment K. Data will be summarized using descriptive analyses, including percentages, means, and interquartile ranges. Within-group comparisons will be made using chi-squared tests, ANOVA, and F-statistic, as appropriate. Multivariable analyses will be done using regression models.

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 L.

### Publication Plans

This information will be used to inform the development of policy briefs, official reports, and peer reviewed scientific papers for publication in journals. Annually, the official estimates of national youth tobacco product use typically are featured in *MMWR*; beginning with the 2019 cycle, the annual estimates were published as a *MMWR* Surveillance Summary (CDC, 2019b). However, other NYTS findings have been published in high profile peer review journals such as the *Journal of the American Medical Association (JAMA), American Journal of Public Health*, the *American Journal of Preventive Medicine*, and *JAMA Pediatrics.* 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.

**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 one months before schools close for the summer.

Key project dates will occur during the following time periods for the 2021 data collection:

**Table A.16: Schedule of Activities for 2021 NYTS**

| **Activity** | **Time Period** |
|---|---|
| Recruit and schedule schools | 1 to 3 months after OMB clearance |
| Program digital survey | <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 February through May 2021. The time schedule for the 2022 and 2023 data collections will be analogous to that of the 2021 data collection. Results will be published by early 2022 initially in *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

There are no exceptions to the certificate.

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