United States Food and Drug Administration

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Center for Tobacco Products

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NATIONAL YOUTH TOBACCO SURVEY, 2024 - 2026

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OMB Control No. 0910-0932

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SUPPORTING STATEMENT PART B

Part B: Statistical Methods

Since 2021, the NYTS has been administered electronically using a pre-programmed web-based survey. Participating students access the survey through a URL. The questionnaire incorporates skip logic to tailor the questionnaire based on respondents' tobacco product use behaviors. Thus, respondents are not asked to respond to questions that do not apply to them, reducing overall respondent burden. Non-branded product images are included in the electronic questionnaire to improve product recognition and recall. Overall, these changes improve validity of response and enhance data quality.

There were no changes of mode of administration between 2021 and the 2024-2026 NYTS. The 2026 NYTS will use the general sampling design framework used in the previous cycles. This survey will be a repeat cross-sectional design to develop annual national estimates of tobacco product use behaviors and correlates among U.S. students enrolled in grades 6-12.

1. Respondent Universe and Sampling Methods

The universe for the study will consist of students in 6^{th} through 12^{th} grade that attend public and private schools in the 50 U.S. States and the District of Columbia. Private schools will include both religious and non-religious schools.

The sampling frame combines the Common Core of Data and the Private School Survey (PSS) from the National Center for Education Statistics (NCES) with school data from Market Data Retrieval Inc. The frame will be subset to schools that are "regular schools." The following schools are not defined as "regular" schools, are considered ineligible, and will be removed from the sampling frame: special education schools, Department of Defense-operated schools, Bureau of Indian Affairs schools, adult education schools, vocational schools, and alternative schools.

2. Procedures for the Collection of Information

Statistical Methodology for Stratification and Sample Selection

A national probability sample will be selected for estimation of tobacco-related knowledge, attitudes, and behaviors in a national population of public and private school students enrolled in grades 6 through 12 in the United States. More specifically, the study is designed to produce precise national estimates by school level (middle and high school), by grade (6, 7, 8, 9, 10, 11, and 12), by sex (male and female), and by race and ethnicity (non-Hispanic white, non-Hispanic Black, Hispanic, non-Hispanic Asian, and non-Hispanic American Indian / Alaskan Native). Additional estimates also are supported for subgroups defined by grade, sex, and race-ethnicity, each within school-level domains; however, precision levels vary considerably according to differences in subpopulation sizes. Additional details of the sampling plan are provided in Attachment L.

Sampling Frame and Stratification. For the 2026 NYTS survey, we will use a frame that combines two files from the NCES; the Common Core Dataset (CCD) which is a national file of public schools and the Private School Universe Survey Dataset (PSS), a file of national non-public schools, with school data from Market Data Retrieval Inc. The principle behind combining multiple data sources is to increase the coverage of schools nationally. The following schools will be considered ineligible and removed from the file: special education schools, Department of War-operated schools, Bureau of Indian Affairs schools, adult education schools, vocational schools, and alternative schools. Schools with an enrollment of fewer than 40 students across the eligible grades will be removed from the frame. Less than 1% of students attend schools with fewer than 40 students. The target population is all "regular" public and private schools in the 50 U.S. states and the District of Columbia with an enrollment of 40 or more students across the eligible grades.

The frame will be partitioned into 7 strata. Two strata consist of schools with high densities of non-Hispanic American Indian /Alaskan Native (hereafter, AI/AN) students. Two strata consist of schools with high densities of non-Hispanic Asian (hereafter, Asian) students. The other 3 strata contain all other schools with only middle school students, only high school students, or with both middle school and high school students. This stratification scheme allows for the number of respondents by school level to be controlled and for oversampling of AI/AN and Asian students to achieve the goal of collecting data on a minimum of 1,000 responding AI/AN and Asian students.

The sample will be structured into geographically defined units, called primary sampling units (PSUs). PSUs are groups of schools within strata and must have at least 10 schools. In high density AI/AN and Asian strata, PSUs are formed by sorting the schools by state Federal Information Processing Standards (FIPS) and county FIPS code and partitioning the list of schools into groups with about 6,000 students per group. In the other strata, in counties with more than 100,000 students, the schools are sorted by ZIP Code and partitioned into multiple PSUs containing between 50,000 and 100,000 students each. For counties that have fewer than 2,500 eligible students, the schools are joined with the schools in other small counties within the same state to form PSU's with at least 2,500 eligible students. In all other counties, the group of schools in the county form a unique PSU.

We will impose a school size threshold as an additional criterion for eligibility. By removing schools with an aggregate enrollment of less than 40 students across eligible grades (grades 6–

12) from the frame, we will improve efficiency and safeguard privacy. The coverage losses are less than 1% of eligible students.

Selection of PSUs. A total of 182 PSUs will be selected using a systematic selection with probability proportional to the student enrollment in the PSU. Within strata, the PSUs are sorted by state FIPS code and county FIPS code, ensuring geographic diversity in the sample. The sampling fractions, the probability of selection of each PSU within a stratum, will be adjusted to ensure the number of responding AI/AN and Asian students is a minimum of 1,000, and that approximately three-sevenths of the responding students are middle school students.

Selection of Schools (Secondary Sampling Units, SSUs). Within each selected PSU, 3 schools are selected using systematic sampling with a random start and probabilities proportional to size (PPS). Probabilities of school selection are proportional to a measure of size (MOS) that is based on the student enrollment for each school. Except for very large schools and very small schools, the MOS is exactly equal to the enrollment in the target grades.

Selection of Classes (Tertiary Sampling Units, TSUs). In the third stage classes are selected. To select classes, within each selected school, the probability of each student being selected is calculated. This probability is defined as the overall sampling rate divided by the product of the probability of the first and second stage of selection. Consequently, every sample member within a stratum has an equal probability of selection. Within each school, the class sampling interval is defined as the inverse of the stage 3 probability of selection.

Within each selected school, the class sampling interval is applied to a random start. For example, for a school with 480 students and a class sampling interval of 4, the random start is a random number between 1 and the sampling interval (4). For example, the random start is 3. The following classes are selected for the survey: 3, 7, 11, 15, … . (3 + 4 = 7, 7 + 4 = 11, etc.) The school coordinator orders the classes in all grades. If there is a total of 8 classes, the 3rd and 7th classes are selected based on the ordering. It is expected that only a portion of the total list of classes will exist and be available. The number of classes in a school is unknown before contacting the school, so, the sampling team will pick a larger number of classes than will be used.

Selection of Students within class (Not considered a sampling stage). In each class, the entire census of students is selected.

Ineligible schools. We expect approximately 4% of the selected school will be ineligible due to frame error. The ineligible schools will be replaced with the next school on the sample frame.

Refusals. School districts, schools, or students who refuse to participate in the study will not be replaced in the sample. We will record the characteristics of schools that refuse along with reasons given for their refusal for analysis of potential study biases.

Estimation and Justification of Sample Size

The NYTS is designed to produce the key estimates with a relative standard error less than 30% and an margin of error for a 95% confidence interval of 5%. Estimates by school level, grade, sex, and grade cross-tabulated by sex, meet this standard, as do estimates for racial/ethnic groups by school level (middle and high school).

Historically, an initial sample size of 420 schools was sufficient for recruiting the targeted number of schools and students. However, overall response rates have decreased drastically since the COVID-19 pandemic. Consequently, additional schools need to be recruited for the 2026 NYTS to reach the goal of obtaining at least 250 participating schools. We will sample 546 schools with the expectation of obtaining up to 28,704 responding students and up to 285 responding schools. We will have adequate precision to make estimates for domains with 1,000 students. All the high priority domains are projected to have at least 1,000 responding students. The number of sampled students was increased from prior years in an effort to allow for valid estimation among all five major racial and ethnic groups (non-Hispanic White, non-Hispanic Black, Hispanic, Asian, and American Indian or Alaska Native [AI/AN]).

To calculate the number of schools and students to sample that will produce enough responding schools and students to ensure adequate precision, we estimated the school and student response rate and the school eligibility rate. Through 15 iterations of the NYTS between 1999 and 2019, the overall response rate ranged from 63.4% to 84.8%. Whereas, during the COVID-19 pandemic years (2020–2024), the overall response rate ranged from 30.5% to 45.2%. Unfortunately, estimating future response rates is difficult due to the rapidly changing school environment. We believe that the school environment, as related to response rates, is improving. We assume a 38% overall response rate for the 2026 NYTS; this was the overall response rate observed in the 2024 NYTS, the latest iteration of the NYTS where the full data collection period was observed.[1] The estimated overall response rate accounts for the challenges in recruiting schools located in states that have proposed or enacted policies that require active parental consent for youth surveys and/or prohibit the use of what districts and schools have referred as “sensitive content” (e.g., items about mental health, sexual orientation, and other questions that may have legal implications, such as underage purchasing of tobacco products).

Attachment L contains details of the justification for the sample size and an analysis of precision of various domains.

Estimation and Statistical Testing Procedures

Sampling weights will be calculated. The sample weights reflect the number of population members each respondent represents and are used in the analysis to link the respondents to the population. The base weight of each school is the inverse of the probability of selecting each school. A school-level nonresponse adjustment is applied, a class-level nonresponse adjustment is applied, then a student-level nonresponse adjustment is applied. Finally, the nonresponse adjusted weights are calibrated to population totals estimated from the sampling frame. The

[1] The relevant 2024 overall response rate is the product of the 2024 school response rate from the first wave of data collection (48.3%) times the student response rate (78.3%). For the 2025 survey cycle, data collection terminated early.

distributions used in the calibration for public schools are grade by sex, and grade by race/ethnicity; private schools are only calibrated to grade.

Survey Instrument

The 2026 NYTS questionnaire (Attachment H1) contains 160 items. The first set of questions on the questionnaire gather demographic data. Most of the remaining questions address the following tobacco-related topics: tobacco use (e-cigarettes, cigarettes, smokeless tobacco [chewing tobacco/snuff/dip], cigars [cigars, little cigars, cigarillos], hookah, roll-your-own tobacco, pipes, snus, oral nicotine products, bidis, heated tobacco products, and nicotine pouches), knowledge and attitudes, media and advertising, minors' access and enforcement, cessation, and environmental exposure to tobacco smoke from combustible tobacco products, secondhand aerosol from e-cigarettes, discrimination and neighborhood environment.

The questionnaire incorporates skip logic to tailor the questionnaire based on respondents' tobacco product use behaviors. Thus, respondents are not asked to respond to questions that do not apply to them, reducing overall respondent burden. Product images also are included in the electronic questionnaire to improve product recognition and recall. Given the efficiencies gained by transitioning to an electronic administration, previous "check all that apply" type questions related to flavored tobacco use and access to tobacco products are now asked separately for each specified tobacco product. This will allow for differentiation in patterns of use for individual products.

Data Collection Procedures

RTI International serves as the data collection contractor for NYTS (see Section B.5). The NYTS is administered as a web-based study via a URL provided to the teachers. Study Liaisons will be trained and available to help troubleshoot technical issues that arise during the session, if needed. The students will be allowed to take the survey in any location using the URL. The following describes the data collection procedures that will be used for the web-based administration of NYTS.

Class Selection
Once each school agrees to participate, a school coordinator is identified to work with the NYTS study liaison to coordinate the logistics of the session. The school coordinator provides a list of classes for each selected grade from which one or two classes per grade are sampled to participate. The school coordinators then work with the classroom teachers of the sampled classes to distribute the parental permission forms and administer the survey to the students.

Web-based survey
The 2026 NYTS will be administered electronically using a pre-programmed web-based survey. Participating students will access the survey using an internet-connected device. The web-based survey is designed to simulate the tablet-based survey. As in previous years, the web-based survey also will be used to obtain make-up surveys from eligible students who are absent on the initial date of data collection.

A classroom-level access code, rather than an individual one, is used to ease the burden on the teachers of the survey (e.g., distribution of printed, individual student sign-in cards is no longer needed). Additionally, this approach is used for privacy concerns to avoid linking unique student-level access codes to individual students (such as through email or other electronic forms of communication or by someone seeing another student's ID card).

If a student's internet connection gets disrupted, or if they need to step away from the survey prior to submitting their responses, they may log out of the web survey application and log back in using the classroom code. As long as the student uses the same computer and web browser to log back into the survey, the survey will restart where the student left off. With the Qualtrics web-based survey platform, this feature is available without having to provide each student an individual ID number.

In-Class Data Collection Procedures

For students physically attending in the classroom, the standard data collection method, with modifications for virtual administration of the survey, will be used. The following steps will occur:

- The designated school coordinator will receive the survey administration materials, packaged by class, and will distribute the materials to the teacher of each selected class.
- Teachers distribute and follow up on parental permission forms sent out prior to the scheduled date of data collection. Schools may choose to distribute parental permission forms in hard copy or electronically, based on their recommendation of the most effective manner of reaching parents.
- In schools requiring active parental permission, teachers send a second form home to any student who has not yet returned one within 3 days of the scheduled administration.
- In all schools, teachers are asked to identify students without parental consent to participate and to make sure they have appropriate alternate activities.
- On the day of the scheduled survey administration, the teacher will distribute a 5-digit classroom access code to all students in a given classroom.
- Teachers read verbatim to eligible students a prepared script (Attachment I2) that emphasizes anonymity and the voluntary nature of the survey.
- Each student will use an internet connected device and will login to the NYTS survey using the provided URL and their unique 5-digit classroom code (Attachment I3).
- Make-up surveys will be conducted with eligible students who were absent on the day of survey administration using the same classroom code provided for the original administration.

The time during the school day in which the survey is administered varies by school. This decision is made in coordination with each school to ensure that the type of class or period of the day selected for sampling: 1) meets the scientific sampling parameters to ensure a nationally representative sample; and 2) results in the least burden/highest possible acceptability for the school.

Students electronically submit their questionnaires upon completion and the data are received in real time. Teachers complete and submit a Class Participation Log (Attachment I4) at the end of the session. This form provides information about the number of students enrolled in the class,

the number of students who participated, and the number of students at each type of nonparticipation (e.g., absent, no permission, etc.) For classrooms with 4 or more students that missed the in-school session, teachers are asked to administer make-up surveys to eligible nonparticipants upon their return to class or provide the URL for the student to participate on their own time if the teacher is unable to conduct a make-up session. Upon submission, make-up surveys are automatically incorporated into the counts data and counts for the appropriate school and class. Quality checks are performed daily to confirm that the expected number of student records are received, that there are no duplicates or anomalies in the data, and that the instrument is functioning as expected, e.g., students were able to make it through the entirety of the survey without technical issues.

Troubleshooting
NYTS Study Liaisons are available to help troubleshoot technical issues that arise during the session, if needed. The Study Liaisons are the same staff who secured school participation and maintain communication with the school coordinator through the school's participation in the study. Study Liaisons are trained to virtually support all components of a data collection, including, but not limited to:

- Confirming receipt of survey administration materials;
- Ensuring the distribution of parental permission forms;
- Confirming accessibility of survey URL;
- Answering questions from the designated school contact and/or teachers before, during, or after the survey administration;
- Monitoring completion of survey administration in classrooms;
- Following up on missing classes or missing classroom enrollment information;
- Obtaining school level enrollment and participation information.

Allowances for Virtual/Distance Learning
For the 2026 administrations, schools will be included that offer virtual or distance learning. Students will still be asked to take the survey during the scheduled "class" time. The procedure for these schools is the same as the procedures outlined above for in-person schools.

In general, data collection procedures have been designed to ensure that:

- Protocol is followed in obtaining access to schools;
- Everyday school activity schedules are disrupted minimally;
- Administrative burden placed on teachers is minimal;
- Parents give informed permission to participate in the survey;
- Anonymity of student participation is maintained, with no punitive actions against non-participants;
- Alternative activities are provided for nonparticipants;
- Control over the quality of data is maintained.

Obtaining Access to and Support from Schools

All initial letters of invitation to participate in the NYTS will be on FDA letterhead from the Food and Drug Administration and signed by Karen Cullen, PhD, MPH, Chief of the

Epidemiology Branch 2 in the Office of Science, Center for Tobacco Products (CTP) at the FDA. The procedures for gaining access to and support from states, districts, and schools will have three major steps:

- First, support will be sought from State Education Agencies and State Departments of Health. The initial request will be accompanied by a study fact sheet and a list of all sampled districts and schools in their jurisdiction. States will be asked to provide general guidance on working with the selected school districts and schools and to notify school districts that they may anticipate being contacted about the survey.

- Once cleared at the state level, an invitation packet will be sent to sampled school districts in the state. Districts will receive a list of schools sampled from within their district in the invitation packet and will be asked to provide general guidance on working with them and to notify schools that they may anticipate being contacted about the study. Telephone contact will be made with the office comparable to the district office (e.g., diocesan office of education), if there is one. Some districts require that a research proposal be submitted and approved to conduct scientific studies among their students. The format, length, and timeline for these proposals varies by district. For these districts, sampled schools cannot be contacted for individual participation until the data collection proposal is approved.

- Once cleared at the school district level, selected schools will be invited to participate. Information previously obtained about the school will be verified. The burden and benefits of participation in the survey will be presented. After a school agrees to participate, a tailor-made plan for collection of data in the school will be developed (e.g., select classes, schedule a date for survey administration, etc.). Well in advance of the agreed upon survey administration date, schools will receive the appropriate number of parental consent forms and instructions. Contact with schools will be maintained until all data collection activities have been completed.

Prior experience suggests the process of working with each state's health and education agencies, school districts and schools will have unique features. Communication with each agency will recognize the organizational constraints and prevailing practices of the agency. Scripts for use in guiding these discussions may be found in Attachment D2 (state-level), E2 (district-level), and F3 (school-level). Copies of letters of invitation can be found in Attachment D1 (state-level); Attachment E1 (district-level); and Attachment F1 (school-level). Attachment F1 also contains a flyer about the study. In addition, in-person recruitment visits may be used to increase school participation as needed.

Informed Consent

Parental permission forms inform parents about the important activity in which the student has the opportunity to participate. By providing adequate information about the activity, it helps ensure that permission to participate will be informed. Copies of the active and passive permission forms are contained in Appendices H2 and H3 (English versions) and H4 and H5 (Spanish versions), accompanied by a study fact sheet. In accordance with the No Child Left Behind Act, the permission forms indicate that a copy of the questionnaire will be available for

review by parents at their child's school. Parental forms are either active (all students who wish to participate must return a signed form) or passive (parents who do not want their child to participate return the form). These forms do not include student name to protect the privacy of the respondents.

A waiver of written student assent is obtained for the participation of children because this surveillance 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.

The NYTS is required by law to notify parents of students selected for NYTS surveys that their child has been selected and that student participation is voluntary. Schools may use various processes to obtain parental permission, forms of notification (electronically, such as email, or a hard-copy letter) either provided by the state or developed by the school. However, the notification shall include the following elements:

- this school will be participating in the NYTS and your child's classroom may be/is selected to participate;
- a brief description of the nature and importance of the NYTS;
- all responses are confidential, and results will not be reported to or about individual students or schools; and
- your child may be excused from participation for any reason, is not required to finish the survey, and is not required to answer any test questions.

Parental permission forms will be sent home with students or e-mailed. Teachers will still be required to track permission forms as they come back. Only students who receive parental permission will be allowed to participate. As with previous administrations, no names will be collected as part of the procedures.

Quality Control

Table 1 lists the major means of quality control. As shown, the task of collecting quality data begins with a clear and explicit study protocol, is supplemented with accurate programming of the NYTS questionnaire, and concludes with the regular submission of data records to a secure repository. In between these activities, and subsequent to NYTS Study Liaison training, measures must be taken to reinforce training, to assist Study Liaisons who express/exhibit difficulties completing data collection activities, and to check on data collection techniques. Also, early and regular inspection of a preliminary data set is necessary to ensure data integrity. Because the ultimate aim is production of a high-quality data set and reports, various quality assurance activities will be applied during the data collection phase.

Table 1: Major Means of Quality Control

Survey Step	Quality Control Procedures
Mailing to Districts and School	▪ Validate district and school sample to verify/update contact information of district/diocese/school leadership (100%) ▪ Verify school selection of hard-copy vs electronic receipt of materials ▪ For hard copy materials, check inner vs. outer label for agreement in correspondence (5% sample) ▪ Verify that any errors in packaging were not systematic (100%)
Follow-up with School Contacts	▪ Monitor early sample of recruitment inquiries to ensure that the recruiter follows procedures, elicits proper information, and has proper demeanor (10%) ▪ Perform spot checks on recruiters' class selection outcomes to confirm procedures were implemented according to protocol (10%)
Pre-Fielding Logistics Verification	▪ Review data collection procedures with school personnel in each school to ensure that all preparatory activities are performed properly in advance of survey fielding (e.g., distribution of permission forms) (100%)
Staff Training and Supervision of Survey Fielding	▪ Issue quizzes during Study Liaison training to ensure that key concepts are understood (daily during training) ▪ Maintain at least one weekly video conference or telephone monitoring of all Study Liaisons throughout the recruitment and data collection period (100%) ▪ Reinforce training and clarify procedures through periodic conference calls (100%) ▪ Verify by telephone or email with a 10% sample of early schools that all data collection procedures are being followed
Questionnaire Programming and Testing	▪ Ensure verbatim wording of displayed text compared to that of the analyst/programmer version of the questionnaire (100% of question and instructional text) ▪ Use a variety of user profiles and behavior combinations to test correct and appropriate skip logic and routing through questionnaire (100% of questions with programmed "triggers") ▪ Verify that any write-in responses are within prescribed ranges (100% of write-in questions) ▪ Create "dummy data set" to verify that all entered responses are correctly captured in the data set as intended (minimum 50 records)
Receipt Control	▪ Verify receipt of data from the field is occurring no later than 48 hours after data collection concludes (100% of schools) ▪ Verify number of data records received in the data base match the number of expected records reported by the teacher in the class participation log (100% of schools) ▪ Capture date/time stamps and staff credentials in the centralized system for all transactions (100%)

Survey Step	Quality Control Procedures
Data Review	▪ During fielding, extract records from at least three schools to verify data set is capturing and storing records as expected (during first week of fielding, or after at least three schools' data have been collected and synced)

3. Methods to Maximize Response Rates and Deal with Non-response

Expected Response Rates

To calculate the number of schools and students to sample that will ensure adequate precision, we estimated the school and student response rate and the school eligibility rate. During the five administrations of the survey since the start of the COVID-19 pandemic, 2020 through 2024, the overall response rate ranged from 30.5% to 45.2%. The response rates established by the NYTS are the results of the application of proven and tested procedures for maximizing school and student participation. For 2026, we assume a response rate equal to the response rate obtained in the 2024 NYTS, the latest completed iteration of the NYTS with the full data collection period was observed. We expect a 38% overall response rate for the 2026 NYTS.

As indicated in Table 6 in Supporting Statement A, it is desirable to complete data collection before the final month of school (i.e., by mid-April to mid-May, depending on location). Many schools are very busy at that time with standardized testing and final exams; in addition, attendance can be very unstable, especially among twelfth grade students.

Methods for Maximizing Responses and Handling Nonresponse

We distinguish among six potential types of nonresponse problems: refusal to participate by a selected school district, school, teacher, parent, or student; and collection of incomplete information from a student.

To minimize refusals at all levels--from school district to student--we will use a variety of techniques, emphasizing the importance of the survey. Given the subject matter is tobacco, we expect that a few school districts or schools will need to place the issue of survey participation before the school board. To increase the likelihood of an affirmative decision, we will: (1) work through the state agencies to communicate its support of the survey; (2) indicate that the survey is being sponsored by FDA; (3) convey to the school district or school that the survey has the endorsement of many key national educational and health associations, such as the National PTA, American Medical Association, National Association of State Boards of Education, Council of Chief State School Officers and the National School Boards Association;(4) maintain both a toll-free hotline and dedicated email account to answer questions from the school board; (5) offer a package of educational products to each participating school, as recommended by OMB in approving the 1998 YRBS in alternative schools (OMB No. 0920-0416, expiration 12/98) and implemented on the NYTS ever since; (6) comply with all requirements from school

districts in preparing written proposals for survey clearance; (7) convey a willingness to appear in person, if needed, to present the survey before a school board, research committee, or other local entity tasked with reviewing the survey; and (8) offer schools a monetary incentive of $750.

Once recruiters encounter district or school refusals to participate, they are encouraged to listen closely to the decision maker's concern(s) and "leave the door open" with the districts and/or schools for additional contact later. NYTS staff will begin targeted outreach to refusals and unresponsive districts and schools during the period of data collections. Initially this targeted outreach primarily includes remailing the original invitation packet with a personalized cover memo and telephone follow-up by the original recruiter. By remailing the information, this presents a fresh request to which the decision maker can respond, since it is likely that the original request is likely lost or discarded. Recruiters are encouraged to identify relevant potential connections between NYTS content and district or school health-related initiatives via strategic plans and curriculum descriptions available on district and school websites and include this in the memo and/or as part of their conversations with the decision maker. A sample memo used for refusal conversion can be found in Attachment F4. Other methods included 1) contact by a different recruiter who provided a "new voice" to the decision maker or 2) on-campus recruitment visits by field staff.

The sampling plan does not allow for the replacement of schools that refuse to participate due to concern that replacing schools would introduce bias. All participating state departments of health and education, school districts, and schools also will have access to the published survey results and a webinar to present the published results.

Maximizing responses and dealing with refusals from parents, teachers, and students require different strategies. To maximize responses, we will recommend that schools help to advertise the survey through the principal's newsletter, PTA meetings, and other established means of communication. The permission form will provide a telephone number at FDA that parents may call to have questions answered before agreeing to give permission for their child's participation. Permission forms will be available in English and Spanish.

Teacher refusals to cooperate with the study are not expected to be a problem because schools will already have agreed to participate. Refusals by students who have parental permission to participate are expected to be minimal. No punitive action will be taken against a nonconsenting student. Nonconsenting students will not be replaced. Data will be analyzed to determine if student nonresponse introduces any biases.

Participation in the NYTS is completely voluntary, and students may skip any question in which they are not comfortable answering. However, to minimize the likelihood of missing values on the survey, particularly on questions on which skip patterns are contingent, the digital-based questionnaire has data range validations and prompts. Thus, students who skip questions on ever or current use of individual tobacco products or who give out-of-range answers will be reminded to provide an appropriate response in a pop-up in the digital-based questionnaire before proceeding further in the survey. For questions that ask participants to specify a written numerical response (e.g., to enter the number of days they have used a product), programming instructions are provided to only allow a specific range of values. Additionally, once students

finish the survey, reach the end of the survey, they are allowed to go back to any unanswered or answered question items to modify responses before the student submits the survey. This provides students a chance to go back directly to each unanswered question item if they choose to do so. In addition, teachers will be guided by NYTS Study Liaisons to ensure that students are able to successfully troubleshoot through any technical issues.

4. Test of Procedures or Methods to be Undertaken

Further cognitive analyses or pretests of the survey were conducted in 2003, 2004, 2005, 2012, 2013, 2015, 2022, 2023, 2024, and 2025, as described in previous Supporting Statements for the NYTS. In 2017, 13 questions and response options were cognitively tested for inclusion in the NYTS, focused primarily on e-cigarettes: rules regarding use in the home, reasons for use, types of e-cigarettes used, and how youth accessed e-cigarettes. In 2018, cognitive testing of 15 questions and response options was completed, again focused on e-cigarette use. Terminology, devices used, substances used, and reasons for use were all explored. Cognitive testing was performed again in 2019, assessing e-cigarette terminology, e-cigarette devices used, substances used in e-cigarettes (e.g., nicotine, marijuana, THC), reasons for using e-cigarettes, exposure to secondhand tobacco smoke and secondhand e-cigarette aerosol, exposure to e-cigarette posts in social media, injunctive and descriptive e-cigarette norms, and indicators for affluence or socioeconomic status (SES) of the student's family. In 2022, cognitive testing was conducted to test selected questions that had been proposed for inclusion in the 2023 NYTS. These questions focused on e-cigarette use, heated tobacco product use, nicotine pouches, sexual orientation and gender identity (SOGI), the Adolescent Discrimination Distress Scale (ADDI), and the Neighborhood Environment Scale (NES). The findings of these testing activities were used to improve questions on the 2023 NYTS. Specifically, the 2022 interviews resulted in updated terminology, brands, and product images for novel tobacco products in the 2023 NYTS. These activities also influenced the inclusion and wording of health equity items included in the 2023 survey.

In 2023, robust cognitive testing was conducted to test selected questions that had been proposed for inclusion in the 2024 NYTS. This testing was conducted with sufficient sample size to make conclusions about the views of the spectrum of likely respondents to the NYTS. Cognitive testing focused on testing of sexual orientation and gender identity (SOGI) items, the Neighborhood Environment Scale (NES), and the Adolescent Discrimination Distress Index (ADDI) using the full range of ages covered in the survey and a geographically diverse sample of youth. To further inform potential changes to the survey, testing also included demographic questions, questions about e-cigarettes and nicotine pouches, measures of psychological stress, measures of socioeconomic status (SES), and an item about academic performance. The findings of these testing activities were used to inform the 2024 NYTS. Specifically, the 2023 interviews confirmed that participants did not experience discomfort or difficulty understanding any of these items, including SOGI items, the ADDI, or the NES. Testing found that respondents with a wide range of characteristics (selected to represent the overall NYTS audience) interpreted the questions and response options as intended. Based on the results of testing, the following changes were made: the Family Affluence Scale was updated to a more comprehensive version that participants understood better, and items related to tobacco products were added or removed

to reflect evolving trends in knowledge, attitudes, beliefs, and behaviors related to tobacco products.

In 2024 and 2025, robust cognitive testing was conducted. The items selected for testing were based on performance in the previous iteration of testing in 2023, guidance from CDC OSH leadership, and terms of clearance from the Office of Management and Budget (OMB). This testing was conducted with sufficient sample size to make conclusions about the views of the spectrum of likely respondents to the NYTS. Cognitive testing in 2024 and 2025 included questions about race/ ethnicity (specifically, the new OMB-required single race/ethnicity question), e-cigarettes, marijuana, and parental education; the ADDI; the NES; SOGI items; and the Family Affluence Scale. Psychometric testing in 2024 also informed questions about e-cigarettes in the 2026 survey, including the selection of e-cigarette device types and brands, methods of purchasing e-cigarettes, instructions asking youth to distinguish between vaping cannabis and using e-cigarettes, and methods of attempting to quit e-cigarettes. Because the 2024 and 2025 psychometric testing occurred later than usual, the findings of these testing activities will be used to inform the 2027 NYTS.

The current ICR includes an updated line item in the burden table to support future testing of changes to the NYTS questionnaire prior to their implementation. Burden is specifically allocated to performing testing of new or modified questions that will provide better measures of tobacco products. The burden also includes pre-testing of the questionnaire to confirm that they can be completed in 45 minutes.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Statistical Review

Statistical aspects of the study have been reviewed by the individuals listed below.

Karen Cullen, Ph.D., M.P.H. Center for Tobacco Products, FDA 10903 New Hampshire Ave, Silver Spring, MD 20993 Phone: 240-402-4513 E-mail: Karen.Cullen@fda.hhs.gov	Eunice Park-Lee, Ph.D., M.S. Center for Tobacco Products, FDA 10903 New Hampshire Ave, Silver Spring, MD 20993 Phone: 301-837-7342 E-mail: Eunice.Park-Lee@fda.hhs.gov
Roberto Valverde, M.P.H. Center for Tobacco Products, FDA 10903 New Hampshire Ave, Silver Spring, MD 20993 Phone: 240-402-3055 E-mail: Roberto.Valverde@fda.hhs.gov	Burton Levine, M.S. Senior Research Statistician RTI International Phone: 919-541-1252 Email: blevine@rti.org

Agency Responsibility

Within the agency, the following individuals will be responsible for receiving and approving contract deliverables and for having primary responsibility for data analysis:

Contract Deliverables
Tarsha McCrae, M.P.H.
Center for Tobacco Products, FDA
10903 New Hampshire Ave,
Silver Spring, MD 20993
Phone: 301-796-6854
E-mail: Tarsha.McCrae@fda.hhs.gov

Data Analysis
Eunice Park-Lee, Ph.D., M.S.
Center for Tobacco Products, FDA
10903 New Hampshire Ave,
Silver Spring, MD 20993
Phone: 301-837-7342
E-mail: Eunice.Park-Lee@fda.hhs.gov

Responsibility for Data Collection

The representatives of the contractor, RTI International, responsible for conducting the planned data collection are Jean Lennon (Project Director), Lauren Dutra (Associate Project Director), Burton Levine, Susan Fleming, Richard Doney, and others as designated by the contractor.

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