

Non-Substantive Change Request
Proposed changes to the 2023 National Youth Tobacco Survey (NYTS) and
Proposed changes to cognitive testing materials with youth for the NYTS
(OMB no. 0920-0621, approved 01/14/2021, exp. date 01/31/2024)

Date of Request: February 24, 2022
OMB approval is requested by: November 1, 2022

Summary

The NYTS is the only nationally representative survey of middle and high school students that focuses exclusively on tobacco use patterns and associated factors. Information collection employs a repeat cross-sectional design to develop national estimates of tobacco use and its correlates. The survey is administered by CDC's Office on Smoking and Health (OSH) and funded in collaboration with FDA's Center for Tobacco Products (CTP). NYTS data are principally used to generate tobacco-related measures that inform (1) CDC's tobacco prevention and control policies and programs, and (2) CTP's regulatory activities.

The content of the NYTS questionnaire is largely consistent from year to year. However, consistent with the OMB terms of clearance, it is expected that the survey instrument will be revised to maintain relevance with emerging tobacco use behaviors. The Terms of Clearance also state that developmental testing of new survey content and incremental improvements to existing wording on the approved instrument (including dropping/adding of a small proportion of the questions), in a manner such that the overall content remains consistent with topics already covered, may be approved through non-substantive change requests.

The current OMB package for the National Youth Tobacco Survey (NYTS) is approved for a total of 18,560 estimated burden hours across all data collection activities, including cognitive testing.

We request the following:

Questionnaire Revisions

We request OMB approval to field the revised NYTS questionnaire content for 2023 in accordance with the current OMB terms of clearance.

The NYTS employs a stratified, three-stage cluster sample design to produce a nationally representative sample of U.S. middle and high school students. There are no requested changes to the sampling plan or recruitment methodology. The NYTS will continue to be administered as an electronic survey. In the most recently completed administration of the NYTS (2021), after exclusion of outliers, the average survey completion time was approximately 22 minutes. However, students will continue to be allotted up to one class period (approximately 45 minutes) to complete the survey. Thus, no changes to the estimated burden per response or the total estimated burden hours are requested.

Questionnaire Revision Attachments:

- Attachment Q1. National Youth Tobacco Survey 2023 Questionnaire.
- Attachment Q2. Crosswalk of Non-Substantive Changes to the 2023 NYTS.

Cognitive Testing

We also request approval to utilize 130 hours of approved burden hours to conduct cognitive testing with youth of the NYTS in accordance with the current OMB terms of clearance.

The cognitive testing activities are in line with the Terms of Clearance issued by OMB for the 2021-2023 NYTS umbrella approval. Similarly, in 2020, CDC cognitively tested a suite of questions with youth to ensure that existing and proposed questions on the NYTS were accurate and relevant. Specifically, we request approval of changes to the 2020 cognitive testing participant screener, assent and consent forms, interview guides, and informational materials.

Cognitive Testing Attachments

- Attachment R1. 2022 NYTS Cognitive Testing Protocol
- Attachment R2. 2022 NYTS Cognitive Testing Parent/Guardian Screener
- Attachment R3. 2022 NYTS Cognitive Testing Parent/Guardian Consent
- Attachment R4. 2022 NYTS Cognitive Testing Invitation to Youth Screener
- Attachment R5. 2022 NYTS Cognitive Testing Youth Screener
- Attachment R6. 2022 NYTS Cognitive Testing Youth Consent
- Attachment R7. 2022 NYTS Cognitive Testing Notice of Non-Selection
- Attachment R8. 2022 NYTS Cognitive Testing Guides

Background and Justification

Questionnaire Revisions

The NYTS is a cross-sectional questionnaire administered to U.S. middle and high school students in grades 6-12. A probability based, nationally representative sample is used to select schools; within selected schools, 1-2 classes per grade level are randomly selected and all students in the selected classes are eligible to participate. In order to minimize the burden on the schools and students, the NYTS is completed in one class period.

Since 2019, the NYTS has been administered electronically. This transition allowed for the programming of skip instructions to tailor the questionnaire to respondents' individual tobacco product use status. In addition to improving both the overall detail and validity of responses, this transition resulted in reduced time to complete the survey, as students only see, and are asked to answer, questions corresponding to tobacco products they report having used. The electronic survey allowed for continued data collection using a web-based URL in 2021 and 2022 to account for changing school instructional models as a result of the COVID-19 pandemic.

For NYTS being currently fielded (2022 NYTS), most schools are operating under in-person instructional models. We anticipate that the 2023 NYTS administration will occur in the school/classroom setting using a web-based URL and will be administered by in-person data collectors.

To comply with the terms of clearance for the currently approved ICR, CDC is requesting approval for non-substantive changes to the 2022 NYTS. The proposed edits will modify the instrument to maintain relevance with emerging tobacco use behaviors and control policies. If approved, the proposed modified instrument will be implemented in the spring of 2023 to collect comprehensive information that will inform public health and regulatory activities.

The proposed changes to the survey instrument reflect:

1. Updates to existing question language or response options:
 - Order of product sections to be consistent with the prevalence of use among youth
 - Tobacco product brand examples throughout (based on market-scan data)

- Flavor questions to address tobacco-flavor, ‘iced’ flavors, and concept flavors
 - Terminology and tobacco product descriptions to reflect the changing product market
 - Questions/answer choices on sexual orientation and gender identity (including non-binary)
2. Addition of brand use questions for cigars and select smokeless tobacco products to maintain consistency of data availability across the most commonly used tobacco products among youth
 3. Addition of Social Determinants of Health Scales to identify disparities in tobacco product use:
 - Adolescent Discrimination and Distress Index (ADDI)
 - Neighborhood Environment Scale (NES)
 4. Rotation off the 2023 survey to limit overall survey length and respondent burden:
 - Section on health care professional assessment of use and advice not to use tobacco products
 - Awareness of The Real Cost and other ads against tobacco
 - Specific questions on beliefs about tobacco products (harm and addiction perceptions of smokeless tobacco and hookah; nicotine in e-cigarette perception; SHS and SHA harm perceptions; peer e-cigarette use acceptability)
 - Sections on e-cigarette advertisements; cigarettes and other tobacco product advertisements
 - Family Affluence Scale questions

The proposed changes to the 2023 survey have resulted in incremental improvements to the approved instrument while maintaining the overall content and topics covered in previous versions in accordance with the current OMB terms of clearance. All newly proposed questions are essential to maintain relevance with emerging tobacco products, behaviors, attitudes, and policies. Overall, these proposed survey changes will improve the quality of the NYTS and will allow for more in-depth reporting on disparities in tobacco product use among youth. The proposed changes allow for continued monitoring of national-level estimates of tobacco product use in a changing tobacco product marketplace while staying within existing estimates of respondent burden.

Cognitive Testing

CDC is proposing to conduct cognitive testing with youth to gain insight into how well participants understand existing and proposed NYTS survey questions and response options. CDC will use the results of the cognitive testing to gain insight into the clarity and effectiveness of question language, framing, construction, and response options for existing and proposed NYTS questions among youth. We are proposing to test questions with students across grades 6–12 (aged approximately 11 to 18 years). Including such a wide range of students will help us to ensure that the survey questions are widely applicable.

This request includes approval for a \$50 incentive for two-hour cognitive testing with youth. This is consistent with previous incentives for cognitive testing activities which provided \$40/hr. Tobacco research studies with adolescents report that recruiting smokers to participate is substantially more difficult than recruiting nonsmokers.¹ Research has shown that incentives are often a key factor in successfully recruiting children and adolescents to research projects, especially for studies of behavioral

¹ McCormick LK, Crawford M, Anderson RH, Gittelsohn J, Kingsley B, Upson D. Recruiting adolescents into qualitative tobacco research studies: experiences and lessons learned. *Journal of School Health*. 1999 Mar;69(3):95-9.

health risk factors.^{2,3} Thus, we propose to offer a \$50 incentive to boost participation in the cognitive interviews among youth.

Areas of emphasis for proposed and upcoming cognitive testing:

The objective of this series of cognitive testing is to test the NYTS instrument in its entirety.

Testing will include existing or adapted NYTS questions on:

- Use behaviors associated with each tobacco product (e-cigarettes; cigarettes; cigars; chewing tobacco snuff, or dip; hookah, pipe tobacco, snus, dissolvable tobacco, roll-your-own tobacco, heated tobacco products, nicotine pouches)
- Healthcare Screening for Tobacco Product Use
- Home and School Experiences
- E-Cigarette advertisements and promotions
- Cigarette and other tobacco product advertisements and promotions
- Social Media
- Demographics
- Antitobacco Messaging
- Secondhand Smoke and Secondhand E-cigarette Aerosol Exposure

Testing will include new questions⁴ on:

- Discrimination (racial and ethnic)
- Neighborhood Environment (perceived safety and security)

To accommodate all proposed 2023 NYTS questions in this cognitive test, OSH has proposed a segmented approach in which the survey questions will be split into three sets, each of which will be tested independently. These three guides will ensure OSH can test all questions without overburdening participants. A brief description of the three cognitive interview guides follows:

Interviewer Guide	Topics Included	Maximum # of Items	Minimum # of Items
Item Set #1	Demographics, E-Cigarettes, Heated Tobacco Products, Messaging, Social Media, Advertisements, and Exposure to Secondhand Tobacco Product Emissions	66	44
Item Set #2	Cigarettes and Other Combustible Tobacco Products, Opinions, and Discrimination.	91	38
Item Set #3	Smokeless Tobacco Products, Healthcare, Opinions, Environment, and Home and School	72	44

A description of the segmentation approach, recruitment plan, interviewer training plan, analysis plan, and data management plan is provided in the Cognitive Testing Protocol (Attachment R1). The cognitive

² Afkinich JL, Blachman-Demner DR. Providing incentives to youth participants in research: a literature review. *Journal of Empirical Research on Human Research Ethics*. 2019 Dec 12:1556264619892707.

³ Schoeppe S, Oliver M, Badland HM, Burke M, Duncan MJ. Recruitment and retention of children in behavioral health risk factor studies: REACH strategies. *International Journal of Behavioral Medicine*. 2014 Oct 1;21(5):794-803.

⁴ New items are derived from existing validated instruments used for youth data collection, including the Adolescent Discrimination Distress Index and the Neighborhood Environment Scale.

testing participant screener, assent forms, and consent forms are included in this request (Attachments R2, R3, R4, R5, R6, R7, R8).

Overall, the proposed formative testing activities will improve the quality of the NYTS and increase the ability of CDC to conduct public health surveillance regarding emerging tobacco use behaviors and control policies among youth. This work is not intended to produce generalizable knowledge.

Cognitive Testing Burden Estimate:

Table 1: Estimated Annual Burden to Respondents				
Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (In Hours)	Total Burden (In Hours)
Cognitive Testing	40	1	120/60	80
Testing Activities (screening)	300	1	10/60	50
Total				130

Inter-agency Coordination and Agency Points of Contact

In the fall of 2011, CDC-OSH and the FDA-CTP entered into a collaboration to fund the NYTS on an annual basis, with each agency funding alternate years. OSH and CTP agreed that in order to minimize unnecessary duplication and redundancy, they would collaborate to leverage the NYTS to meet both agencies’ goals. The collaboration agreement between OSH and CTP is that the content of NYTS will be decided collaboratively to meet the needs of both agencies. The agreement is described in the Supporting Statement for the current NYTS clearance. The NYTS instrument content is decided in collaboration between CDC and FDA in order to inform CDC’s non-regulatory public health approaches and inform FDA’s regulatory activities. Thus, the survey is specifically being designed to avoid duplication while meeting the needs of both agencies.

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Requested OMB Approval Date and Rationale

OMB approval is requested by November 1, 2022. Approval by this date will support logistical preparations for the digital-based data collection procedures. High participation rates are important because the sampling frame does not allow for replacement of schools that choose not to participate. Therefore, lead time is needed to:

- (a) Program, test, and transform the 2023 NYTS questionnaire into the digital-based (web) survey. CDC and the data collection contractor are unable to complete these programmatic activities until the questionnaire content and data collection procedures are finalized and approved by OMB.

Adequate lead time is required to allow CDC and the data collection contractor time to coordinate these activities and allow for testing of the digital-based questionnaire in an efficient and cost-effective manner.

- (b) Coordinate with the data collection contractor to print and distribute supplementary materials (e.g., district and school invitation materials, permission forms, factsheets, etc.). Adequate lead time is required to coordinate survey logistics in an efficient and cost-effective manner.
- (c) The production schedule for NYTS materials also affects school participation. End of school year testing schedules often conflicts with data collection activities, particularly during the later months of the data collection period (April, May, and June). Thus, many schools prefer earlier data collection dates (January, February) so as not to disrupt test preparation and administration activities. However, many schools are unable to confirm their participation without guaranteed survey administration dates.

Estimated Timeline

11/01/2022	Target date for receipt of OMB approval
11/02/2022	Begin programming of 2023 NYTS digital-based survey
12/01/2022	Initiate distribution of printed supplementary materials to selected schools and survey administrators
01/15/2023	Target for initiation of information collection for selected schools
05/31/2023	Complete information collection