

Change Request
2019 National Youth Tobacco Survey (NYTS)
(OMB no. 0920-0621, approved 04/30/2018, exp. date 04/30/2021)

Date of Request: August 22, 2018
OMB approval is requested by: November 1, 2018

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. The NYTS has been conducted periodically since 1999 and annually starting in 2011 using a paper and pencil design. Information collection employs a repeat cross-sectional design to develop national estimates of tobacco use and its correlates, including exposure to pro- and anti-tobacco influences among youth. The survey is administered by CDC's Office on Smoking and Health (OSH) 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 public health programs and activities, and (2) CTP's regulatory activities. The content of the NYTS questionnaire is largely consistent, however in a given year, a subset of questions may be added and others removed to reflect changes in the tobacco product landscape as well as to address emergent data needs. Beginning in 2019, the NYTS will collect data using a digital-based survey design. This transition will allow for the programming of skip instructions so that questions are tailored to respondents' individual tobacco product use behaviors. Furthermore, this change will eliminate non-applicable response options (e.g., "I have never smoked a cigarette, not even a puff") from existing questions. In 2019, new questions have been added to the survey that are in line with the current OMB terms of clearance regarding new and emerging tobacco products, behaviors, and control policies.

We request the following:

OMB approval of revised NYTS questionnaire content for 2019. See **Attachment I-1**, National Youth Tobacco Survey 2019 Questionnaire. Changes relative to the 2018 version of the questionnaire are summarized in **Attachment I-2**, Crosswalk of non-substantive changes to 2019 NYTS.

There are no changes to the sampling plan or recruitment methods. Despite the transition to an electronic mode of administration, the NYTS will continue to be administered during a single class period (approximately 45 minutes). Thus, there are no changes to the estimated burden per response or the total estimated burden hours.

Background and Justification

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, classes are randomly selected and all students in the selected classed are eligible to participate. In order to minimize the burden on the schools and students the NYTS is completed in one class period.

Since its initiation in 1999, the NYTS has been completed using a paper and pencil administration. In 2018, CDC piloted a digital-based survey design for the NYTS, completing 2,769 surveys across 36

schools (OMB No. 0920-1205). The school, student, and overall response rate for the pilot survey was 60.0%, 81.4%, and 48.8%, respectively. Beginning in 2019, the NYTS survey will transition fully from a paper and pencil administration to a digital-based survey design.

To comply with the terms of clearance for the currently approved ICR, CDC is requesting approval for non-substantive changes to the 2018 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 2019 to collect comprehensive information that will inform public health and regulatory activities.

The proposed changes to the approved instrument primarily reflect incremental improvements to existing question wording while maintaining consistency with previous content and topics. For example, in 2019, all tobacco product brand examples have been updated using current market-scan data. Revisions have also been made in response to the most recent OMB terms of clearance: *“In response to the most recent public comments suggesting more updated question options for cigars and e-cigarettes, CDC will evaluate the suggestions for incorporation prior to the next expected NYTS revisions request in 2019.”* This includes the addition of new questions to assess the type of cigar currently used; the type of e-cigarette device currently used; the brand of e-cigarette currently used; and observing e-cigarette use at school.

Also in response to the OMB terms of clearance (*“This clearance is based on the continued expectation that the survey instrument will be revised to maintain relevance with emerging tobacco use behaviors and control policies”*), the proposed changes include additional questions to capture awareness and use of heated tobacco products. Although this emerging class of tobacco products is currently not widely available on the U.S. market, manufacturers of heated tobacco products have submitted proposals to the FDA for the marketing and sale of these products as modified risk tobacco products in the United States. Thus, it is important to have baseline data on heated tobacco products before they are widely available on the U.S. market. Additionally, in response to this language in the terms of clearance, we have proposed a question to assess harm perceptions toward low nicotine cigarettes. FDA recently published an advanced notice of proposed rulemaking (ANPRM) to obtain information for consideration in developing a potential product standard to lower nicotine in cigarettes to a minimally or non-addictive level. Little is known on youth harm perceptions of low nicotine cigarettes. This data will be informative from a regulatory perspective, should such a product standard be developed.

The proposed changes for 2019 also reflect the introduction of skip logic due to the transition from paper and pencil to a digital-based mode of administration. This change may reduce individual respondents' burden by eliminating the need to answer non-applicable questions based on their respective tobacco use status. Existing questions also have been modified to exclude non-applicable response options (ex. “I have never smoked a cigarette, not even a puff”). This transition to an electronic mode provides the opportunity for new survey content for non-tobacco product users, as this group will not be asked questions about current tobacco product use behaviors, including use in the past 30 days, purchasing behaviors, or about cessation behaviors. Thus, we propose to include questions to assess non-tobacco product users' susceptibility to use of cigars and smokeless tobacco products. Curiosity and susceptibility are useful measures to identify those at different stages of future risk of experimentation and established tobacco product use. These measures may be used to target specific populations for public education campaigns or for surveillance and evaluation of tobacco control and regulatory efforts.

In summary, this request includes the addition of 17 new or reinstated questions and the deletion of one question from the 2018 survey. However, due to the transition to an electronic survey mode and the introduction of skip instructions, not all respondents will be asked all survey questions. Preliminary estimates from the 2018 NYTS electronic pilot survey suggest that the mean time to complete the digital-based survey with skip logic was 11.9 minutes. However, the electronic survey administration procedures will continue to allow up to one class period (45 minutes) for survey completion. Thus, there is no change in the estimated burden time to complete the 2019 survey compared with previous NYTS administrations.

The proposed changes to the 2019 survey have resulted in incremental improvements to the approved instrument while maintaining the overall content and topic covered in previous versions. All newly proposed questions are essential to maintain relevance with emerging tobacco products, behaviors, attitudes, and policies. Overall, these proposed changes will improve the quality of the survey while maintaining existing estimates of respondent burden.

The 2019 NYTS questionnaire is provided as Attachment I-1.
Changes from the 2018 version of the questionnaire are summarized in Attachment I-2.

Inter-agency Coordination and Agency Points of Contact

In the fall of 2011, OSH and CTP entered into a collaboration to conduct 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 (see Section A.4, "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... 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 mission of both agencies.").

HHS established a working group on tobacco to improve the coordination, efficiency, and usability of information collected for surveillance, research, regulatory action, and program management. The working group includes representation from ASPE, CDC, FDA, NIH, and SAMSHA. The draft instrument was circulated for comment to the HHS working group and additional partners including NCHS and the CDC/YRBS program. The 2019 NYTS Questionnaire submitted for OMB approval reflects CDC and FDA priorities and incorporates recommendations made by the HHS working group.

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Requested OMB Approval Date and Rationale

OMB approval is requested by November 1, 2018. Approval by this date will support logistical preparations for the transition to a digital-based survey mode in a school setting. 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 load the NYTS questionnaire onto the tablets used for the digital-based survey. CDC and the data collection contractor are unable to complete these programmatic activities until the questionnaire content is 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 new 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., permission forms). Production and distribution of these materials may be complicated by end-of-year holidays or inclement weather. Adequate lead time is required to coordinate survey logistics in an efficient and cost effective manner.
- (c) The production schedule for NYTS materials also impacts school participation, as many schools are unable to confirm their participation without guaranteed survey administration dates.

Estimated Timeline

11/01/2018	Target date for receipt of OMB approval
11/02/2018	Begin programming of 2019 NYTS digital-based survey (data collection contractor)
December, 2018	Submit print order for supplementary materials (permission forms) to CDC/MASO with print due dates of Mid-January
Mid-January 2019	Initiate distribution of printed supplementary materials to selected schools and survey administrators
02/04/2019	Target for initiation of information collection for selected schools
June 2019	Complete information collection