

Non-Substantive Change Request

Proposed Changes to Cognitive Testing Materials with Youth for the National Youth Tobacco Survey (NYTS)

(OMB no. 0920-0621, approved 04/30/2018, exp. date 04/30/2021)

Date of Request: April 3, 2020

Summary

In 2018, CDC cognitively tested a suite of questions with youth in order to ensure that existing and proposed questions on the National Youth Tobacco Survey (NYTS) were accurate and relevant. CDC now seeks OMB approval to conduct cognitive interviews of a new suite of questions regarding tobacco use using the already-approved 78 burden hours listed under clearance number 0920-0621.

Specifically, we request:

- Approval of non-substantive changes to the 2018 cognitive testing participant screener, assent and consent forms, interview guides, and informational materials.

There are no changes to the total overall estimated burden hours.

Attachments

Attachment Q1. Youth Cognitive Testing Interview Guide – Users

Attachment Q2. Youth Cognitive Testing Interview Guide – Non-users

Attachment Q3. Cognitive Testing Participant (Minor) Assent Form

Attachment Q4. Cognitive Testing Parental Consent Form

Attachment Q5. Youth Cognitive Testing Informational Materials

Attachment Q6. Youth Cognitive Testing Screener

Background and Justification

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. 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, CDC may add or remove a subset of questions to reflect changes in the tobacco product landscape and to address emergent data needs.

In its approval of 0920-0621 on 4/30/18, OMB stated to CDC in the Terms of Clearance: “This clearance is based on the expectation that the survey instrument will be revised to maintain relevance with emerging tobacco use behaviors and control policies. 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 done through non-substantive changes.”

CDC conducts cognitive testing with youth to gain insight into how well participants understand existing and proposed NYTS survey questions and response options. In 2020, CDC is focusing on questions related to or correlated with e-cigarette use, which has reached epidemic levels among youth. In 2019, 27.5% of high school students and 10.5% of middle school students reported current use of an e-cigarette.¹ The diversity of existing and emerging e-cigarette products and the evolving terminology related to e-cigarettes can pose challenges to measuring use among target surveillance audiences. CDC will use 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 middle schoolers. We are proposing to test questions solely among middle schoolers because we have less information on the validity and salience of questions and response options in students at this school level compared to high school students. One of the major and unique strengths of the NYTS is its inclusion of a large sample of middle schoolers in grades 6-8. Therefore, cognitive testing among this group is essential to ensure that our estimates are accurate.

The 0920-0621 NYTS package included approval for a \$40 incentive for cognitive testing with youth, the amount provided to middle and high school students during our 2018 round of cognitive testing. Tobacco research studies with adolescents report that recruiting smokers to participate is substantially more difficult than recruiting nonsmokers.² Research has shown that incentives are often a key factor in successfully recruiting children and adolescents to research projects, especially for studies of behavioral health risk factors.^{3,4} Thus, we believe the \$40 incentive will be particularly important in ensuring we can successfully complete cognitive testing with this hard-to-reach population.

Areas of emphasis for proposed and upcoming cognitive testing include:

- Updating the brand examples for e-cigarette products based on current market data
- Updating the social media examples based on previous rounds of cognitive testing
- Testing existing or adapted NYTS questions on:
 - Perception that e-cigarettes contain nicotine (used by participants)

¹ Cullen KA, Gentzke AS, Sawdey MD, Chang JT, Anic GM, Wang TW, Creamer MR, Jamal A, Ambrose BK, King BA. E-Cigarette use among youth in the United States, 2019. *JAMA*. 2019 Dec 3;322(21):2095-103.

² 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.

³ 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.

⁴ 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.

- Sources for getting e-cigarettes
- Heated tobacco products
- Screening for e-cigarette use and counseling against e-cigarette use during health care interactions
- Reasons for use of e-cigarettes
- Sources for buying e-cigarettes
- Flavors in e-cigarettes
- Social media posts related to e-cigarettes
- Use of e-cigarettes in schools
- Prevalence of e-cigarettes in media advertising
- Sexual orientation (known to be associated with tobacco product use)
- Testing new questions on:
 - Types of e-cigarette products received/bought from another person
 - Nicotine perception in e-cigarettes (in general)
 - Purchase of e-cigarette device at school
 - Acceptability of e-cigarette use among peers
 - Gender identity (known to be associated with tobacco product use)
 - Anxiety and depression (known to be associated with tobacco product use)

OSH is seeking approval of two cognitive interview guides: one for past-30 day users of e-cigarettes and one for non-users of e-cigarettes. The use of two separate guides will help OSH gain insight into questions that only apply to users (e.g., “What are the reasons that you currently use e-cigarettes?”), while also allowing OSH to test a wider range of questions with non-users. Using two protocols will ensure OSH can test several relevant questions without overburdening participants.

Finally, OSH is seeking approval of cognitive testing participant screener, assent and consent forms, and informational materials. We made non-substantive changes to the informational materials to ensure that participants receive the most up-to-date resources about e-cigarettes.

This request provides the opportunity to cognitively test new survey content and existing NYTS questions and response options with middle-schoolers in a manner that aligns with the current terms of clearance. 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.

Effect of Proposed Changes on the Burden Estimate

There are no substantive changes to the overall burden estimate. Burden will be allocated as presented below in Table 1.

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	60/60	40
Testing Activities (screening)	285	1	8/60	38
Total				78

Effect of Proposed Changes on Currently Approved Instruments and Attachments

Table 2 describes those attachments which have been updated as a result of changes in the cognitive testing questions or screener language of the NYTS.

Table 2: Attachments updated as a result of proposed changes to cognitive testing materials

Previous Attachment Title	Change Request Attachment Title
P1. Youth Cognitive Interview GUIDE	Attachment Q1. Youth Cognitive Testing Interview Guide – Users
	Attachment Q2. Youth Cognitive Testing Interview Guide – Non-users
P2. Cognitive Interview Assent Form, Individuals Under 18 Years of Age - Understanding Use of Electronic Vapor Devices (EVDS) Among Youth.	Attachment Q3. Cognitive Testing Participant (Minor) Assent Form
P4. Cognitive Testing: Parental Permission for Minor Child to be in a Cognitive Interview on Understanding Use of Electronic Vapor Devices Among Youth	Attachment Q4. Cognitive Testing Parental Consent Form
P5. Cognitive Testing Youth Materials – Electronic Nicotine Delivery Systems Key Facts	Attachment Q5. Youth Cognitive Testing Informational Materials
P6. Cognitive Testing Youth Materials – Tools for Quitting	
P7. Cognitive Testing Participant SCREENER	Attachment Q6. Youth Cognitive Testing Screener