OMB Control Number 0910-0932
Expiration Date 05/31/2027

Attachment 5

2026 NYTS Cognitive Testing Youth Consent

Qualitative Inquiry to Support Tobacco-Related Surveillance

Parent/Guardian Email and Youth Informed Consent for Cognitive Interviews

Note: After the child has been selected to participate, the parent/guardian will be sent the email and informed assent form for their child to review and electronically sign. The consent section is at 6.9 readability on the Flesch-Kincaid Grade Level scale.

Dear PARENT NAME

Your child has been selected to participate in two interviews.

Please provide four dates and times between [INSERT DATE] and [INSERT DATE] that your child can participate in the interviews.

Prior to their participation, your child must review and sign an informed consent. Please have your child click the link below to view the informed consent for the interviews. They will be able to electronically sign.

LINK

Many thanks for your assistance in helping Food and Drug Administration (FDA) pretest questions on health, tobacco use, and e-cigarette use.

Sincerely,

Deloitte

**** YOUTH ASSENT FORM BELOW IS LINKED FROM EMAIL ABOVE ****

U.S. Food and Drug Administration (FDA) has hired Deloitte to interview 24-30 youth to participate in two interviews, with each interview scheduled approximately 2-4 weeks apart. Deloitte and FDA want to learn about how middle school and high school students understand and respond to survey questions on health behaviors. Your feedback will help improve the questions. The first interview will test the original questionnaire, and the second interview will test the modifications made to the questionnaire based on the first round.

Before you agree to participate in an interview, please read the information listed below:

Procedures

- Each interview will be through Zoom.
- Each interview will last up to, but no more than1 hour.
- You will be asked to read and answer questions being shown through Zoom. You will then be asked to talk about why you selected your answers.
- The interviews will be audio recorded.

Confidentiality

- The interviews will be confidential. Your name and personal information will not be connected to recording or records of the interviews.
- All responses shared during the interviews are private (unless comments indicate a threat or danger to self or others).

Voluntary Participation

- Your participation in the interviews is voluntary.
- You may choose not to answer questions that you do not want to answer.
- You can end the interviews at any time, for any reason. You will still receive your incentive.

Risks of Participation

- There is very little risk to you.
- Some of the questions you will review are on topics that might be considered personal. It might be uncomfortable for some people to answer questions on these topics. You don't have to answer a question if it makes you feel uncomfortable.
- It is best to do the interview in a private setting.
- All records and recordings are kept in private files. Only study staff will be allowed to use them. Your name and personal information will be stored separately. Your name will not be reported when study results are published or presented. All responses shared during the interviews are private (unless comments indicate a threat or danger to self or others).

Incentive

- You will be given $50 in Amazon credit after each of the two interviews.

For More Information

Email Deloitte's Project, Lauren Degiorgi, at ldegiorgi@DELOITTE.com.

Typing my name below indicates that I consent to participate in this study. I have been given a copy of this form.

_____

Participant Signature Date

Public reporting burden for this collection of information is estimated to average 30 minutes per survey, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov, ATTN: PRA (0910-0932).