

[NOTE: PROGRAMMING LANGUAGE IN ALL CAPS IS NOT VISIBLE TO PARTICIPANTS]

[PROGRAMMING NOTES: ASSENT OCCURS AFTER SCREENING. TEXT VARIES AS SHOWN BY WHETHER RECRUITED THROUGH PARENT ON A PANEL (SOURCE = PANEL_PAR) OR DIRECTLY ON SOCIAL MEDIA (SOURCE = SM).]

[DISPLAY OMB NUMBER AND EXP. DATE AT TOP OF SCREEN]
OMB# 0910-0810
Exp. 12/31/2024

Youth Assent Form

Sponsor / Study Title: Food and Drug Administration (FDA) / “Copy Testing of Tobacco Prevention and Cessation Advertisements Research Study”

Principal Investigator: Matt Eggers, MPH

Telephone: 919-990-8380 (24 Hours)

Address: RTI International
3040 East Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709

If you want to, you can be a part of this research study. People do research to try to find answers to questions.

Key information

- Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0810. The time required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov.
- The goal of this study is to learn how well we are able to assess young peoples' responses to short videos about vaping.

- If you take part in the study, you will answer some survey questions about vaping, tobacco use, and other topics. You may also watch a short video about vaping and answer questions about the video.
- You can stop participating in the study at any time or skip questions if they make you feel uncomfortable.
- There are no benefits to you from being in this research study.
- If you complete the survey, [IF SOURCE = PANEL_PAR: your parent or legal guardian; IF SOURCE = SM: you] will receive a token of appreciation.
- This research is paid for by the United States (US) Food and Drug Administration's (FDA's) Center for Tobacco Products and the research is being conducted by RTI International. The mission of the FDA is to promote and protect public health.

Why are we doing this research study?

We are asking young people in the US to take part in this research. In total, there will be about 900 participants in this study. The reason we are doing this research is to learn how well we are able to assess young peoples' responses to short videos about vaping.

Why are you being asked to be in this research study?

We are asking young people between the ages of [IF SOURCE = PANEL_PAR: 13; IF SOURCE = SM: 15] and 17 if they are interested in participating. [IF SOURCE = PANEL_PAR: Your parent or guardian has given permission for you to take part in this study.]

What will happen during this study?

You can take part in this study by answering some survey questions online using your computer, phone, iPad, tablet, or other device. We will ask your opinions about vaping and other tobacco products. We may also ask you to watch a short video about vaping and other tobacco products and answer some questions about the video and about yourself.

The study will last up to 20 minutes. We will not contact you again about this study after it is over.

What are the problems that might happen in this study?

Sometimes people feel uncomfortable answering questions about vaping or tobacco use or watching videos about the possible effects of vaping. Some people may also feel uncomfortable answering questions about their race, ethnicity, family origin, or family income. This may or may not happen to you. Sometimes things that bother one person don't bother another person at all, so let your parents, legal guardian, or school counselor know if something is bothering you.

We will take care to protect the data you share. However, as with all studies, there may be risks which are currently unknown. There is a chance that privacy could be broken by accident or as the result of hacking. You will be asked to answer questions about your tobacco/vaping experience, which may not be legal in your age group. We will try

our best to maintain the privacy of data collected during the study by using standard online data safeguards.

What are the good things that might happen in this study?

There are no benefits to you from being in this research study. Your responses may help researchers understand what people think about videos about vaping.

Who will be told the things we learn about you in this study?

The information we collect during this study will be used for research purposes only. Your answers to the study questions will be combined with answers from many others and reported as a summary. Your name will not be in any report of the results of this study. We may use this data, without your name or identifying information, again for future studies. If we do, we will not contact you beforehand.

The answers you give to the questions we ask during this study will be separated from your name and any other personal information. We do this to try to keep your answers from being linked to your personal information. The information that we will collect from you during the study will be kept in a secure database that can only be accessed by authorized research staff. We will make every effort so that no one will be able to know how you answered the questions, not even your parents/legal guardians or teachers.

This research study has a Certificate of Confidentiality. This means that the researchers cannot be forced to provide any of your private identifiable information if a court or a lawyer asks for it. Disclosure of your research information may only occur in limited specific instances such as:

- You can freely discuss your involvement in this research.
- The FDA can request information from the researchers.
- If someone is in serious danger, the law may require the researchers to disclose information to keep people safe.

Will you get any money or gifts for being in this research study?

[IF SOURCE = PANEL_PAR] If you complete the survey, your parent/legal guardian will receive up to \$10 worth of points that they can trade in for goods, coupons, etc. Your parent/legal guardian will receive this compensation within 10 days of you completing the survey.

[IF SOURCE = SM] If you complete the survey, you will receive a \$10 digital gift card from Amazon within 1-2 weeks of survey completion as a token of appreciation. You will only receive **one gift card** for completing the survey.

Whom To Contact About This Study

During the study, if you have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of psychological discomfort;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;

- Eligibility to participate in the study; or
- The investigator's decision to exclude you from participation

please contact the investigator at the telephone number listed at the top of this consent document.

An IRB is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00065519.

What if you change your mind?

You can stop answering the survey questions at any time, for any reason. You can skip a survey question if you prefer not to answer it. If you decide not to take part in this study or to stop participating later on, no one will be angry or upset with you. If you have any questions, you may call the investigator or Advarra at the numbers listed above.

[Y_ASSENT] Do you agree to participate in this study?

1. Yes, I agree to participate in this study. [GO TO SURVEY]
2. No, I do not agree to participate in this study. [TERMINATE AND GO TO END]

[END]

Thank you for your time.