

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

[PROGRAMMER NOTES: ADMINISTER ONLY IF SOURCE = PANEL_PAR]

THANK YOU FOR YOUR INTEREST. If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed.

[WILLING] To get started, we first need to ask a few questions to see if your child is eligible to take the survey. Are you willing to answer a few questions to see if your child is qualified to participate in the study?

1. Yes
2. No

[IF WILLING = 2, TERMINATE AND DISPLAY: We're sorry, but you are not eligible to participate in this study. Thank you again for your interest.]

Are you a parent or legal guardian of at least one child who lives in your household who is...?

[USE SCROLLING LIST]

1. Yes
2. No

[P1] Younger than 8 years old?

[P2] 8 years old through 12 years old?

[P3] 13 years old through 17 years old?

[IF P3≠ 1, TERMINATE AND DISPLAY: We're sorry, but you are not eligible to participate in this study. Thank you again for your interest.]

[P_INFO]

This survey is intended for youth aged 13-17. If you have more than one child between the ages of 13-17, we recommend choosing the one who is currently available to take the survey.

[NEXT SCREEN]

[DISPLAY OMB NUMBER AND EXP. DATE AT TOP OF SCREEN]

OMB# 0910-0810

Exp. 12/31/2024

Informed Consent Form for Parental and Legal Guardian Consent

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

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 4 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.
- We are asking your child to take part in a research study to learn about youth reactions to videos about vaping prevention.
- This research study consists of a single survey that will take up to 20 minutes for your child to complete if your child qualifies.
- Some children who participate will see a short video about vaping prevention. Your child may have questions about vaping or about the video, if they see one. We will provide your child with information about who to contact if they have questions.
- There are no direct benefits to you or your child for participating.
- As a token of appreciation, you will receive the reward stated in the study description or invitation if your child qualifies and completes the survey.
- Your child can stop participating in the study or skip questions if they feel uncomfortable.
- This survey is part of a research study funded by the United States (US) Food and Drug Administration’s (FDA’s) Center for Tobacco Products and conducted by RTI International.

About the FDA

The mission of the FDA is to promote and protect public health. In conducting this study, FDA does not intend to sell tobacco, nor promote, condone, normalize, or encourage its use. The questionnaires, surveys, and messages in this study are not intended to promote, directly or indirectly, other behaviors that may be a gateway to subsequent risky behaviors, such as illegal drug use, binge drinking, and smoking.

Selection of Youth

We are asking youth ages 13-17 in the US to take this survey. In total, there will be about 900 participants in this study. We need permission from a parent or guardian before we survey your child. If you give permission for your child to participate, your child may choose whether or not to take the survey.

Types of Questions

Youth will be asked to complete an online survey. If your child qualifies to participate, they will be asked some questions about their experiences with tobacco/nicotine use and vaping. The survey will also ask your child to view some 15-30 second videos and answer some questions about the videos.

Voluntary Participation

It is your choice and your child's choice whether or not to participate in this study. There will be no penalty and you and your child will not lose any benefits or rights you would normally have if you or your child chooses not to volunteer or leaves the study at any time. Your child can skip any questions if they prefer not to answer them or stop the survey at any time. If you or your child has any questions about this study, you may call the investigator at the telephone number listed at the top of this form.

The investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you or your child fails to follow directions for participating in the study;
- If it is discovered that you or your child does not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

Risks

There are minimal psychological risks to participating in this study. Your child may want to talk to you about any concerns they have about how the ad made them feel, if they see an ad. Your child may also want to talk with you about any questions or concerns they have about vaping or using tobacco. Part of this research asks your child about their vaping and tobacco use. If you or your child has any questions about this study, you may call the investigator at the telephone number listed at the top of this form. **Your child may stop participating in this study at any time if they become upset or want to stop participating.**

We will take care to protect the data your child shares. 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. We will try our best to maintain the privacy of data collected during the study by using standard online data safeguards.

Benefits

There are no direct benefits to your child from taking the survey. Results will help improve public education campaigns about vaping and tobacco use.

Alternatives

This study is for research purposes only. The only alternative is to not participate in this study.

Use of Information

Information will be used solely for research purposes. As will be mentioned in the following “Confidentiality” section, your child’s responses will only be shared at an aggregate (compiled and summarized) level and will not include any personally identifiable information. In the future we may use or share your child’s deidentified data with other researchers for other studies. If we do so, we will not contact you to ask for your additional informed consent.

Token of Appreciation for Participating

If your child completes the survey, you (as a parent/legal guardian panel member) will be awarded up to \$10 worth of points that you can trade in for goods, coupons, etc. You will be awarded this compensation within 10 days of your child completing the survey.

If your child should stop participating before the study is over, you will not receive the token of appreciation. Your child will not receive any payment or compensation for taking part in this study.

Cost

There will be no charge to you for your or your child’s participation in this study.

Confidentiality

Every effort will be made so that no one will be able to know how your child answered the questions. However, protection of your child’s information cannot be guaranteed. The information collected from your child during the screener and survey will be kept in a secure database to which only authorized project staff members will have access. Your child’s answers to the study questions will be combined with answers from many others and reported in summary form. Upon completion of the study, we are required to store study data for 5 years. Study data will be stored securely on a password-protected computer without any of your child’s personal information. Information from this study may be published in professional journals or presented at scientific conferences, but your child’s identifiable information will not be included in any report or presentation. All project staff are committed to privacy and have signed an agreement to maintain the privacy of study data.

The investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the US FDA and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name.

This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection makes sure that project staff involved in this study protect your child's privacy. This means that project staff generally cannot provide your child's name, or any other information that could identify your child, to anyone who is not connected with the project. Project staff cannot share this information in court or during other legal proceedings, unless you or your child agree, even if there is a court order for the information. However, in other settings, project staff may share study information that could identify your child if:

- You or your child agrees to share information (for example, to get medical treatment);
- The study information is used for other scientific research, as allowed by law;
- The FDA, which is paying for the study, needs information to check how their research money is being spent; or
- A law requires sharing information (for example, when project staff must report to FDA, or if project staff hear threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you and your child from sharing any personal information or information about your child's involvement in this study with others, if you choose to. For example, you can share that your child is taking part in this study or your child's history of vaping or tobacco use.

Whom To Contact About This Study

During the study, if you or your child has 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 or your child's 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 or your child's 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.

If you would like a copy of this parent/legal guardian permission form for your records, you can print it out or take a screenshot of the screen(s) showing this information.

[P_CONSENT] Do you agree to allow your child (aged 13-17) to take the survey?

1. Yes, I agree to allow my child to take the survey [GO TO P_INTRO]
2. No, I do not agree to allow my child to take the survey [TERMINATE AND GO TO END]

[P_INTRO]

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Continue" when your child is ready to begin OR Please forward this link to your child. [GO TO SCREENER]

[END]

Thank you for your time.