

U.S. Food and Drug Administration
Center for Tobacco Products

[DISPLAY THE FOLLOWING TEXT IN SMALLER FONT IN UPPER CORNER (E.G., AS HEADER) ON ALL PAGES OF THE PARENT PERMISSION FORM]

Study Name: Evaluating Tobacco Education Messages

Study Coordinator: Susana Peinado

OMB #0910-0810, Expires 12/31/2024

Parent/Guardian Permission for Child to Participate in a Research Study

This survey is intended for youth aged 13-17. 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 approximately 15 minutes for your child to complete if your child qualifies.

This survey is part of a research study funded by the U.S. Food and Drug Administration's (FDA's) Center for Tobacco Products and conducted by RTI International. 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

2,400 youth are being asked to take this survey. We need permission from a parent 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, the survey will ask your child to view four 15-30 second anti-vaping videos online and answer some questions about the videos and about their experiences with vaping in an online survey. The videos that your child will be asked to view as part of the survey will be randomly selected from a set of about 90 videos that take different approaches to conveying the potential consequences of vaping. Some videos address the potential physical or psychological effects of vaping and may use graphic depictions, while others address the possible social consequences or use humor to get the point across. All videos are similar to public service announcements (PSAs) that are shown on television as part of a public information campaign.

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 choose not to volunteer. 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 have any questions about this study, you may call the Study Coordinator or RTI's Office of Research Protection listed below.

Risks

There are minimal psychological risks to participating in this study. Your child may want to talk to you about any concerns he/she has about how the ad made him/her feel. Your child may also want to talk with you about any questions or concerns he/she has about vaping or using tobacco. If you or your child have any questions about this study, you may call the Study Coordinator at the telephone number listed on the last page of this form. **Your child may stop participating in this study at any time if he/she becomes upset or wants to stop participating for any reason.**

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. In the unlikely event that the study data are hacked, we will tell you within 5 business days of discovery. 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 may help improve public education campaigns about vaping and tobacco use.

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 level and will not include any personally identifiable information. The information from this research study will not be used or distributed in any future research studies.

Token of appreciation for Participating

You will receive the reward stated in the email invitation for this study if your child completes the survey. The reward can be saved and traded for material items or for cash. If your child should stop participating before the study is over, you will not receive a token of appreciation.

Confidentiality

Every effort will be made so that 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 surveys 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 at least 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 research staff are committed to privacy and have signed an agreement to maintain the confidentiality of study data.

This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection makes sure that staff involved in this project 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 project or your child's history of vaping or tobacco use.

Questions

If you have any questions about this study, you can contact the Study Coordinator, Susana Peinado, at 919-316-3190 or speinado@rti.org. If you have a question about your rights as a study participant, you can call RTI's Office of Research Protection toll-free at (866) 214-2043.

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

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
2. No, I do not agree to allow my child to take the survey

[IF YES, GO TO P_INTRO]

[IF NO, GO TO END]

[INCLUDE THE STATEMENT BELOW IN SMALLER GREY FONT AT THE BOTTOM OF THE PARENTAL PERMISSION PAGE]

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2 minutes to complete this permission form (the time estimated to read and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

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. [GO TO YOUTH ASSENT]

END

Thank you for your time.