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

Youth Assent to Participate in Research

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

Why are we doing this research 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. We are asking about 2,400 young people to take part in this research.

This research is paid for by the U.S. 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 you being asked to be in this research study?

Your parent or legal guardian has given permission for you to take part in this study. We are asking young people between the ages of 13 and 17 if they are interested in participating.

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. First, we will ask you a few questions to see if you qualify for the study. If you qualify, we will ask your opinions about vaping. We will also ask you to watch four short videos about vaping that are 15 to 30 seconds long and answer some questions about the videos and about yourself. The four videos you will be asked to view as part of the survey will be chosen at random from a larger set of videos about vaping. These videos present the possible consequences of vaping in different ways. All videos are similar to the public service announcements (PSAs) that are shown on television as part of a public information campaign.

The study will last about approximately 15 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, 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. In the unlikely event that the study data are hacked, we will tell your parent 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.

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.

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 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 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 you complete the survey, your parent will receive a reward, as stated in the email invitation for this study. This reward can be used to purchase items online or traded for cash.

Who should you ask if you have any questions?

If you have any questions about this study, you can call the Study Coordinator, Susana Peinado, at 919-316-3190. If you or your parents have any questions about your rights as a research participant, you can call RTI's Office of Research Protection at 1-866-214-2043.

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 Study Coordinator or RTI's Office of Research Protection listed above.

Y_ASSENT. Do you agree to participate in this study?

1. Yes, I agree to participate in this study.
2. No, I do not agree to participate in this study.

[IF YES, GO TO SCREENER]
[IF NO, GO TO END]

[INCLUDE THE STATEMENT BELOW IN SMALLER GREY FONT AT THE BOTTOM OF THE YOUTH ASSENT PAGE]
Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2 minutes to complete this assent 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 PRAStaff@fda.hhs.gov.

END

Thank you for your time.