

2019 Electronic Nicotine Delivery Systems Formative Data Collection to Inform Experimenter and Established User Definitions - YOUTH ASSENT

[DISPLAY THE FOLLOWING TEXT IN SMALL GREY FONT IN UPPER OR LOWER CORNER (E.G., AS HEADER OR FOOTER) OF YOUTH ASSENT PAGE: "OMB #0910-0810, Expires 10/31/2021"]

Introduction to the Study

Your parent or legal guardian has given permission for you to take this survey. The survey asks people what they think about vaping and tobacco use. Up to 1,600 youth are being asked to take this survey. 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. First you will answer a few questions, then if you qualify you will complete the survey. The survey will take about 18 minutes.

Voluntary Participation

If you don't want to take the survey, that is okay. You can drop out of the survey at any time, for any reason. If you have any questions about this study, you may call the Study Coordinator or RTI's Office of Research Protection listed below. If you qualify and complete the survey today, your parent's Global Test Market account will be credited with 100 Lifepoints.

Risks

There are minimal psychological and social risks to participating in this study. You may or may not feel comfortable answering some of the questions in this survey, such as those about vaping or tobacco use.

Benefits

There is no direct benefit to you from participating. Your responses may help researchers understand what people think about vaping and tobacco use.

Confidentiality

Every effort will be made so that that no one will be able to know how you answered the questions, not even your parents. However, protection of your information cannot be guaranteed. The information will be kept private to the fullest extent allowable by law. The information that was collected from you during the screener will be kept in a secure database with access only to authorized project staff members. Your answers to the study questions will be combined with answers of many others and reported in the summary form. Any personal information that can be used to identify you is stored in a separate database from your survey responses, and your survey responses will not be linked to your personally identifiable information. 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 personal information. Information from this study may be published in professional journals or presented at scientific conferences, but your identifiable information will not be included in any report or presentation. All research staff are committed to privacy and have signed a Privacy Pledge.

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

- you agree to share information (for example, to get medical treatment);
- the study information is used for other scientific research that follows federal 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 researchers must report to FDA, or if researchers hear threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you from sharing any personal information or information about your involvement in this study with others. For example, you can share that you are in this research study or your history of vaping or tobacco use.

Questions

If you have any questions about this study, you can call the Study Coordinator, Annice Kim at 919-541-8702. If you have a question about your rights as a study participant, you can call RTI's Office of Research Protection at (866) 214-2043.

Y_ASSENT. Do you agree to participate in the study?

1. Yes
2. No

[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 1 minute per response 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.