

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

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

Introduction to the Study

This survey is intended for youth aged 13-17. We are reaching out to youth to understand what they think about vaping and tobacco use. This research study consists of a single survey that will take on average 18 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.

Selection of Youth

Up to 1,600 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 about their experiences with and opinions about vaping and tobacco products. Youth will take the survey online.

Voluntary Participation

Your child can 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. You will receive 100 Lifepoints if your child completes the survey.

Risks

There are minimal psychological and social risks to participating in this study. It is possible that some questions might make your child uncomfortable, depending on his or her responses.

Benefits

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

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 will be kept private to the fullest extent allowable by law. The information that was collected from your child during the screener and surveys will be kept in a secure database with access only to authorized project staff members. Your child's answers to the study questions will be combined with answers of many others and reported in a 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 a Privacy Pledge.

This research is covered by a Certificate of Confidentiality from FDA to help us protect your child's privacy. This means that the researchers cannot disclose your child's name or other information that could identify him/her in any civil, criminal, administrative, legislative or

other proceedings (like a court trial), without your consent. Information collected for this research that could identify your child also cannot be used as evidence in a legal proceeding without your consent.

In addition, with the Certification of Confidentiality, researchers involved in this study generally may not provide your child's name, or any other information that could identify your child, to anyone who is not connected with the research. However, in the following situations, the Certificate does not prevent the researchers involved in this study from disclosing study information that could identify your child:

- if you consent to someone receiving your child's information from this study, including situations where the information is necessary for his/her medical treatment;
- when your child's study information is used for other scientific research, as allowed by federal regulations protecting research subjects;
- when information is needed by FDA, which is funding this study, in order to audit or evaluate federally funded studies;
- when a law otherwise requires disclosure (such as requirements to make certain reports to FDA, reporting threats of harm to self/others, or reports of child abuse), except this does not apply to disclosure in a legal proceeding.

The Certificate does not prevent your child from voluntarily providing information about him or herself or his/her involvement in this research study to others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document: Your child's vaping and tobacco use history.

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 toll-free at (866) 214-2043.

Do you agree to allow your child to take the survey?

1. Yes
2. No

[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 1 minute per response 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 "Next" when your child is ready to begin. [GO TO YOUTH ASSENT]

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END

Thank you for your time.