[PROTOCOL TITLE: Formative Research Support: Outcomes and Awareness Measurement Research

RTI PRINCIPAL INVESTIGATOR: Matthew Eggers

Version 12-13-21]

OMB# 0910-0810 EXP: 12/31/2024

[Text within brackets will not show to participants]

[Appendix B: Online Survey Parental Permission]

Parental Permission for Youth to Participate in Research Study

We are talking to teenagers ages 13-17 all over the United States for a study sponsored by the Center for Tobacco Products at the U.S. Food and Drug Administration (FDA). The mission of the FDA is to promote and protect public health. In conducting this study, FDA does not intend to encourage tobacco use, and FDA does not sell tobacco. The questions in this study are not meant to promote risky behaviors such as drug use, binge drinking or smoking.

This research study asks people about their beliefs and behaviors related to vaping. About 2,400 teenagers are being asked to take 2 surveys over the course of 2 weeks as part of this research study conducted by RTI International. This is the second survey for your child (ages 13-17) who filled out the first survey two weeks ago. The second survey is estimated to take your child 15 minutes to complete.

We need permission from a parent or guardian before we survey your child. Your child will be asked what they think about health behaviors like tobacco use and for their opinions about some television and social media advertisements. Your child will take the survey online.

There are minimal psychological or social risks to participating in this study. Your child may or may not feel comfortable answering some of the questions in these surveys, such as those about tobacco use. There is no direct benefit to your child from participating. However, your child's responses are very important because they will help researchers understand how people interpret tobacco product information.

The information that your child provides in the study will be handled confidentially. To help ensure your child's answers are kept private, please have your child complete the surveys in a place where no one can look over his or her shoulder and view his or her answers.

We have procedures in place that are designed to ensure that RTI International and FDA will not connect your name or your child's name to his or her answers. Although there is a chance his or her data could be seen by someone who shouldn't have access to it, we're minimizing this risk in the following ways:

- The surveys will not ask for your child's name. Lightspeed Research, the company hosting this survey, will identify your child only with a code number. Your name and your child's name will not be part of this study's dataset. Only Lightspeed Research maintains a link between code numbers and personally identifying panel profile information for Lightspeed Research panelists. Although we cannot guarantee that no one can reidentify this data, it is highly unlikely that this will occur.
- If you are a panelist for one of Lightspeed Research's partner panels, the partner panel will never have access to your child's survey responses. Lightspeed Research will only share code numbers with partner panels for the purpose of distributing your compensation.

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• The dataset from this survey will be kept on a secure RTI server with access only to authorized project staff members.

Information from this study may be published in professional journals or presented at meetings, but no names will ever be used. In the future we may use or share the survey dataset with other researchers for other studies. If we do so, we will not contact you to ask for your additional informed consent.

Your child's participation in this research study is completely voluntary. If your child doesn't want to take the second survey, that is okay. If your child gets to a question on the survey that he or she does not want to answer, he or she can skip it. Your child can drop out of a survey at any time for any reason by closing the Internet browser. If your child completes the second survey, your account will be credited with the reward points as stated in each communication. If your child does not complete the second survey, you will not receive reward points for that survey.

This project is funded by FDA and holds a Certificate of Confidentiality that offers additional legal confidentiality protections. The most important protection is that members of the research team cannot be forced to disclose or provide any of your child's private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your child's research information may only occur in limited instances, such as:

- You can freely discuss your child's involvement in this research.
- The researchers cannot refuse requests for information from the FDA, the survey's sponsor.
- In situations involving imminent danger, the law requires the researchers to disclose certain information.

The Institutional Review Board (IRB) at RTI International has reviewed this research. An IRB is a group of people who are responsible for ensuring that the rights of participants in research are protected. The IRB may review the records of your child's participation in this research to ensure that proper procedures were followed.

If you have any questions about this study, you may call Matthew Eggers of RTI at 919-990-8380, or at 1-800-334-8571, extension 28380. If you have any questions about your child's rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043. You can print or take a screenshot of this form if you would like a copy for your records.

1. What is the date of birth of the child you will invite to participate in the second survey? Please select the same child who completed the first survey.

[P_	_BMONTH] Month:	[P_BDAY] Day:	[P_BYEAR] Year:

[VALIDATE CORRECT DATE FORMAT. DO NOT ALLOW FUTURE DATES. IF THE DATE IS NOT

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VALID, PLEASE DISPLAY A HARD ERROR, "Please enter a valid date."]

[GENERATE CALCULATED VARIABLE FOR AGE OF CHILD [AGE]. TERMINATE IF AGE < 13 OR >17.]

2. Do you give permission for your child to participate in the second survey?

1 Yes

2 No

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

[P_INTRO]

Now we will be asking your child survey questions. It is important that your child be allowed to answer all questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Please bring your child to this device, and press "Continue" when your child is ready to begin.

[GO TO ASSENT]

[END]

If you are a tobacco user or have a friend or family member who is a tobacco user, and you would like information on how to quit, please visit https://smokefree.gov/. Thank you for your time.

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Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2 minutes per response Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.