[PROTOCOL TITLE: Nicotine Education Project RTI PRINCIPAL INVESTIGATOR: Youn Lee

Version 02-18-221

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

[Text within brackets will not show to participants]

# [Appendix B: Online Survey Youth Assent] Research Study Assent Form

If you want to, you can be a part of this research study. About 2,004 people are being asked to take a survey for this research study that is sponsored by the U.S. Food and Drug Administration (FDA) and led by RTI International (RTI). 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. People do research to try to find answers to questions. Research studies help us learn new things.

## Why are we doing this research study?

The reason we are doing this research is to learn people's thoughts and opinions about nicotine and tobacco products.

# What will happen if I join this research study?

You will be asked to take a survey that will take about 15 minutes. The survey will ask you questions about nicotine and tobacco products.

## What are the problems that might happen in this research study?

Some of the questions might be hard to answer or make you feel uncomfortable. You should know that:

- You get to decide if you want to take part in this research study. You can say "No" or you can say "Yes".
- If you do not want to answer a question on the survey, you can skip it. That is okay.
- You can stop taking the surveys at any time by closing your Internet browser.

## Who will be told the things we learn about you in this study?

Your name will not be in any report of the results of this study, and your parents or guardians will not be told how you answered the questions. Please take the surveys in a place where no one can look over your shoulder and view your answers. Please do not take the survey while driving.

Some personal information, like your email address and date of birth, will be gathered. Your answers will be labeled with a number. This makes it so only study staff will know these are your answers. Only the authorized study staff will have access to your responses. We are only interested in the combined responses from everyone who is selected to participate, not just one person's answers. Your answers combined with all other responses will be shared with FDA. Your e-mail address and date of birth will not be shared with FDA. In the future we may use or share the combined survey answers (but no personal information) with other researchers for other studies, but we will not contact you again.

This research study has a Certificate of Confidentiality. This means that the researchers

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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.

## What are the good things that might happen in this study?

People may have good things happen to them because they are in research studies. These good things are called "benefits." There are no benefits to you from being in this research study.

# Will you get any money or gifts for being in this research study?

If you complete the survey, you will get a \$5 gift card at the email address you provide within 1-2 weeks as a token of our appreciation. You can drop out of the survey at any time for any reason by closing your Internet browser. If you do not complete the survey, you will not receive a gift card. Responses will be verified prior to issuing the gift card; If we find that you have completed the survey more than once, you may not receive a gift card. In order to receive the gift card, you must provide an email address. The email address will only be used to send your incentive (through Creative Group Inc.) and will not be otherwise sold or shared.

#### Who should you ask if you have any questions?

If you have questions, you should ask us. You may call Youn Lee (RTI Researcher) at 919-541-8735, or at 1-800-334-8571, extension 28735. If you have any questions about your 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. 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 guit, please visit https://smokefree.gov/.

### Do you agree to take part in the study by answering survey questions?

1 Yes

2 No

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 2.5 minutes per response (the time estimated to read, review, respond). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.

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

#### [END]

Thank you for your time.