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

RTI PRINCIPAL INVESTIGATOR: Matthew Eggers

Version 03-02-22]

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

[Text within brackets will not show to participants]

[Appendix C: Online Survey Youth Assent] Research Study Assent Form

If you want to, you can be a part of this research study. This research study is sponsored by 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 is led by RTI International (RTI). About 2,400 teenagers are being asked to participate in this study. 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 tobacco use and about advertisements people might see on television, streaming channels, or social media.

What will happen if I join this research study?

You will first be asked to take an online survey that will take about 20 minutes. After that, you will be asked to take another survey in 2 weeks. The surveys will ask you questions about tobacco and marijuana use and television advertisements.

Your parent or guardian has given permission for you to take these surveys. You do not have to be in this study if you don't want to, even if your parent or guardian has already given us permission.

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". That is okay.
- If you do not answer some of the questions at the beginning of the survey, you cannot take the rest of the survey. That is okay.
- For most of the questions, if you do not want to answer it, you can skip it. That is okay.
- You can stop taking the surveys at any time by closing your Internet browser. That is okay.

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

Your name will not be in any dataset and/or report of the results of this study. 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. Your risk of taking

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this survey is no greater than everyday use of the Internet.

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:

- 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.

In the future we may use or share survey data with other researchers for other studies. If we do so, we will not contact you to ask for your permission.

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 direct benefits to you from being in this research study. However, your participation in this study will provide valuable information that will help researchers understand more about what teens think about tobacco use and related advertising.

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

If you choose to participate and complete the survey, your parent or guardian will receive reward points. If you withdraw from the online study after completing the screener and do not complete the online survey, your parent will not receive any reward points.

Who should you ask if you have any questions?

If you or your parents or guardians have questions or concerns about this survey, you may call Matthew Eggers (RTI Researcher) at 919-990-8380, or at 1--800-334-8571, extension 28380. If you have any questions now, you should ask them before starting the survey. If you or your parents or guardians 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.

Do you agree to:

- 1. Take a short screening survey to find out if you are eligible for the study, and
- 2. If you are eligible, take part in the study by answering questions in a longer survey?

1 Yes 2 No [IF YES, GO TO SCREENER] [IF NO, GO TO END]

[END]

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.