OMB No. 0910-0796
Exp. 06/30/18

Assent to Participate in Focus Group
Qualitative Study on Acute Nicotine Toxicity Warnings for E-Liquids

Introduction and Purpose:

You have been asked to participate in a focus group as part of a research project. The purpose of the focus group is to better understand how young people feel and think about e-cigarettes and labels that might be used on future e-cigarettes and packaging.

RTI International, a non-profit research company in North Carolina will be doing the focus group. The research is sponsored by the Food and Drug Administration (FDA).

Procedures:

During the focus group you will be joining a group of about 11 other people your age to talk with a member of the project team from RTI International. You will be asked some questions about labels that might be used on future e-cigarettes and e-cigarette packaging. You will also be asked to fill out a worksheet about these labels. The focus group will last no more than 60 minutes.

We will be conducting focus groups around the country with young people for this study. You are one of approximately 144 participants who will take part in this study.

Some of the people working on the project may watch the focus group through a one-way mirror and take notes. We will also video-stream the discussion to other staff who couldn't be here. The focus group will be audio recorded. All recordings will be destroyed at the end of the project.

Risk/Discomforts:

There are small psychological, social, and legal risks to you from being in this study. Though unlikely, there is a small chance that you might feel embarrassed or upset by the things that are talked about during the focus group since we talk about things such as tobacco use. You can say you do not want to talk about any topic for any reason. You can also stop being in the focus group at any time without penalty. If the moderator believes that it would be best for you or the rest of the group, they may ask you to leave the group. You will still be compensated. As with all research there is a chance that confidentiality of the information we collect from you could be breached. We will take steps to minimize this risk.

Benefits:

There is no direct benefit to you for being in this study. What we learn from the study will help the FDA better understand how people think about tobacco and health.

Privacy:

We will audio-record but not video-record the focus group. Notes will be made of the recordings. We will not share information with anyone outside of the study unless it is

necessary to protect you, or if it is required by law. Information you share about your tobacco-related attitudes, beliefs and behaviors will not be shared with others, including your parents.

We will only use first names in the notes. Your comments will be kept private to the extent allowed by law. The audio recordings and notes will be kept on a password-protected computer. Only certain project staff who have been trained on the project will be able to see them. Any forms for the project that have your name or anything that could identify you will be kept in a locked file cabinet. Except for this consent form, these forms will be destroyed once the focus groups ends. However, there is still a small chance that your privacy could be broken.

Payment:
We will give you $25 for your time, effort and travel costs. Your parent/guardian that comes with you will also receive $15.

Right to Refuse or Withdraw:
It is your choice to be in this study. You can choose not to talk about any topic. You can stop your participation in the focus group at any time without penalty.

Persons to Contact:
You may ask questions or express concerns about this assent form, the study, your rights as a research subject, or report problems (e.g. any research–related injuries) at any time before, during or after the study. You may contact the research team through the Principal Investigator of the study, Jennifer Alexander of RTI at 301-770-8219. If you have concerns about how you are treated in the study, you may contact RTI's Office of Research Protection toll-free at 1-866-214-2043.

Your Assent:
I have read this assent form. I understand what I am being asked to do. My questions have been answered and any words I did not understand have been explained to me. I agree to be in this research study for the purposes listed above. I will receive a copy of this assent form for my records.

_____
Print your name here if you want to be in this study

_____ _____
Sign your name here if you want to be in this study Date