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

Parental Permission Form for Focus Group
Qualitative Study on Acute Nicotine Toxicity Warnings for E-Liquids

PURPOSE: Your child has been asked to participate in a focus group as part of a research project. The purpose of the focus group is to get information on how young people feel and think about cigarettes and smoking. 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: If you agree to let your child participate in a focus group, your child will join about 11 others and be asked questions to help us understand what teens think and know about e-cigarettes and nicotine exposure. They will also be asked about labels that might be used on future e-cigarettes and e-cigarette packaging and to fill out a worksheet about these labels. We will explain the procedures to your child and ensure he/she is comfortable before we begin. The focus group will take no more than 60 minutes. Each focus group will be audio-taped and may be video-streamed (but not recorded) to project staff members.

RISKS/DISCOMFORTS: As part of the focus group, your child will be asked questions about perceptions, awareness, beliefs, and behaviors around tobacco products. Your child may feel uncomfortable being asked these questions. There are minimal psychological, social, or legal risks to participating in this study. The study is minimally sensitive in nature because we ask participants to report on tobacco use. Participation is voluntary and your child can choose not to answer any of the questions. Your child can also stop being in the focus group at any time without penalty. If the moderator believes that it would be best for your child or the rest of the group, they may ask your child to leave the group without penalty. As with all research there is a chance that confidentiality of the information we collect from your child could be breached. We will take steps to minimize this risk.

BENEFITS: There are no direct benefits to you or your child for participating in this study. However, the results from this study will help FDA better understand how people think about tobacco products.

CONFIDENTIALITY: Any forms for the project that have your name or your child's name or anything that could identify you will be kept in a locked file cabinet. Except for this consent form and your child's assent form, these forms will be destroyed once the focus group ends. We will not collect any personal identifying information during the focus group. Neither your name nor your child's name will be connected to his/her answers; therefore, no information provided during the focus group can be used to identify you or your child. We will not share information with anyone outside of the study unless it is necessary to protect you or your child, or if it is required by law. **Information your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others, including you.**

CONSENT WITHDRAWL: Your child's participation in this study is completely voluntary. You may withdraw your consent and stop your child's participation at any time. If you decline to allow your child to participate in this study, you and your child will not be affected in any way.

PAYMENT: Your child will receive $25 for his/her time and opinions plus $15 for a parent/guardian that accompanies them to the study facility.

By signing this form, you agree to allow your child to participate in our research study.

You may ask questions or express concerns about this permission form, the study, your child's 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.You will receive a copy of this (permission) form for your records.

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Parent or Guardian's Printed Name	Date	Parent or Guardian's Signature