

OMB No.

Exp. Date:

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parental Permission Form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

Parental Permission Form

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 nicotine and addiction to products. 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 9 others and be asked questions to help us understand how teens think about tobacco products. 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 90 minutes. Each focus group will be audio-taped and may be videostreamed to project staff members.

REQUIREMENTS FOR CONTINUED PARTICIPATION: Your child may end his/her participation or refuse to answer any questions at any time for any reason. There will be no consequences, and your child will still be paid. Additionally, if at any time the moderator feels it is not in your child's best interest to continue, he/she will stop your child's participation in the focus group.

RISKS/DISCOMFORTS: As part of the survey, your child will be asked questions about perceptions, awareness, beliefs, and behaviors around tobacco products. Your child may feel uncomfortable being asked these questions. None of the questions are sensitive in nature. Participation is voluntary and your child can choose not to answer any of the questions.

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: 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.

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

PAYMENT: Your child will receive \$30 for his/her time and opinions plus \$25 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 consent 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, Denise

Dickinson of RTI at (919) 485-5594. If you have concerns about how participants are being treated in the study, you may contact RTI's Office of Research Protection toll-free at 1-866-214-2043.

Parent or Guardian's Printed Name

Date

Parent or Guardian's Signature