

Parent Permission Form for Focus Group Tobacco Discussion

Introduction and Purpose:

Your child is being asked to participate in a focus group as part of a research project. This research is voluntary. The purpose of the focus group is to get your child's reactions to some pictures and short sentences that might be used in the future on cigarette packages and on advertisements as a part of a warning. RTI International is a non-profit research company in North Carolina. RTI will be doing the focus group. The Food and Drug Administration (FDA) sponsors the research.

Procedures:

If you agree to let your child participate, your child will join a group of about 9 other people his/her age to talk with a member of the project team from RTI International. Your child will give his/her reactions to pictures and sentences that might be used in the future on cigarette packages and on advertisements and be asked to fill out a worksheet about these pictures and sentences. The focus group will last about 90 minutes. We will be having focus groups around the country for this study. Your child will be one of about 240 participants 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 cannot attend. The focus group will be audio recorded. RTI will give the recording to FDA and they will destroy it once the project ends.

Risk/Discomforts:

There is no known physical risk to your child from being in this study. There is a small chance that your child might feel embarrassed or upset by the things discussed. Your child can say that he/she doesn't want to talk about any topic for any reason. 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 the information we collect from your child could be breached. We will take steps to minimize this risk.

Benefits:

There is no direct benefit to your child for being in this study. The study will help the FDA better understand how people think about tobacco and health.

Privacy:

We will audio record and may video stream (but not video record) the focus group. Notes will be made of the audio recording. We will only use first names in the notes. Your child's comments will be kept private to the extent allowed by law. Information from this study may be used in published reports or presentations but your child's privacy will be respected. No names will be used in any report or presentation. We will keep the audio recording and notes on a password-protected computer. Only certain trained project staff will be able to see them. RTI will give the recording to FDA and they will destroy it once the project ends. We will keep any forms that have names or anything that could identify your child in a locked file cabinet. Except for this permission form and your child's assent form, we will destroy all forms once the project

ends. However, there is still a small chance that your child's privacy could be broken. **We will not share information your child shares with anyone outside of the study, including you, unless it is necessary to protect your child, or if it is required by law. Future Contact:** We will not contact you or your child in the future.

Payment:

We will give your child \$40 for his/her time, effort and travel costs. You will also receive \$35 when you come with your child.

Right to Refuse or Withdraw:

It is your choice whether or not to allow your child to be in this study. Your child can choose not to talk about any topic. Your child can stop being in the focus group at any time without penalty.

Persons to Contact:

You may ask questions or express concerns about this permission form, the study, or your child's rights as a research participant at any time before, during or after the study. You may report problems (such as any research-related injuries) at any time. You may contact the leader of the study, Denise Dickinson of RTI, at (919) 485-5594. If you have concerns about how your child is treated in the study, you may contact RTI's Office of Research Protection toll-free at 1-866-214-2043. You may also contact FDA's Research Involving Human Subjects Committee at 301-796-9605, or at RIHSC@fda.hhs.gov.

Your Permission:

I have read this permission form. I understand what my child is being asked to do. My questions have been answered and any words I did not understand have been explained to me. I agree to allow my child to be in this research study for the purposes listed above. I have received a copy of this permission form for my records. I understand that by agreeing for my child to participate in this research, neither I nor my child are giving up any of our legal rights.

Child's name

Parent or Guardian's Printed Name

Parent or Guardian's Signature

Date

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting burden for this information collection has been estimated to average 10 minutes per response to complete the Parent 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 PRAStaff@fda.hhs.gov.