

## **Assent to Participate in Focus Group Tobacco Discussion**

### **Introduction and Purpose:**

You are 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 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:**

You will join a group of about 9 other people your age to talk with a member of the project team from RTI International. You will give your reactions to pictures and sentences that might be used in the future on cigarette packages and on advertisements. You will also 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 with young people for this study. You are one of about 240 participants who will be 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. 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 you from being in this study. There is a small chance that you might feel embarrassed or upset by the things you talk about. 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 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. 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 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 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 for the project that have names or anything that could identify you in a locked file cabinet. Except for this assent form and the permission form, we will destroy all forms once the project ends. However, there is still a small chance that your privacy could be broken. **We will not share information you share with anyone outside of the study, including your parents, unless it is necessary to protect you, or if it is required by law.**

**Future Contact:**

We will not contact you in the future.

**Payment:**

We will give you \$40 for your time, effort, and travel costs. Your parent/guardian that comes with you will also receive \$35.

**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 being 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, or your 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 you are 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](mailto:RIHSC@fda.hhs.gov).

**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.

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

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

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Date

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Name of Witness to Assent  
(Print)

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Signature

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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 Youth Assent (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](mailto:PRASStaff@fda.hhs.gov).