

**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 Assent statement (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).

### **Assent for Participation in Focus Group**

#### **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 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:**

During the focus group you will be joining a group of about 9 other people your age to talk with a member of the project team from RTI International. You will be asked for your opinions on tobacco and health. The focus group will last no more than 90 minutes.

We will be conducting about 12 focus groups around the country with young people for this study.

Some of the people working on the project may watch the focus group through a one-way mirror and take notes. It may also be video streamed 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 is no known physical risk 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. 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.

#### **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 tape and may video stream the focus group. Notes will be made of the recordings. 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. These forms will be destroyed once the project ends. However, there is still a small chance that your privacy could be broken.

**Payment:**

We will give you \$30.00 for your time, effort and travel costs.

**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 consent 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, 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.

**Your Assent:**

I have read this assent form. I had a chance to ask questions and my questions were answered. I was given a copy of this assent form.