

## Parent Permission Form

11-30-2016

### Introduction

We are asking your child to participate in an interview as part of a research study. Before you decide if you want your child to be interviewed, you need to read this form. It will explain what the study is about and what your child will be asked to do.

### Purpose

RTI International (RTI) will be doing the interview. The purpose of the interview is to get information and opinions about different tobacco products.

### Procedures

Your child will be one of about 20 youth and 30 adults who will be interviewed. They will be asked questions to help us understand what people think and know about tobacco. We will explain this to your child and make sure they are comfortable before we start. The interview will be audio recorded and transcribed. We will use the transcripts to make a summary of each interview. Study staff may view the interview from behind a one-way mirror or on video-streaming.

### Study Duration

Your child's interview will take no longer than 60 minutes.

### Possible Risks or Discomforts

There are minimal risks to being in this study. Your child's participation is voluntary. Your child will be asked to share their thoughts and opinions but the topic is not sensitive in nature. Some of the information they read may be upsetting. They can choose not to answer any of the questions.

### Benefits

There are no direct benefits to you or your child from participating in this study. Your child's opinions will help us understand how people think about tobacco products.

### Payment for Participation

Your child will receive \$20 for his/her participation. You will receive \$20 for bringing your child to the interview. These will be given to you and your child at the end of the interview. You or your child have the right to stop participating at any point, without penalty. If your child must leave or is asked to leave for any reason before the end, you and your child will receive the full amount.

### **Privacy and Confidentiality**

Only your child's first name will be used during the interview. Your child's name will never be linked to what they say during the interview. Transcripts will be stored securely on a password-protected computer. At the end of this study, the audio recordings will be destroyed. Information from this study may be published in professional journals or presented at meetings, but no names will ever be used.

Your child's answers will be kept confidential to the extent allowable by law and will not be shared with anyone outside of the study. We will take care to protect the information your child provides. In all studies, there is a chance that privacy could be broken because of an accidental error or a security breach. In the event a breach occurs, all participants will be notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

### **Future Contacts**

We will not contact you or your child in the future.

### **Your Rights**

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 do not allow your child to participate in this study, you and your child will not be affected in any way.

### **Your Questions**

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. If you have questions about the study, you may contact the research team through the Principal Investigator, Jonathan Blitstein of RTI at 919-541-7313.

The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration and the Institutional Review Board (IRB) at RTI have reviewed this research. These groups are responsible for protecting the rights of people in research. They may review the records to make sure that proper procedures were followed.

If you have concerns about how you or your child are treated in the study, you may contact RIHSC at 301-796-9605, or at [RIHSC@fda.hhs.gov](mailto:RIHSC@fda.hhs.gov). You may also call RTI's Office of Research Protection toll-free at 1-866-214-2043.

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### **YOU WILL BE GIVEN A COPY OF THIS PERMISSION FORM TO KEEP.**

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Your signature below indicates that you have read the information provided above, have received answers to any questions you may have, and have freely decided to allow your child to participate in this research. By agreeing for your child to participate in this research, you and your child are not giving up any of your legal rights.

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OMB Control #0910-0796

6/30/18

RIHSC #

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Parent or Guardian's Printed Name

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Date

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Parent or Guardian's Signature

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 5 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 [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).