

Youth Assent to Participate in RTI Research

11-30-2016

Introduction

We are asking you to participate in an interview as part of a research study. Please read this form so that you understand what the study is about and what you will be asked to do. You can ask the researcher to explain anything you don't understand.

Purpose

RTI International (RTI), a non-profit research company in North Carolina, will be doing the interview. The purpose of the study is to get information and opinions about different tobacco products.

Procedures

If you agree, you will be one of about 20 youth and 30 adults who will be interviewed. You will be asked questions to help us learn what people think and know about tobacco. 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 interview will take no longer than 60 minutes.

Possible Risks or Discomforts

There are minimal risks to being in this study. Some of the information you read may be upsetting. You will be asked to share your thoughts and opinions; however, the topic is not sensitive. Your participation is voluntary. You can choose not to answer any of the questions.

Benefits

There are no direct benefits to you from participating in this study. Your answers will help us understand how people think about and use tobacco products.

Payment for Participation

You will receive \$20 for being interviewed. Your parent/guardian will receive \$20 for bringing you to the interview. This will be given to you and your parent/guardian at the end of the interview. You have the right to stop at any point, without penalty. If you stop or if the interview is stopped before the end, you and your parent/guardian will receive the full amount.

Privacy and Confidentiality

Only your first name will be used during the interview and your name will never be linked to what you say. We will not share any information you give us with your parents, or anyone outside the research team, and all of your answers will be kept private to the fullest extent possible by law. We will make transcripts from the audio recordings. They will be stored securely on a password-protected computer and will be destroyed

after 3 years. At the end of this study, the audio recording will be destroyed. Information from this study may be published in professional journals or presented at meetings, but no names will ever be used.

We will try to protect the information you provide. In all studies, there is a chance that privacy could be broken because of an accidental error or a security breach. If this happens, you will be told about the extent of the breach, any damages, and future potential risks, and given contact information if you have questions.

Future Contacts

We will not contact you in the future.

Your Rights

Your decision to take part in this research study is completely voluntary. You can refuse any part of the study and you can stop at any time. You can refuse to answer any question. If you agree to be interviewed and later change your mind, you will not be contacted again or asked for further information.

Your Questions

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 International have reviewed this research. These are groups of people who are responsible for making sure that the rights of people in research are protected. They may review the records to make sure that proper procedures were followed. If you have concerns about how you are treated in the study, you may contact RIHSC at 301-796-9605, or at RIHSC@fda.hhs.gov. You may also call RTI's Office of Research Protection toll-free at 1-866-214-2043.

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

Your signature below shows that you have read this form. You have gotten answers to any questions you have and have decided to participate. By agreeing to participate, you are not giving up any of your legal rights.

Date

Signature of Participant

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 PRAStaff@fda.hhs.gov.