Adult Consent 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 to be interviewed, 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 in nature. 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 $40 for being interviewed. This will be given to you 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 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 during the interview. Your answers will be kept private to the extent possible by law. We will create transcripts from the audio recordings. Transcripts 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 take care 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. 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 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 CONSENT FORM TO KEEP.

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

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Date Signature of Participant