Consent to Participate in RTI Research

Introduction

You are being asked to participate in a research study. Before you decide if you want to take part in this study, you need to read this Informed Consent form so that you understand what the study is about and what you will be asked to do. This form also tells you who can be in the study, the risks and benefits of the study, how we will protect your information, and who you can call if you have questions. Please ask the researcher to explain anything you don't understand before you make your decision.

Purpose

This research study is being conducted by RTI International for the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). The purpose of today's focus group is to get information and opinions about different tobacco products. You are one of approximately 240 participants who will take part in this study.

Procedures

If you agree to participate, you will be asked to participate in a focus group discussion with about 9 other people and answer some questions about your opinions and experiences with tobacco products. Tonight's discussion will be audio-taped. We will use the tapes to prepare a summary of each group's discussion; however, your name will not be associated with your responses in any reports. At the completion of this study, the audio recordings will be destroyed. Before we start the focus group discussion, we have a brief questionnaire we would like you to complete. We would also like to take a photo of the product you brought with you; we will not take a photo of you. Staff members from FDA and RTI may be viewing tonight's discussion in person (behind a one-way mirror) or remotely (via videostreaming).

Study Duration

Your participation in this study will take no longer than 90 minutes.

Possible Risks or Discomforts

There are minimal psychological, social, or legal risks to participating in this study. You will be asked to share your attitudes and opinions in a group setting; however, tonight's topic is not sensitive in nature. Your participation is voluntary, and you can choose not to answer any of the questions.

Benefits

There are no direct benefits to you from participating in this study. Your opinions will help us improve our understanding of how people think about and use tobacco products.

Payment for Participation

You will receive $75 for your participation. This will be given to you at the end of the focus group session. You have the right to terminate your participation at any point, without penalty. If you must leave or are asked to leave for any reason before the conclusion of the session, you will receive the full incentive amount.

Confidentiality

We will create transcripts of tonight's discussion. To help protect your privacy, only your first name will be used during the group discussion and your identity will never be linked to what you say during the discussion. Upon completion of the study, we are required to store these transcripts for at least three years.

Transcripts will be stored securely on a password-protected computer. Information from this study may be published in professional journals or presented at scientific conferences, but your privacy will be respected and no names will be used in any report or presentation.

The Institutional Review Board (IRB) at RTI International has reviewed this research. An IRB is a group of people who are responsible for assuring that the rights of participants in research are protected. The IRB may review the records of your participation in this research to assure that proper procedures were followed.

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 participating at any time. You can refuse to answer any question. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

Your Questions

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, Jennifer Alexander of RTI at 301-770-8219. 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 WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

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 participate in this research. By agreeing to participate in this research, you are not giving up any of your legal rights.

_____ _____

Date Signature of Participant

_____

Printed Name of Participant

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above-named individual.

_____ _____

Date Signature of Person Obtaining Consent

_____

Printed Name of Person Obtaining Consent

_____

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 Consent Form (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.