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Paperwork Reduction Act Statement

The public reporting burden for this collection of information has been estimated to average 1.1 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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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 consent 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 the study is to collect consumers' opinions about various types of cigarettes and other tobacco products. You are one of approximately 160 adults who will participate in this study.

Procedures

If you agree to participate, you will be asked to participate in a focus group discussion. Tonight's discussion will be audio-taped to collect your attitudes and opinions. 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. Additionally, staff members from FDA may be viewing tonight's discussion.

Study Duration

Your participation in this study will take about 60 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 FDA learn more about what people think about tobacco products.

Payment for Participation

You will receive $50.00 in cash for your participation in the study. This will be given to you at the end of the focus group session. In the event that you cannot complete the discussion session because you choose to leave or because you are asked to leave due to disruptive behavior, you will receive the full incentive.

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 confidentiality will be respected and no names will be used in any report or presentation.

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. If you have any questions about the study, you may contact the research team through the Principal Investigator, Sarah Johnson at (301)796-6890, or Katherine Kosa of RTI, at (800) 334-8571, extension 23901. If you have any questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043. If you prefer to contact someone outside of the research team, you may contact the Call Center at the Center for Tobacco Products at 1-877-287-1373. If you call after hours, select option #5 (general public), then option #4 (general public) to leave a message.

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