

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 Centers for Disease Control and Prevention (CDC) with women ages 18 to 40 years old who smoke or recently quit and who are pregnant or planning to become pregnant. The purpose of the study is to collect women's opinions about various types of cigarettes and other tobacco products. You are one of approximately 150 women who will participate in this study.

Procedures

If you agree to participate, you will be asked to participate in a [focus group/one-on-one] discussion. Tonight's discussion will be audio- [INSERT FOR FOCUS GROUPS and videotaped] to collect your thoughts 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- [INSERT FOR FOCUS GROUPS and videotapes] will be destroyed. Additionally, study team members from CDC and the Food and Drug Administration (FDA) maybe viewing tonight's discussion.

Study Duration

Your participation in this study will take [90/60] 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 thoughts and opinions in a [group/one-on-one] 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 CDC shape intervention and policy strategies to prevent smokeless tobacco use among women of reproductive age.

Payment for Participation

You will receive \$75 for your participation.

Confidentiality

Your name will not be connected to the answers you provide; therefore, no information you provide during the study can be used to identify you.

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. A representative of the IRB may contact you for information about your experience with this research. This representative will be given your name, but will not be given any of your confidential study data. If you wish, you may refuse to answer any questions this person may ask.

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

If you have any questions about the study, you may call Katherine Kosa of RTI at 1-800-334-8571, 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.

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