

## ATTACHMENT 7 CONSENT FORM



### Consent to Participate in Focus Group

**Title:** Focus Groups about Cigarette Smoking during Pregnancy and Adverse Outcomes,  
Including Birth Defects

#### ***Introduction***

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

#### ***Purpose***

The project “Focus Groups about Cigarette Smoking during Pregnancy and Adverse Outcomes, Including Birth Defects” is paid for by the Centers for Disease Control and Prevention (CDC). The focus groups are being conducted by RTI International, a research organization headquartered in Research Triangle Park, North Carolina. The purpose of this study is to learn about women’s attitudes, beliefs, and knowledge related to smoking and reproductive health. You are one of approximately 120 people being asked to participate in this study.

#### ***Procedures***

If you agree to participate, you will take part in a group discussion about women, smoking, and reproductive health.

An experienced focus group leader from RTI will moderate the discussion. **We will digitally record the interview.** A note taker will also observe the session from the observation room. Representatives of CDC, the sponsor for this study, may also observe the focus groups on site or listen via telephone. However, no one from CDC will know your full name.

#### ***Study Duration***

Your participation in the focus group will take about 90 minutes.

#### ***Privacy***

Public reporting burden of this collection of information is estimated to average 5 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0798)

Many precautions have been taken to protect your information. Your identifiable information will be kept by the recruitment firm and the audio recording and notes from the interview will be kept by RTI, under lock and key. Identifiable information such as names, addresses, and phone numbers will be kept separate from the focus group notes and will not be included in a report or in subsequent publications or presentations. The findings from the focus groups will be reported in summary form so that the participants cannot be identified. RTI will retain a copy of the digital audio files on password-protected computers and a share drive to which only RTI team members have access. The digital audio files will be destroyed within a year of the project's end.

Project staff will use only participants' first name or a pseudonym during the focus group for their privacy. We ask that you please respect the privacy of the other participants in the focus group, and do not share what is said in the group after it is over.

Also, any information that this local facility already has about you—because you have been in other projects—will still be kept there. You may be contacted by them to be in other projects in the future.

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

#### ***Possible Risks or Discomforts***

Although the recruiting agency is making every effort to secure your identifying information, there is the potential risk of loss of privacy. Every effort will be made to protect your information, but this cannot be guaranteed. It is also possible that some of the focus group questions may make you uncomfortable or upset. You can refuse to answer any question or you may take a break at any time during the focus group.

#### ***Benefits***

**Your Benefits:** There are no direct benefits to you from participating in the focus group. However, you may learn information about how to have a healthy pregnancy.

**Benefits to Others:** We hope that these focus groups will help CDC better understand issues relating to women, smoking, and reproductive health so that they may develop better health messages.

#### ***Incentive for Participation***

You will receive \$75 for your time, effort, and any travel expenses you incurred in order to participate in the focus group.

#### ***Future Contacts***

RTI and CDC will not contact you in the future regarding this project.

**Your Rights**

Your decision to take part in this focus group is completely voluntary. You can refuse any activity 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 focus groups, you may call Brenda Stone-Wiggins at 1-800-334-8571 ext. 23328 or e-mail her at [bwiggins@rti.org](mailto:bwiggins@rti.org). If you have any questions about your rights as a focus group participant, you may call RTI's Office of Research Protection toll-free at 1-866-214-2043.

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

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Your initials below indicate that you have read (or been read) the information provided above, have received answers to your questions, and have freely decided to participate in this focus group. By agreeing to participate in this focus group, you are not giving up any of your legal rights.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Initials of Participant

**If the participant is unable to read this form, a witness must sign here:**

Note: the witness should not be the person who obtains consent.

I was present while this consent document was read to the above focus group participant. The participant was given an opportunity to ask questions about being in this study and I believe that he/she has agreed to take part in the focus group.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Printed Name of Witness

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

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Printed Name of Person Obtaining Consent