Form Approved
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Attachment 6—Consent Form

Consent to Participate in Focus Group

Title: Formative Focus Groups on Women, Alcohol, and Reproductive Health

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 the 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 don't understand before you make your decision.

Purpose

The Formative Focus Groups on Women, Alcohol, and Reproductive Health are 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 your attitudes, beliefs, knowledge, and information sources related to alcohol use and reproductive health. You are one of approximately 140 people being asked to participate in this study.

Procedures

If you agree to participate, you will take part in a group discussion about the women, alcohol and health. In addition you will complete a short questionnaire to provide descriptive information about yourself and your reproductive health and alcohol use behaviors.

An experienced focus group leader from RTI will moderate the discussion. **We will digitally audio-record the interview.** Note takers will also observe the session from behind the one-way mirror.

Study Duration

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

Possible Risks or Discomforts

It is possible that some of the focus group or questionnaire 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. There is also a potential risk of loss of confidentiality. Every effort will be made to protect your information, but this cannot be guaranteed.

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, alcohol, 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.

Confidentiality

Many precautions have been taken to protect your information. Your identifiable information, the audio recording and notes from the interview will be kept by the evaluation contractor, 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 offer participants the option of using only their first name or a pseudonym during the groups 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.

Future Contacts

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

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 Elvira Elek at 1-800-RTI-1958 ext. 2048 or email her at eelek@rti.org. If you have any questions about your rights as a focus group participant, you may call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

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

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

_____

Printed Name of Person Obtaining Consent
