

FOCUS GROUP PARTICIPANT CONSENT FORM

Sponsor / Study Title : The Centers for Disease Control and Prevention (CDC) /
"Enhanced Message Development Focus Groups (Creative
Concept Testing)"

Principal Investigator: Ronne Ostby, MA
Telephone: 571-858-3757 (24-hours)
Additional Contact(s): Study Staff
Natalie Namrow
Address: Fors Marsh Group
4250 Fairfax Dr. Suite 520
Arlington, VA 22203

What is the key information?

You are being asked to participate in a research study collecting information about perceptions of alcohol. This form describes the purpose, procedures, benefits, risks, and precautions of the information collection. It also describes your right to withdraw at any time. A member of the study staff is available to read through this form with you and discuss all the information, if you wish.

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This information collection is being done to test health education materials related to alcohol. Fors Marsh Group (FMG) is conducting this project on behalf of the Centers for Disease Control and Prevention (CDC). The findings will inform the development of a health education campaign about alcohol use.

What do I need to know about this study?

Adults aged 21 to 64 are invited to participate. If you choose to participate, the project team will tell you when and where your assigned focus group is scheduled. During the session, you will be asked to share your thoughts with the moderator about different alcohol-related health materials. The focus group will last about 90 minutes and you will be audio-recorded while you respond to questions, worksheets, and other simple written activities that have been designed to facilitate discussion. You do not have to answer any questions that you don't want to.

People from the project team will be observing the session (both from FMG and CDC)—either in-person or via livestreaming. The observers will take notes and listen, but they won't interact with the group. You will only be talking to the moderator and a small group of other participants.

What are the potential risks of being in this study?

There are minimal risks associated with this project. There is a possible risk of breach of confidentiality. This risk is minimized by protections described in the "Who will see the results of this project or my information?" section below. Please help protect the privacy and confidentiality of others by not discussing anything from this session outside of the group. If you share stories about others during the group, please avoid using real names or other identifying information. The study staff will do its due diligence to remove any personally identifying information from the transcripts of the session.

Does participating in this project provide any benefits?

This study is for research purposes only. There is no direct benefit to you from participating in this project. The information from the focus groups will help us decide what ideas and messages might be useful in health education outreach about alcohol consumption.

Are there alternatives to participating?

This research study is for research purposes only. The only alternative is to not participate in this study.

Will it cost me anything to participate in the project?

There are no costs to participate in the project, other than possible transportation costs to and from the facility. Participants in the focus groups will receive \$75 for their participation, you will be paid at the end of your participation in this study..

Do I have to be in this project?

Your participation is voluntary, which means you can stop or withdraw at any time. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled.

Your part in the research may stop at any time for any reason, such as, the sponsor or the study doctor decides to stop the study.

Who will see the results of this project or my information?

Everything you say during the focus group will be heard by the study staff. We will be very careful to only let people working on the project see your information. There is a small risk that others might find out what you say, despite all of our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

The focus group will be audio-recorded and transcribed. The session may also be livestreamed with audio only so that other members of the project team and/or members of the sponsoring agency can observe remotely. You will be told at the start of the focus group whether it is being livestreamed. By signing this form, you consent to being audio-recorded and audio livestreamed during the focus group.

Your name and other personal information (for example, contact and demographic information) will not be linked to your responses and will not be shared with the sponsoring agency or distributed for future research studies. This means that no one outside of the project team will be able to link what you said back to you. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. Everything you share will be kept private to the extent allowed by law. This means that we will not share anything you provide with anyone outside the project unless it is required to protect you, or if required by law. However, if you show a direct threat of harm to yourself or others, we have the right to take action out of concern for you and concern for others.

All of the information we collect, including anything you say in the focus group, activity worksheets completed during the focus group, information collected during screening, audio files, and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the project team can access. We will collect some personal information from you, like your age and race, but we will not collect any information that could identify you personally. After three years, all of the collected information will be destroyed by securely shredding documents or permanently deleting electronic information. Results from this project might appear in professional journals or scientific conferences or shared with other project teams. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:

Study Subject Adviser

Advarra IRB

6940 Columbia Gateway Drive, Suite 110

Columbia, MD 21046

- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
[Pro00031948].

Statement of Consent

Please mark a box and sign below. By signing this form, you have not waived any of your legal rights.

Yes, I agree to participate in this project. I have read, understand, and had time to consider all of the information above. My questions have been answered, and I have no further questions. I will receive a copy of this signed and dated consent document.

No, I do not agree to participate in this project. I have read, understand, and had time to consider all of the information above. My questions have been answered, and I have no further questions.

Subject's Printed Name

Subject's Signature

Date

Printed Name of the Person Conducting the
Consent Discussion

Signature of the Person Conducting the
Consent Discussion

Date