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# Front of Pack Focus Groups Consent Form

Expiration Date: 11/30/2023

## About this study

The U.S. Food and Drug Administration (FDA) contracted [Contractor] to conduct this research study to learn how consumers respond to information on the food label. You are being asked to take part in this study. If you agree, you will participate in a focus group discussion. Focus groups are a form of research used to gather thoughts and opinions on a certain topic.

#### What is involved

The focus group discussion leader will ask you some questions about your experiences with the food label. There will be about 5 other participants in the focus group with you. You will be asked to share your thoughts with the discussion leader and the rest of the group. The discussion will take about 90 minutes. There are no costs to you to participate in this study.

The study team will know your name but will do their best to make sure no one outside the study knows you were part of the study. During the group, the discussion leader, you, and other participants will only use first names. Your name or any other information about you will not be linked to any of your responses. The study team may include quotes that you provide in their reports, but they will not attribute the quote to your name, and these quotes will not be linked to any of your information. You will not be identified in any published or presented materials. Your data will only be used for this study, and not for other studies.

The focus group will be live-streamed so that other researchers can watch and listen to the discussion. The discussion will also be recorded using audio and video recorders. These recordings will help the team document everything that was talked about during the focus groups. These recordings will be available to the study staff from both [Contractor] and FDA. The recordings will be used to prepare transcripts. The transcripts will be combined with transcripts from the other focus groups that are part of this study for the final report. Your information [Contractor] collects will be separated from the information that identifies you and it will be combined with information from other people taking part in the study. FDA will not have access to any record of your full name or contact information. All data collected for the focus group will be stored in a locked file cabinet or on a password-protected computer for a period of three years, after which they will be destroyed.

All information collected in this study will be kept secure to the extent permitted by law. This means that the study team will not share anything you tell us with anyone outside the study unless it is required to protect you or if required by law.

## **Confidentiality & Risks**

There are no known risks for participation in this discussion. We do not expect that any of the topics discussed during the focus group will make you uncomfortable or upset you; however, if they do, you do not have to participate in that part of the discussion.

[Cotractor] will take several steps to keep your participation secure to the extent provided by law. Even with these steps, there is still a small risk that your privacy could be breached.

- FDA will not receive any record of your full name or contact information.
- Your personal information (name, address, phone number) will not be linked to any of your responses.
- All data collected for the focus groups will be kept secure to the extent provided by law. The study team will not disclose your name or any of your responses.
- All data collected for the focus groups will be stored in a locked file cabinet or on a password-protected computer for a period of three years, after which they will be destroyed.
- When we analyze the results, your information will be separated from the information that identifies you and it will be combined with information from other people taking part in the study.

## **Participation and Withdrawal**

This study is completely voluntary. You may decide not to answer any questions that you do not want to answer. You may leave the discussion at any point without penalty. You will receive the full token of appreciation for your participation in the focus group even if you choose not to answer some questions.

#### **Benefits**

There are no direct benefits to you for participating in this study. However, you will be helping with an important research project. The information that FDA learns from this project may help other nutrition educators, and the populations they serve.

### Questions

If you have questions about the study, you may contact the project manager, [Contractor name], by e-mail at [Contractor email] or by phone at [Contractor phone number].

You will receive \$75 as a 'thank you' for participating.

The focus group discussion leader will ask for your verbal consent before beginning the interview. Please keep this copy of the consent form for your records.