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Focus Groups on Childhood Obesity Education Consent Form

About this study

You are being asked to take part in a research study for the U.S. Food and Drug Administration (FDA). 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. The things we learn from the discussion will be used to help the FDA learn more about family eating behaviors.

What will I do during the study?

The discussion leader will ask you some questions about your experiences with food shopping and feeding your child/children. There will be about 5-8 other people in the focus group with you. You will be asked to share your thoughts with the 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.

Who will see the results of 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 use your name and these quotes will not be linked to any of your information.

The focus group will be live-streamed so that other researchers who could not be here can watch, too. 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. The transcript will be combined with the transcripts from other focus groups for the final report of the study. The recordings will be kept on Westat's and FDA's secure servers and will be destroyed after three years.

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. However, if you show a direct threat of harm to yourself or others, the study team has the right to take action out of concern for you and concern for others.

Could anything bad happen to me during this study?

There are no known risks for participation in this discussion. 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.

What good comes from my participation?

There are no direct benefits to you for participating in this study. However, you will be helping with an important research project. The things the FDA learns from this project may help other parents with young children.

What if I have questions?

If you have questions about the study, you may contact the project director, Dr. Jocelyn Newsome, by email at jocelynnewsome@westat.com or by phone at 1-800-937-8281, extension 3734. If you have any questions or complaints about your rights as a research subject, please contact the Human Subjects Protection Program Management Staff (HSPPMS) at <u>HSPPMS@fda.hhs.gov</u> or by phone at 301-796-9605

Participation and Withdrawal: Do I have to be in this study? What if I want to stop participating? This study is completely voluntary. You can stop at any time. You also do not have to answer any questions that you do not want to. You will receive the full token of appreciation for your time in the focus group even if you choose not to answer some questions.

You will receive \$75 as a 'thank you' for participating and completing the discussion.

If you agree to participate, please sign below.

I have read and understand the statements above. I consent to participate in this focus group.

Participant's signature

Date