

**Paperwork Reduction Act Statement:** The public reporting burden for this collection of information has been estimated to average 90 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

### **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?**

We will ask you some questions about your experiences with food shopping and feeding your child/children. There will be about 7-9 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 local study team will know your name but we will do our best to make sure no one outside the study knows you were part of the study. Your name or any other information about you will not be linked to any of your responses. We may include quotes that you provide in our reports, but 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. We will also be recording the discussion using audio and video recorders. We will use the recordings to type everything said at the focus groups. This typed summary will be combined with the summaries from other focus groups to help us write and present our final report of the study. The recordings will be kept on Fors Marsh Group'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 we 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, we have 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 we learn 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. Shane Mannis, at Fors Marsh Group at 571-858-3757 or pi@forsmarshgroup.com. The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration has reviewed this research. RIHSC is an institutional review board (IRB), a group of people who are responsible for ensuring that the rights of participants in research are protected. The RIHSC is not involved in the conduct of this study. If you have any questions or complaints about your rights as a research subject, please contact RIHSC at 301-796-9605 or at RIHSC@fda.hhs.gov

**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