OMB Control No: 0910-0891 **Expiration Date: 8/31/2023**

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 PRAStaff@fda.hhs.gov.

Infant Formula Focus Groups

Consent Form

Purpose:

- This study is about infant formula.
- The U.S. Food and Drug Administration (FDA) is conducting this study to learn consumers' views about and experiences with infant formula.

What is involved:

- You are being asked to be part of a discussion with 5-6 other people.
- Your participation in this study is voluntary. You do not have to participate if you do not want to.
- If you choose to participate, we will ask you some questions about your experiences with infant formula.
- The focus group discussion will take approximately 90 minutes.

Confidentiality:

- Your name and information will be kept secure to the extent permitted by law.
- We will video record the discussions. We will keep the recordings secure and destroy them by 2022.
- Project staff from FDA may be observing the discussion.
- What you say will not be connected with your name. We will report our results in a summary report. We may use quotes you say in our report, but we won't use your name.

Risks:

- It is your choice to do this focus group discussion.
- You can stop participating at any time.
- You also do not have to answer questions from the moderator if they make you uncomfortable.
- There are no known risks for participation in this research activity.

Benefits:

- There are no direct benefits to you for participating in this study.
- You will be helping with an important research project.

Questions:

- If you have questions about the project you may call the Westat Project Director, Cynthia Robins, at 610.593.7389 or 240.367.4753.
- If you have any questions or complaints about your rights as a research subject, please contact FDA's IRB, Human Subject Protection Program Management Staff, at HSPPMS@fda.hhs.gov and 301-796-9605.

You will receive $75 as a token of appreciation for your participation in the discussion.