

Appendix II – Consent Form

In-depth Interviews with Healthcare Professionals and Health Educators on Environmental Contaminants in Food for Young Children Consent Form

OMB No: 0910-0891

Expiration Date: 09/30/2026

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0891. The time required to complete this information collection is estimated to average 70 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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.

Purpose:

- You are being asked to take part in a research study for the U.S. Food and Drug Administration (FDA).
- Westat, an independent social science research firm, is conducting the study on behalf of the FDA.
- The purpose of this study is to help FDA better understand healthcare professionals and nutrition educators' current practices related to providing information to parents and caregivers about foods intended for infants and young children.

What is involved:

- Your participation / nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law. Your participation is voluntary. You do not have to participate if you do not want to. You may also choose not to answer a question for any reason.
- If you choose to participate, we will ask you some questions about your experiences with educating parents and caregivers on nutrition and diet, the challenges you have faced, and your thoughts on drafted educational materials.
- The interview will take approximately 60 minutes.

Confidentiality:

- Your name and information, and everything you say will be kept private to the fullest extent provided by law.
- Only the recruiter has your contact information. Westat and FDA does not. After the interview, no one from Westat or FDA will contact you about this discussion.
- Your responses during the interview will not have an effect on your eligibility to receive any FDA services.
- We will audio and video record the discussion to make sure we hear everything you say correctly.
- Only the research team working on this project will be able to listen to the recording and see our notes. The recordings and our notes will be destroyed after we finish the project.
- 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:

- There are no known risks for participation in this research study.

Benefits:

- There are no direct benefits to you for participating in this study. The results of this research will help FDA learn what information parents need to ensure the foods they are feeding their babies are as safe as possible.

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 Westat's Human Subject Protections Office at 1-888-920-7631. Please leave a message with your first name, the name of the research study that you are calling about (Environmental Contaminants Interviews), and a phone number beginning with the area code. Someone will return your call as soon as possible.

You will receive [\$225/\$200/\$150/\$125] from Westat as a token of appreciation for your contribution to the discussion.