OMB No. 3041-0136 Expiration Date: 01/31/2024

FOCUS GROUP
PARTICIPANT CONSENT FORM

Sponsor/Study Title:	The U.S. Consumer Product Safety Commission (CPSC) Refining Sleep Messaging for Seated/Non-Sleep Infant Products Focus Group Study
Principal Investigator:	Dr. Miriam Colman
Telephone:	610-349-2116
Additional Contact(s): Study Staff	Rachel Ingersoll
Address:	Fors Marsh Group 901 N. Glebe Rd Suite 1010 Arlington, VA 22203

What is the key information?
You are being asked to participate in a research study that will collect information about seated infant products in which infants may fall asleep, but that are not intended by the manufacturer for sleep. This form describes the purpose, procedures, benefits, risks, and precautions of the information collection. It also describes your right to withdraw at any time. A member of the study staff is available to read through this form with you and to discuss all the information if you wish.

Fors Marsh Group (FMG) is conducting this study on behalf of the U.S. Consumer Product Safety Commission (CPSC). This information is being collected to improve CPSC's understanding of consumers' perceptions, comprehension, interpretation, and use of warning label information on seated infant standards.

What do I need to know about this study?
If you agree to be a part of the research study, you will be asked to participate in a focus group, during which you will discuss your thoughts and experiences related to seated infant products and warning labels. The focus group will last about 90 minutes, and you will be audio and video recorded while you respond to questions, worksheets, and other simple written activities that have been designed to facilitate discussion. You do not have to answer any questions that you do not want to answer.

People from the project team (both from FMG and CPSC) will observe the session either in person or via livestreaming. They will take notes and listen, but they will not interact with the group. You will only be talking to the moderator and a small group of other participants.

What are the potential risks of being in this study?
There are minimal risks associated with this project. There is a possible risk of breach of confidentiality. This risk is minimized by protections described in the section below titled, "Who will see the results of this project or my information?" Please help protect the privacy and confidentiality of others by not discussing anything from this session outside of the group. If you share stories about others during the group, please avoid using real names or other identifying information. The study staff will do its due diligence to remove any personally identifying information (PII) from the transcripts of the session.

Does participating in this project provide any benefits?
This study is for research purposes only. Although you may not benefit directly from participating in this study, others may benefit because the findings of this study may be used to improve communication or messaging around safe use of infant non-sleep products.

Are there alternatives to participating?
This research study is for research purposes only. The only alternative is not to participate in this study.

Will it cost me anything to participate in the project?
There are no costs to participate in the project, other than possible transportation costs to and from the facility. Participants in the focus group will receive $90 via a TangoCard, which can be redeemed for an incentive of their choice (*e.g.*, gift card, Visa card). Participants will be paid at the end of this study.

Do I have to be in this project?
Your participation is voluntary, which means you can stop or withdraw at any time. You may choose not to participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled.

Your part in the research may stop at any time for any reason, such as if the sponsor decides to stop the study.

Who will see the results of this project or my information?
Everything you say during the focus group will be heard by the study staff. We will be very careful only to let people working on the project see your information. There is a small risk that others might find out what you say, despite all our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

The focus group will be audio and video recorded and transcribed. The session may also be livestreamed to other members of the project team and/or members of the sponsoring agency, so they can observe remotely. You will be told at the start of the focus group whether it is being livestreamed. By signing this form, you consent to being audio and video recorded and livestreamed during the focus group.

Your name and other personal information (*e.g.*, contact and demographic information) will not be linked to your responses and will not be shared with the sponsoring agency or distributed for future research studies. This means that no one outside of the project team will be able to link what you said back to you. The principal investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the institutional review board (IRB) will be able to inspect and copy confidential study-related records that identify you by name. This means that absolute confidentiality cannot be guaranteed. Everything you share will be kept private to the extent allowed by law. This means that we will not share anything you provide with anyone outside of the project, 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 act out of concern for you and concern forothers.

All the information we collect, including anything you say in the focus group, information collected during screening, and audio files will be stored on a password-protected computer and/or in locked cabinets that only the project team can access. We will collect some personal information from you, such as your age and race, but we will not collect any information that could identify you personally. After 3 years, all the collected information will be destroyed by securely shredding documents or permanently deleting electronic information. Results from this project might appear in professional journals or

scientific conferences or might be shared with other project teams. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation.

Whom to contact about this study:
If you have questions, concerns, or complaints about the study, please contact the principal investigator at the telephone number listed on the first page of this consent document.

An IRB is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the study subject adviser: *[ ]*.

Statement of Consent
Please mark one box and sign below. By signing this form, you have not waived any of your legal rights.

☐ Yes, I agree to participate in this project. I have read, understand, and have had time to consider all the information above. My questions have been answered, and I have no further questions. I will receive a copy of this signed and dated consent document.
□ No, I do not agree to participate in this project. I have read, understand, and have had time to consider all the information above. My questions have been answered, and I have no further questions.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date