Appendix I

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Focus Groups on Bioactives in Infant Formula
Screener – Phase I

# Recruiting Goals

* The target audience for these focus groups is primary purchasers of formula for infants (newborn to 12 months of age).
* Twenty-four (24) virtual focus groups will be conducted, and segmented as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| Group | Time Zone | Education | Language, Race/Ethnicity |
| **Phase 1** |
| **Mock\*** | TBD | TBD | English-Speaking, All Races/Ethnicities |
| **Grp 1** | Eastern  | Lower Edu | English-Speaking, All Races/Ethnicities |
| **Grp 2** | Eastern  | Lower Edu | Spanish-Speaking Hispanics |
| **Grp 3** | Eastern  | Higher Edu | English-Speaking, All Races/Ethnicities |
| **Grp 4** | Eastern  | Higher Edu | Spanish-Speaking Hispanics |
| **Grp 5** | Central/Mountain | Lower Edu | English-Speaking, All Races/Ethnicities |
| **Grp 6** | Central/Mountain | Lower Edu | Spanish-Speaking Hispanics |
| **Grp 7** | Central/Mountain | Higher Edu | English-Speaking, All Races/Ethnicities |
| **Grp 8** | Central/Mountain | Higher Edu | Spanish-Speaking Hispanics |
| **Grp 9** |  Pacific | Lower Edu | English-Speaking, All Races/Ethnicities |
| **Grp 10** | Pacific | Lower Edu | Spanish-Speaking Hispanics |
| **Grp 11** | Pacific | Higher Edu | English-Speaking, All Races/Ethnicities |
| **Grp 12** | Pacific | Higher Edu | Spanish-Speaking Hispanics |
| **Phase 2** |
| **Mock\*** | TBD | TBD | TBD |
| **Grp 13** | Eastern  | Lower Edu | English-Speaking, All Races/Ethnicities |
| **Grp 14** | Eastern  | Lower Edu | Spanish-Speaking Hispanics |
| **Grp 15** | Eastern  | Higher Edu | English-Speaking, All Races/Ethnicities |
| **Grp 16** | Eastern  | Higher Edu | Spanish-Speaking Hispanics |
| **Grp 17** | Central/Mountain | Lower Edu | English-Speaking, All Races/Ethnicities |
| **Grp 18** | Central/Mountain | Lower Edu | Spanish-Speaking Hispanics |
| **Grp 19** | Central/Mountain | Higher Edu | English-Speaking, All Races/Ethnicities |
| **Grp 20** | Central/Mountain | Higher Edu | Spanish-Speaking Hispanics |
| **Grp 21** | Pacific | Lower Edu | English-Speaking, All Races/Ethnicities |
| **Grp 22** | Pacific | Lower Edu | Spanish-Speaking Hispanics |
| **Grp 23** | Pacific | Higher Edu | English-Speaking, All Races/Ethnicities |
| **Grp 24** | Pacific | Higher Edu | Spanish-Speaking Hispanics |

\*Data collected from mock focus group will not be included in analysis; South region will be captured in Eastern and Midwest

* The groups will include people who are at least 18 years of age and who are primarily responsible for choosing and buying infant formula for infants (newborn -12 months).
* If possible, would encourage recruiting in any group a participant whose infant is enrolled in WIC[[1]](#footnote-2)
* All participants must be able to read, understand, and speak the language of the group: English for English-speaking groups and Spanish for Spanish-speaking groups.
* Participants cannot have participated in a focus group or a similar study in the past six months. Participation in phone surveys is allowed.
* Participants will need to have access to adequate internet, hardware, and software to participate virtually (see screener questions for specifications).
* Sufficient recruits will be invited in order to achieve a target of 4-6 participants for virtual/online groups.
* Each participant will receive a $75 as a token of appreciation for participating in the focus group.

# Study Protocol

* Each focus group will last approximately 90 minutes (excluding time needed for signing in before the group starts and signing out after the group ends).
* Groups will be audio- and video-recorded and also video-streamed and archived via a password-protected website.
* Westat will request a waiver of documentation of informed consent from the Westat IRB. Participants will receive a copy of the informed consent form when they are sent the details about the group (e.g., date, time, web link), but will not be required to sign the form and return it. Moderators will review the elements of informed consent prior to beginning the formal discussion.
* The identity of the participants will be kept secure d to the extent permitted by law.
* Groups will be observed by a research team including staff from FDA.
* Participants do not have to answer any questions that they do not want to, but will be encouraged to participate.

Participant Screener Script

Hello Mr./Mrs./Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration. We are looking for individuals to take part in upcoming online focus group discussions about infant formula.

[INTERVIEWER: IF EXPLANATION IS NEEDED: A focus group is a when a small group of individuals come together to talk about a certain topic.]

1. If you are interested in participating, could you answer a few questions? This will only take a few minutes of your time.
* Yes
* No → ELIMINATE [thank respondent politely]

1. Do you live with and care for an infant?
* Yes
* No → ELIMINATE [thank respondent politely]
1. How many months old is your infant?

[If older than 12 months, → ELIMINATE [thank respondent politely]]

1. How often do you give your infant formula?
* No, never or almost never → ELIMINATE [thank respondent politely]
* Occasionally
* Often
* Always or almost always

**5a.** **Are you the person who usually decides what infant formula you use?**

* Yes → SKIP to Q6
* No, never or almost never

**5b.** **Is the person who usually decides what infant formula to use available and interested in participating in this focus group discussion instead?**

* Yes → See dialog box (below)
* No, never or almost never → ELIMINATE [thank respondent politely]

Hello Mr./Mrs./Ms. \_\_\_. My name is \_\_\_\_ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration. We are looking for individuals to take part in upcoming online focus group discussions about infant formula.

[INTERVIEWER: IF EXPLANATION IS NEEDED: A focus group is a when a small group of individuals come together to talk about a certain topic.]

**5bi**. **If you are interested in participating, could you answer a few questions? This will only take a few minutes of your time.**

* Yes
* No  ELIMINATE [thank respondent politely]

**5bii. Are you the person who usually decides what infant formula you use?**

* Yes
* No, never or almost never  ELIMINATE [thank respondent politely

**5biii.** **The person I was previously speaking with said that you all live with and care for an infant. How many months old is your infant?**

[If older than 12 months,  ELIMINATE [thank respondent politely]]

**5biv.** **How often do you give your infant formula?**

* No, never or almost never  ELIMINATE [thank respondent politely]
* Occasionally
* Often
* Always or almost always

continue to q6

1. Have you participated in a focus group within the past 6 months?
[Interviewer: participation in online or telephone surveys is allowed. If explanation is needed: A focus group is a when a small group of individuals come together to talk about a certain topic.]
* Yes  ELIMINATE [thank respondent politely]
* No
1. Do you or someone from your immediate family work for any of the following:
* A Market Research Firm  ELIMINATE [thank respondent politely]
* Nutritionist or Dietitian  ELIMINATE [thank respondent politely]
* Food Industry, Restaurant or Food Retailer  ELIMINATE [thank respondent politely]
* A Public Health Organization  ELIMINATE [thank respondent politely]
* State or Local Food Agency  ELIMINATE [thank respondent politely]
* U.S. Department of Agriculture  ELIMINATE [thank respondent politely]
* U.S. Food and Drug Administration  ELIMINATE [thank respondent politely]
1. Are you of Hispanic or Latino origin?
* No
* Yes  SKIP to Q10
* Prefer not to answer  ELIMINATE [thank respondent politely]
1. What is your race? I am going to read several categories of race. You may choose one or more categories. Are you…?
* White
* Black or African American
* Asian
* Native Hawaiian or other Pacific Islander
* American Indian or Alaska Native
* Prefer not to answer
1. What language do you feel most comfortable reading? \_\_\_
* Spanish  RECRUIT to SPANISH LANGUAGE GROUP
* English  RECRUIT to eNGLISH LANGUAGE GROUP
* Either or Both English or Spanish  CONTINUE
* Neither English nor Spanish  ELIMINATE [thank respondent politely]
1. What language do you feel most comfortable speaking in a group? \_\_\_
* Spanish  RECRUIT to SPANISH LANGUAGE GROUP
* English  RECRUIT to eNGLISH LANGUAGE GROUP
* Either or Both English or Spanish  RECRUIT to SPANISH LANGUAGE GROUP
* Neither English nor Spanish  ELIMINATE [thank respondent politely]
1. I am going to read some age categories, could you please tell me in which category your age falls?
* Under 18 years old  ELIMINATE [thank respondent politely]
* 18-30
* 31-40
* 41-50
* 51-60
* 61 and over
1. What is your yearly household income? Your best guess is fine:
2. Are you, or is anyone in your household, currently receiving benefits from WIC—that is, the Special Supplemental Nutrition Program for Women, Infants, and Children?[[2]](#footnote-3)

[For Recruiter: WIC is short for the Special Supplemental Nutrition Program for Women, Infants, and Children. This program provides food assistance, nutrition education including breastfeeding support, and nutritional screening to low-income pregnant and postpartum women and their infants, as well as to low-income children up to age 5.]

* Yes
* No
1. Is the infant you live with and care for currently receiving benefits from WIC?[[3]](#footnote-4)

[For Recruiter: WIC is short for the Special Supplemental Nutrition Program for Women, Infants, and Children. This program provides food assistance, nutrition education including breastfeeding support, and nutritional screening to low-income pregnant and postpartum women and their infants, as well as to low-income children up to age 5.]

* Yes  try to rECRUIT at least 1 for each group, prioritizing lower education groups
* No
1. What is your gender? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Recruit no more than two men/males per group]

*
1. What is the highest level of education that you have completed?
* Less than high school → RECRUIT TO LOWER EDUCATION GROUP
* High school graduate or GED → RECRUIT TO LOWER EDUCATION GROUP
* Technical/vocational school → RECRUIT TO LOWER EDUCATION GROUP
* Community college → RECRUIT TO HIGHER EDUCATION GROUP
* Some college (1-3 yrs towards Bachelor’s) → RECRUIT TO HIGHER EDUCATION GROUP
* College (Bachelor’s degree) → RECRUIT TO HIGHER EDUCATION GROUP
* Advanced degree (postgraduate degree)  RECRUIT TO HIGHER EDUCATION GROUP; NO MORE THAN 2 PER GROUP
1. For this discussion, you would be required to use your computer’s webcam and your computer audio to participate. Do you have a computer (laptop or desktop) with a webcam and audio that you can use to participate?
* No 🡪 ELIMINATE [thank respondent politely]
* Yes 🡪 continue
1. Do you have access to high-speed (in other words, not dial-up) internet?
* No  🡪 ELIMINATE [thank respondent politely]
* Yes 🡪 continue
1. Do you have a quiet place where you can access high-speed internet and participate in the focus group without interruption?
* No 🡪 ELIMINATE [thank respondent politely]
* Yes 🡪 continue
1. Can you login to the Internet on your own?
* No 🡪 ASK:

Is there someone at home who can help you?

* No 🡪 ELIMINATE [thank respondent politely]
* Yes 🡪 continue
* Yes 🡪 continue

## Elimination Script for Ineligible Participants:

Thank you for answering all of my questions. Unfortunately, you are not eligible to participate in this project. There are many possible reasons that people may not be eligible. These reasons were decided earlier by the research team. We value your interest in the focus groups. Thank you for being willing to help us.

## Invitation Script for Eligible Participants:

Thank you for answering these questions. We would like to invite you to participate in a focus group to discuss infant formula. The discussion will last about 90 minutes. The discussion will be video- and audio-taped, and also observed by members of a research team. Your participation and everything you say during the discussion will remain secure to the extent permitted by law, and your personal identifying information will not be included in any reports. At the end of the focus group, you will receive $75 as a token of appreciation for your participation.

Are you interested in participating in this focus group?

* Yes
* No  [Thank the person for his/her time]

I’m glad that you are interested! The online focus group will take place on (Day), (Date), at [X:00 or X:00 p.m.] at [website/streaming application].

Will you be available to participate at this time?

* Yes
* No  [Thank the person for his/her time]

I would like to send you a confirmation email or letter containing log-on instructions. In order to do so, could you please tell me the best way to reach you (e.g., email and/or a phone number)?

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address (if needed to reach participant): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­\_\_\_\_\_\_
State: \_\_\_\_\_\_\_\_\_ Zip:\_\_\_\_\_\_\_\_\_\_\_\_\_

Email (if needed to reach participant): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone (if needed to reach participant): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of focus group: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call [recruiter] at [telephone number] if this should happen. We look forward to seeing you on [date] at [time]. Please have any aids (hearing aids, reading glasses) with you to participate in the focus group.

1. See Questions 14 and 15 [↑](#footnote-ref-2)
2. <https://www.fns.usda.gov/wic/frequently-asked-questions-about-wic> [↑](#footnote-ref-3)
3. Wording for WIC participation adapted from NHANES: <https://wwwn.cdc.gov/nchs/data/nhanes/2011-2012/questionnaires/rhq_capi.pdf> [↑](#footnote-ref-4)