

**FDA OFFICE OF WOMEN'S HEALTH
Diverse Women in Clinical Trials
Moderator Guide**

Focus Group Purpose & Objectives

The FDA Office of Women's Health (OWH) will conduct three (3) focus groups with women of various races/ethnicities, ages, health profiles, and income levels in order to examine perceptions and attitudes about participating in clinical trials. OWH collaborating with the NIH Office of Research on Women's Health on a campaign to raise awareness about the importance of the participation of diverse women in clinical trials and to share best practices about clinical research design, recruitment, and subpopulation analyses. The specific objectives of the focus group discussions are:

- 1) Solicit participant feedback on the layout, messaging, and usability of the 2013 OWH fact sheet 'Women in Clinical Trials';
- 2) Learn more about women's general knowledge and perceptions about clinical trials;
- 3) Learn more about information sources regarding clinical trials;
- 4) Conduct general concept/message testing to inform the development of digit and print resources.

Road Map of Discussion

Discussion Categories	Approximate Allotted Time
Welcome and Opening Remarks	2-3 minutes
Focus Group Process	5 minutes
Introductions and Warm-Up	5 minutes
Topic 1: General Knowledge and Attitudes about Clinical Trials	15 minutes
Topic 2: Information Sources	10 minutes
Topic 3: Fact Sheet Testing	15-20 minutes
Topic 4: General Concept/Message Testing (<i>TBD</i>)	15-20 minutes
Closing	5 minutes
Total Allotted Time	85 minutes

Welcome and Opening Remarks (2-3 minutes)

Good evening and welcome. I want to thank you for taking the time to join us for this focus group. We do appreciate that you have taken time from your evening to participate.

My name is _____, and my role is to guide the discussion. I'm going to tell you a little bit about what you can expect tonight--the purpose of this focus group discussion is to ask your opinions and perceptions about clinical trials. Our discussion is going to last about an hour and half. Once we get started, I am going to ask you questions and you are going to share your thoughts and opinions. We want to learn from you; I am here to listen to what you have to say. Your opinions are very important. We may use what we learn from you today and from other focus groups to create materials and resources that can help women learn about how clinical

trials help to show if medical products, tests, and other treatments are safe and effective—for both women and men.

The research team will keep what you say this evening in strict confidence. This research is not being conducted by a pharmaceutical or drug company or by any organization that profits from the sale of medications or medical treatments.

Participation in the discussion group is voluntary. You may choose to leave at any time without penalty.

Focus Group Process (5 minutes)

Before we get started, there are just a few additional things I would like to point out about the process. In order to make this session successful, there are few guidelines for everyone to follow:

- 1. No "Right" or "Wrong" Answers:** I want to assure you that there are no "right" or "wrong" answers. Please feel free to share your point of view, even if it is different from what others have said. In fact, it's really important for us to hear all the different points of view and participation from everyone is important. If you want to follow-up on something someone said, or if you want to agree or disagree, feel free to do that. I want you to speak your mind. Please speak one at a time, in a loud enough voice for all to hear and no side conversations. Please silence your cell phones.
- 2. Tape Recording and Observation:** I want to remind you that we will be tape recording the session because we don't want to miss any of your comments. Since we are taping, it is important for you to talk one at a time and to not have side conversations. This will help us not to miss any of your important comments. As you may have noticed, there is a one-way mirror in this room. Behind the mirror are staff members who are observing and taking notes. They are not in the same room with us because they can be distracting. The session is being taped so I can write an accurate report, not of "who said what," but "what was said."
- 3. Confidentiality:** Although we will be on a first name basis today, we will not use your real names in any reports. We will keep the information you give us private and confidential. We ask that you do not talk about what other group members say to anyone outside this group.
- 4. Incentive and Timing:** We expect to be here until 7:30pm. We appreciate you taking this time with us so we want to make sure we end on time. I will be watching the clock and may need to break off the discussion at times to be sure we have time to discuss all topics. Then we will distribute to each of you the cash incentive of \$75 as a token of our appreciation for participation.

Lastly, I just want to say that your health is private. So, please do not feel that you need to share details about your health if you are not comfortable sharing them with the group.

Introductions and Warm-Up (5 minutes)

Let's begin by going around the room and please tell us:

- Your first name or the name you would like to be called this evening?
- What you would be doing if you weren't here tonight? Favorite thing to do on weekends?
- What is your favorite food to cook or eat?

I'll start.

Warm up Question: As you know, we are interested in your perceptions about clinical trials and women. Before we start, let's briefly discuss-

What are some things that you can think of that affect women differently than men? [PROBE: medications, food, exercise]

Topic 1: General Knowledge and Attitudes about Clinical Trials (15 minutes)

I would like to begin our discussion by starting with our 1st topic about clinical trials.

1. *What are clinical trials?*
2. *Why are clinical trials important?*
3. *What type of women should participate in clinical trials? Who do you think should participate? (PROBE: women with certain health conditions? Healthy women?)*
4. *Would you ever consider participating in a clinical trial? Why or why not?*
5. *What would make you want to participate?*
6. *What would be your top reason for participating in a clinical trial?*
7. *What would be your top reason for deciding not to participate in a clinical trial?*

Topic 2: Clinical Trial Information Sources (10 minutes)

Now, I would like to discuss how you get information about you health and treatment for health conditions.

1. *Have you heard about clinical trials before this group?*
2. *Where did you hear about clinical trials?*
3. *Where would you expect to get information about clinical trials?*
4. *Have any of you searched the Internet to learn more about clinical trials?*

Topic 3: Fact Sheet Testing and Fact Sheet Check (15-20 minutes)

Next I'd like to discuss what you think about this fact sheet 'Women in Clinical Trials (*Distribute Fact Sheet*). Please take a few minutes to read it and then we will discuss what you think about it.

The first questions I have are based on the design of the fact sheet, not the content:

1. *What do you like about how the fact sheet is designed? What works for you? What does not work for you?*

PROBE AS NECESSARY:

- *Title*
 - *Message*
 - *Organization of the information*
 - *Design and layout*
 - *Colors*
 - *Photo –appropriate/relevant?*
 - *Type size (font size)*
2. *Was this fact sheet clear/easy to understand? (Ask participants to raise hand to indicate: easy, fair, or difficult to understand) If not, what part(s) was not clear to you?*
 3. *Who should read this fact sheet?*
 4. *Where would you expect to find this fact sheet?*

Now I'd like to ask you about the information presented on the fact sheet:

[PASS OUT FACT SHEET CHECK] Please use the pencil provided to answer the questions on this sheet and do NOT put your name on the paper. When everyone has finished the sheet, we will go over a few more questions.

1. *What was the one main message of the fact sheet you remember most?*
2. *Is this information new to you? Raise your hand if you learned something new from the fact sheet. [RECORD THE NUMBER] What is new?*
3. *Are there any other questions or issues that should be included?*
4. *If you could change anything about the fact sheet to make it better and more useful, what would you change?*
5. *After reading this, do you feel differently about clinical trials than you did when we first started the discussion?*

Topic 4: General Concept/Message Testing (20 minutes)

Now I want to share a few messages about the importance of women participating in clinical trials and get your feedback on what you think and ways to improve the messages.

[Rotate campaign message order across the 3 discussion groups. Ask all questions for each campaign message.]

Messages: main tagline followed by sub-messages:

Be a Face of Clinical Trials

- Help Women Like You. Join a Clinical Trial.
- Join a clinical trial for yourself...for women like you (or for future generations – if targeting older women)

Clinical Trials Need Women Like You

- Join a clinical trial for yourself...for women like you (or for future generations – if targeting older women)
- Help Women Like You. Join a Clinical Trial.

Answer the call...Join a clinical trial.

- Ask your doctor or nurse.

Initial Reactions [ask participants to CIRCLE responses on handout]:

1. *What do you think? What is your first reaction?* [pass out paper with list of words to describe feelings/gut responses]

Communication:

1. *What is the main point of this message? Why do you think that?*
2. *Does this message grab your attention? Why or why not?*

Likes/Dislikes:

1. *What, if anything, do you like about this message? [PROBE: words/phrases that you especially liked?]*
2. *What, if anything, do you not like about this message? [PROBE: anything about this message that turns you off, or concerns you, as a woman?]*

Relevance/Motivation:

1. *Who do you think this message is talking to? (Probe: you? Other types of women?)*
2. *Does this message make you want to participate in a clinical trial?*

Overall Reactions and Message:

1. *What do you think of the message?*
2. *Is this message important to you? Why or Why not?*

Now that we have discussed your impressions of all the messages, I would like to ask you to vote on which message you liked best [write down on the same paper].

1. *Overall, did you like these messages/ideas the same, or was there one that you liked better than the other? Explore reasons why.*

Closing (5 minutes)

Now for the last few questions:

1. *What is the most important thing we talk about this evening?*
2. *Is there anything we missed that you would like to talk about?*

Before we wrap things up, I am going to step into the observation room to see if there are any additional questions from the research team. I will back in just a couple minutes.

That wraps up the questions I have for you this evening. Do you have any final questions for me before we end? THANK YOU again for your time.