

Diversity in Clinical Trials Brochure

Cognitive Interview Guide

Introduction

Hello, my name is **INTERVIEWER NAME** and with me on the line is **NOTETAKER NAME**. We work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to participate in this study.

Westat is working with the U.S. Food and Drug Administration, or FDA, to test material about volunteering for research studies. They're interested in getting feedback about the material from people such as yourself.

It is important that the information from the material makes sense, is easy to understand, and that everyone understands it in the same way. If you agree to take part in this interview, we will talk about the material, which we sent you in the mail. After you've looked over the information, I will ask you some questions about your general impressions and reactions to the information. I'm not looking for any specific reaction from you, just your genuine opinions about the material.

Let me check, do you have the package we mailed you with you at the moment?

IF YES, CONTINUE

IF NO BUT BROCHURE IS NEARBY, ALLOW PARTICIPANT TIME TO GET IT

IF NO AND NOT NEARBY, CONTINUE USING ON-SCREEN VERSION

Color Key:

Purple – Section headings and titles

Black –Text for interviewer to read

Red – Interviewer instructions (not to be read aloud)

Green – Research questions (for interviewer's information, not to be read aloud)

Informed Consent

Before we get started, there are a few things I should mention. This is a research project, and your participation is voluntary. If you prefer not to answer any questions just say so and we'll go on to the next one. It's also okay if you change your mind after starting and would rather not participate.

All of your answers, everything you say, will be kept confidential. We will not use your name or other identifying information in any reports. The interview will take about 45 minutes and you will receive \$50. With your permission, we'd also like to audio record our conversation. Even though **NOTETAKER NAME** is taking notes while you are talking, the recording helps ensure we have an accurate description of what you tell us. Only project staff will have access to the recording and other project materials. These materials will be destroyed once we have completed the project. {Finally, some of the staff at FDA are listening in on our interview to learn if there are things that might need to be changed to improve the material.}

Before we begin, do you have any questions? Do you agree to take part in the interview? May I record it?

TURN ON RECORDER. The date and time is _____. Now that the recorder is running, let me ask again, is it okay with you if we record this interview?

Background Questions and Brochure Review

I'm going to ask you a few background questions before we discuss the material.

Have you heard of or are you familiar with clinical trials?

- IF YES, What have you heard/what do you know about them?
- IF NO, Skip to next question

Would you ever consider participating in a clinical trial?

- IF YES, What are some of the reasons why you would?
- IF NO, What are some of the reasons why you wouldn't?

Now please open the envelope we sent you, and you should find inside a brochure with the title "Become a Research Volunteer." Please take a few minutes to look through it. After you're done I'll ask you some questions about it to get your general reactions.

CHECK IN AFTER 5 MINUTES. ALLOW 2-3 MORE MINUTES IF NEEDED.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.

NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:

- Any verbal reaction to images or statements in the brochure.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which images or statements evoked any of these reactions.

RETROSPECTIVE GENERAL PROBES

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.
SHOW BROCHURE PANELS ON SCREEN AS NEEDED TO AID DISCUSSION.

RESEARCH QUESTIONS

Do any brochure images come across as offensive or stereotypical?

Is the language culturally appropriate?

Do participants pick up on the diversity of the pictured people? What is their reaction to FDA's attempts to promote diverse participation in clinical trials?

Does the brochure change people's minds about clinical trials?

Does the brochure provide useful information for deciding whether to participate in clinical trials?

Thank you for looking this over. Now I'm going to ask you some questions about it.

First, just tell me your overall impressions.

What do you like about this brochure?

What don't you like?

DESIGN AND LAYOUT

What do you think about the colors?

How well do the pictures of the people fit with what's written in the brochure?

Take a look at the green, orange, and blue circles that show symbols -- what do they mean to you?

- Are they helpful?

What do you think of the way the brochure is organized?

- Is it easy to read?
- Does each page flow well to the next page?

If you saw this at your doctor's office or picked it up at a health fair, what would you do? **IF NEEDED**, Read it, ignore it, act on it, etc. What is it about the brochure that would make you do that?

CONTENT

Now let's talk a little bit about what this brochure has to say.

Who do you think this brochure is for?

- Do you feel like it's for you? Why or why not?

In your own words, what is the overall, main point that the brochure is trying to tell you?

- What, if anything, is it asking you to do?
- Is the most important information easy to find?
- Is the most important information in the place where it should be?
- Of all the things you've read in this brochure, what to you are the most important things to put on the cover?

Please take a look at Panel #2 (**SHOW ON SCREEN**). What's your reaction to it?

- What do you think would be the benefit to you personally of participating in research based on what you've read in that panel?

IF R HAS HEARD OF CLINICAL TRIALS, After looking at this, what new information, if any, have you learned about clinical trials?

What other questions, if any, do you still have about clinical trials?

ASK IF IN BACKGROUND QUESTIONS R SAID THEY **WOULD** CONSIDER PARTICIPATING:

Before reading the brochure, you said that you **WOULD** consider participating in a clinical trial. Now that you've read the brochure, on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely, how likely are you to participate in a clinical trial?

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- **IF R IS 4 or 5 ON THE SCALE**, If you were interested in signing up for a clinical trial right now, how would you go about doing that, based on what the brochure says?

ASK IF IN BACKGROUND QUESTIONS R SAID THEY **WOULD NOT** CONSIDER PARTICIPATING:

Before reading the brochure you said you would **NOT** consider participating in a clinical trial. Now that you've read the brochure, on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely, how likely are you to participate in a clinical trial?

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- **IF R IS 4 or 5 ON THE SCALE**, What did you see in the brochure that changed your mind?
- If you were interested in signing up for a clinical trial right now, how would you go about doing that, based on what the brochure says?
- **IF R IS 1-3 ON THE SCALE**, it seems like the brochure did not change your mind. Is there anything the brochure should have said that could have changed your mind?

BROCHURE OBJECTIVES

FDA feels it's important that participation in clinical trials looks like America. That means people of different racial and ethnic backgrounds, age groups, different parts of the country, and different educational backgrounds.

Do you think the brochure does a good job of encouraging people from all different kinds of backgrounds to participate in clinical trials? Why or why not?

Given what FDA is trying to do with this brochure, what should it say?

Do you have any other suggestions for improving the brochure?

- What information, if any, is NOT needed or can be removed?
- What information, if any, could be added?
- What, if anything, could maybe be stated more clearly?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT R SEEMED CONFUSED ABOUT).

Closing and Incentive

IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.

Those are all the questions I have for you. Is there anything we haven't discussed that you would like to mention?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.