

Terminology Routinely Used in CDER Communications Cognitive Interview Guide

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)

Introduction

Hello, my name is [INSERT INTERVIEWER NAME]. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is conducting this study, which is sponsored by the U.S. Food and Drug Administration (or FDA), to see what people think about health information related to medicines.

In a moment, I will share my screen with you so you can see a series of sentences that I will ask you to read aloud. After you read each sentence, I will ask you some questions about your thoughts and feelings about the information. There are no right or wrong answers, and any ideas you have are okay. After I ask my questions, we will move to the next sentence in the series and repeat the process. There are 20 sentences in total that I will ask you to read aloud, one at a time.

IF PARTICIPANT CANNOT USE SCREENSHARING, RESCHEDULE INTERVIEW.

Informed Consent

Before we get started, there are a few things I need to tell you. Your participation in this interview is voluntary, and you don't have to answer any questions you prefer not to. It is also okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means we will not share your name or contact information. The interview will take about 45 minutes and you will receive \$50 as a token of appreciation. We would like to record this conversation 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. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

IF FDA STAFF ARE ON THE PHONE: I also want you to know that a couple members of the FDA research team are listening to this interview so they can hear directly from you.

Any questions? Is it okay if I record the interview? **IF NO, TERMINATE.**

TURN ON RECORDER. The date and time is _____. Now that I am recording, I want to ask again, is it okay if I record this interview?

Research Questions

1. Do participants understand the key words/phrases? If not, how does this inhibit their understanding of the messages?
2. What suggestions do participants have for replacing and/or defining difficult to understand words/phrases?

Background Questions

To start, I have a few general questions.

How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy? Would you say never, rarely, sometimes, often, or always?¹

Have you ever looked online for health information related to medicines?

- o **IF YES**, What specific websites have you visited for information about medicines? Have any of these websites been particularly difficult to understand?

- **IF YES**, What do you remember being difficult to understand?

DISPLAY SENTENCES ONE AT TIME USING THE FOLLOWING ROTATION PLAN TO ASSIGN TERMS TO PARTICIPANTS

	Terms 1-5	Terms 6-10	Terms 11-15	Terms 16-20
Participants 1-5	Plain language	Plain language	More technical	More technical
Participants 6-10	Plain language	More technical	Plain language	More technical
Participants 11-15	Plain language	More technical	More technical	Plain language
Participants 16-20	More technical	More technical	Plain language	Plain language
Participants 21-25	More technical	Plain language	More technical	Plain language
Participants 26-30	More technical	Plain language	Plain language	More technical

*After deciding the mix of more technical and plain language terms for each group of participants, the order of terms will be randomized for each individual participant.

¹ Morris, N. S., MacLean, C. D., Chew, L. D., & Littenberg, B. (2006). The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. <https://doi.org/10.1186/1471-2296-7-21>

Now I am going to share my screen with you. Do you see a sentence that starts with “[**READ A FEW WORDS**]?” This is the first of the 20 sentences I will show you. The 20 sentences are not about the same topic or related to each other. The 20 sentences are just examples of information about medicines you might get from your doctor or pharmacy, or that you might read online.

Please read this first sentence aloud, and then I will ask you some questions about what you have just read.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.

NOTE ANY DIFFICULTY PRONOUNCING ANY WORDS IN THE SENTENCES.

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

- Any verbal reaction to the information.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which terms/phrases evoked any of these reactions.

RETROSPECTIVE GENERAL PROBES

TO BE REPEATED AFTER PARTICIPANT READS EACH SENTENCE ALOUD.

COMPREHENSION

In your own words, what does the sentence you've just read mean?

How easy or difficult is it to understand the sentence? Why is that? **IF NEEDED**: What about the sentence is difficult to understand?

Are there any words or phrases that are confusing, that you aren't sure of, or you think others might find confusing?

- **IF YES**, Which word or phrase? How could that be stated more clearly? **IF NEEDED**: As used in this sentence, what does **[INSERT TERM]** mean to you? **IF UNSURE**: If you had to guess, what does it mean to you?

ONLY FOR THE TERM ENDPOINT, What do you think the word **[INSERT "participants" OR "subjects"]** means here? Is this the word you would use to refer to people in a clinical trial, or would you suggest using a different word? **IF DIFFERENT**, What word would you use instead?

Ok, now I'm going to show the next sentence and have you read it aloud.

WRAP-UP AFTER REVIEWING ALL 20 SENTENCES

Thinking of all the sentences I've shown you today, did any words or phrases stand out as especially difficult to understand?

- **IF YES**, Which ones? What would you do if you came across that word/phrase?
IF NEEDED, Skip it and keep reading, look it up, or something else?
 - o Do you have any additional thoughts about how that word/phrase could be stated more clearly?

Thinking of information about medicines you've received from your doctor or pharmacy, or that you have read online, can you think of any other words or phrases that have been difficult to understand?

- **IF YES**, Which ones? **IF NEEDED**: How would you suggest stating them more clearly?

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

CLOSING

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

Those are all the questions I have for you. Is there anything else you would like the FDA to know about making health information easier to understand?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.