

CBD Messages

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 **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 working with the U.S. Food and Drug Administration, or FDA, to see what people think about information related to cannabidiol, or CBD. The FDA is interested in getting opinions about the material I am about to discuss with you.

You should have gotten a packet in the mail for this study. Do you have the packet we mailed to you with you right now?

IF YES, CONTINUE

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

IF NO AND NOT NEARBY, CONTINUE USING ON-SCREEN VERSION OR ASK IF IT'S OKAY TO EMAIL THE DOCUMENT TO RESPONDENTS

Please wait to open the packet until I tell you it is time to start. After you look at the material inside the packet, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

Informed Consent

Before we get started, there are a few things I need to tell you. This is a research project, and this interview is voluntary. That means that if you do not want to answer a specific question just tell me and I'll go to the next one. It is 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 that we will not share your name or information. Also, we will not link any information to your answers to figure out who you are. The interview will take about 30 minutes and you will receive \$35 as a token of appreciation. We would like to record this conversation if you are okay with that. The recording helps us make sure we hear everything you say correctly. Only the people who work on this research 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 other people from the FDA who work on this research project are listening to this interview to take notes as we talk.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay with you if I record the interview?

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?

Background Questions and Information Review

To start, I have a few questions.

IF USED IN PAST 3 MONTHS

You told us when you volunteered for this interview that you've used CBD in the past 3 months. Do you currently use CBD? How often do you use it?

- What type of CBD products have you used? **IF NEEDED**, Did you buy it as a medicine, an oil or lotion, a food, a dietary supplement, a cosmetic, or something else?
- How did you first hear about CBD? Did someone recommend it to you?
- Why did you start using CBD? **IF NEEDED**: Were you curious or experimenting, did you use it for a specific purpose, or was there some other reason?
 - o **IF SPECIFIC PURPOSE**, For what purpose or condition do you use CBD?
 - o What benefit do you get from using it?
 - o Have you heard of other reasons for taking CBD?
- What else do you know about CBD?

IF NEVER USED

You told us when you volunteered for this interview that you have never used CBD. What is CBD? What do you know about it? **IF NOTHING**: CBD is a chemical compound that comes from the cannabis plant. Two types of cannabis plant are marijuana and hemp. The cannabis plant contains many chemical compounds, the most commonly known are THC and CBD. THC produces the "high" that is often associated with marijuana. CBD comes from marijuana or hemp but does not produce a "high."

- What reasons have you heard for taking CBD? What do you think are the benefits of using CBD?

Now please open the envelope we sent you in the mail. Do you see a piece of paper that reads, "What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabidiol (CBD)?" Please take a few minutes to look at it now. When you are done, I have some questions for you about the material.

CHECK IN AFTER 2 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 statements in the information.

- Any verbal expressions of confusion, surprise, discomfort, offense. Note which statements evoked any of these reactions.

RETROSPECTIVE GENERAL PROBES

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

RESEARCH QUESTIONS

Are the risks clear and understandable?

What is the main message that participants get from the material?

What do participants recognize as the call to action?

Do participants indicate that any of the material's information is new to them?

Do participants find any of the warnings concerning?

What information do participants find useful? Not useful?

Do participants understand the grouping of the information into 3 categories?

Is there information that is missing or that would be helpful to add?

GENERAL IMPRESSIONS

First, just tell me your overall thoughts about what you've just read.

What do you like about it?

What don't you like?

How easy or difficult is it to understand the information in the bulleted list? Is there anything confusing or unclear about any of the bullets?

Were there any words or phrases that confused you or that you weren't sure of?

CONTENT

Now let's talk a little more specifically about the information.

In your own words, what is the overall, main message that this material is trying to tell you?

- What is it asking you to do?
- Why do you think FDA is telling you this information?

After looking at this material, what new information have you learned about CBD?

Does anything you've read in this material concern you? Why is that?

What additional questions do you have after reading this material?

Does the grouping of the bullets into three sections make sense? Why?

- What are your thoughts on the risks listed under number 1? Are the risks of using CBD clear and understandable? **IF YES**, What makes you say it is clear? **IF NO**, Can you say more about what wasn't clear?
 - o **IF NOT MENTIONED**:
 - It says, "CBD can affect the metabolism of other drugs," what does that mean to you?
 - Section 1 mentions Central Nervous System depressants. What are those, and can you name any?
- What are your thoughts on the side effects listed under number 2? Are the side effects clear and understandable? **IF YES**, What makes you say it is clear? **IF NO**, Can you say more about what wasn't clear?
 - o **IF USED IN PAST 3 MONTHS**, Have you experienced any side effects from CBD?
- What do you think about the questions listed under number 3? Are these questions clear and understandable? **IF YES**, What makes you say it is clear? **IF NO**, Can you say more about what wasn't clear?
 - o **IF NOT MENTIONED**:
 - The last question is about male reproductive toxicity. What does that phrase mean to you?
 - o Are these questions of interest to you?
 - o Why do you think these unknown questions about CBD are included in this material? How do these questions make you feel about the rest of the information?

How well does the title of this document describe the information it provides?

- Does the title grab your attention? **IF YES**, What about it caught your attention? **IF NO**, How would you change it to better catch your attention?

IMPACT

Now, thinking about all of this information, who do you think this material is for?

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

- Where would you expect to see this information?

Would you look for more information about CBD after reading this material?

- **IF NO**, What makes you say that? **IF NEEDED**, Is it because the material seems complete, because you're not interested, or some other reason?
- **IF YES**, What type of information would you look for? Where would you look for additional information?

How useful is this material to you? Please respond on a scale of 1 to 5 where 1 is not at all useful and 5 is extremely useful.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- Which parts of the material are of most interest to you?

IF USED IN THE PAST 3 MONTHS

Before seeing this material, you said you used CBD [**INSERT FREQUENCY**] for [**PURPOSE**]. Now that you've seen this material, how likely are you to keep using CBD? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

Now that you've seen this material how likely are you to talk with your doctor about using CBD? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.

- o What will you discuss?
- o Will this material help you and your doctor talk about the risks of CBD?

IF NEVER USED

Now that you've seen this material, how likely are you to try using CBD? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- **IF NEUTRAL, LIKELY, OR VERY LIKELY[3 - 5]**, How likely are you to talk with your doctor about using CBD? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.
 - o What will you discuss?
 - o Will this material help you and your doctor talk about the risks of CBD?

WRAP-UP

Do you have any other suggestions for improving this material?

- Is there any other information that is NOT needed or can be removed? **IF YES**, What information?
- Is there any other information that could be added? **IF YES**, What information?
- Is there any other information that could be stated more clearly? **IF YES**, What could be stated 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 we haven't talked about that you would like to tell me?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.