

COVID Question and Answer and Video 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 (2 mins)

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 (parents/caregivers/adults) think about health information about COVID-19 vaccines.

In a moment, I will give control of the screen to you so you can look at a document. After you look at the document, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

IF PARTICIPANT CANNOT USE SCREENSHARING ASK IF OK TO SEND EMAIL TO PARTICIPANT. IF PARTICIPANT IS NOT ABLE TO RECEIVE OR SCREENSHARE AND VIEW THE DOCUMENT, RESCHEDULE INTERVIEW.

[FOR THOSE WHO NEED INFORMATION EMAILED TO THEM] Please wait to open the email attachment until I tell you it is time to start. After you look at the material inside the attachment, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

Informed Consent (2 mins)

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 a digital gift card for the amount of \$50 (parents/caregivers/adults) 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, but 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 OBSERVING: I also want you to know that a couple members of the FDA research team are observing this interview so they can hear directly from you, but they will not interact with you at all.

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. What main message(s) do participants get from the material?
2. Overall, how do participants feel about the information they read/saw and why/what specifically caused that reaction?
3. What are the materials recommending and are they described clearly?
4. Do participants understand from the material that the vaccine is safe and approved for children/adults?
5. What is unclear or hard to understand?
6. How much, if any, of the material's information is new to them and if so, what?
7. Do participants see themselves/their children as at risk for COVID-19?
8. How does the information in the QA change participants minds about getting themselves/their children vaccinated?
9. Does the information in the QA provide useful information for deciding whether participants want to get themselves/their children vaccinated?
10. How likely are adult/parent/caregiver participants to get/have their child/children vaccinated for COVID-19?
11. What would motivate/motivated participants to get themselves/their children vaccinated?
12. What in the information would cause participants to hesitate to get themselves/their children vaccinated?
13. What additional information would participants like to see included?
14. Do the images and language in the video resonate with participants? (For the videos)
15. How well do participants think the visuals match the messages? (For the videos)

Background Questions (5 mins)

FOR PARENTS/CAREGIVERS

You told us when you volunteered for this interview that you have a child [Fill specific age from screener] years old living in your household. Is this correct? **IF NO, TERMINATE.**

- **FOR PARENTS/CAREGIVERS WHOSE CHILD(REN) HAD COVID**

You also told us that your child/at least one your children was diagnosed with COVID-19 or you were pretty sure they had it, is that right? After this I will just use the shortened name of COVID when I am talking about COVID-19.

Before your child/at least one of your children got COVID, did you think they were at risk? Why/why not?

- **FOR PARENTS/CAREGIVERS WHOSE CHILD(REN) HAVE NOT HAD COVID**

You also told us that your child/at least one your children had not had COVID, is that right?

Do you think they are at risk for getting COVID? Why/why not?

- **FOR PARENTS/CAREGIVERS WITH UNVACCINATED CHILDREN**

In the screening survey, you indicated you had not gotten your [5 to 11 OR 12- 15 YO child/children vaccinated, is that still the case? [For those who verify they haven't gotten your child vaccinated]; Tell me what lead you to that decision.

FOR ADULTS

- **FOR ADULTS (Who have not had COVID)**

You also told us that you have never had COVID-19, is that right? **After this I will just use the shortened name of COVID when I am talking about COVID-19.**

Do you think you are at risk for getting COVID? Why/why not?

- **FOR ADULTS (Who have had COVID or suspected they did)**

You also told us that you were diagnosed with COVID-19 or you were pretty sure you had it, is that right? **After this I will just use the shortened name of COVID when I am talking about COVID-19.**

Before your got COVID, did you think they were at risk? Why/why not?

- **FOR UNVACCINATED ADULTS**

In the screening survey, you indicated you have not received the COVID vaccine, is that still the case? [For those who verify they haven't gotten the vaccine]; Tell me what lead you to that decision.

QUESTION and ANSWER (Q&A) (20 mins)

Now I am going to share my screen with you. Do you see a document titled “[INSERT Question and Answer (Q&A) TITLE]?” This is a draft of Questions and Answers that might appear on FDA’s website. Please take a few minutes to read it now. I will give you control of the screen so you can review at your own pace. [HAND CONTROL TO PARTICIPANT] Let me know when you finish, and I will ask you some questions about the information.

CHECK IN AFTER 3-4 MINUTES. ALLOW 1 MORE MINUTE 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 Q&A

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.

GENERAL IMPRESSIONS

All of the questions I’m going to ask you relate to the information included in the Q&A you just read unless I tell you otherwise

In your own words, what is the overall, main message of what you’ve just read?

What are your overall thoughts about what you just read?

What do you like about the Q&A and why?

What don’t you like and why?

Is there too little or too much information and why?

How easy or difficult is it to understand the information and why?

CONTENT

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

Are there any words or phrases that confuse you or that you aren't sure of?

Is there any information that could be stated more clearly? **IF YES**, What could be stated more clearly? How would you change it to make it more clear?

IF PARENT/CAREGIVER:

- After reading this, what new information, if any, have you learned about the COVID vaccine for children [5 to 11 years OR 12 to 15 years]? Was the new information helpful and why/why not?
- After reading this, what do you think about the safety of the COVID vaccine for children [5 to 11 years OR 12 to 15 years]?
- After reading this, what do you think about the effectiveness of the COVID vaccine for children [5 to 11 years OR 12 to 15 years]?

IF ADULT:

- What new information have you learned about the COVID vaccine? Was the new information helpful and why/why not?
- What do you think about the safety of the COVID vaccine?
- What do you think about the effectiveness of the COVID vaccine?

BOTH GROUPS:

Just a reminder, the next set of questions are all asking your opinion based on what you have just read.

What are the benefits of the COVID vaccine? Are the benefits of the COVID vaccine clear and understandable? **IF YES**, What makes you say they are clear? **IF NO**, Can you say more about what isn't clear and how you would change it to make it clearer?

What are the risks of the COVID vaccine? Are the risks of the COVID vaccine clear and understandable? **IF YES**, What makes you say they are clear? **IF NO**, Can you say more about what isn't clear and how you would change it to make it clearer?

How trustworthy is the information you read? What makes you say that? IF NEEDED: How could this be changed to increase your trust in this information?

Does anything you read in this Q&A concern you? What and why? IF NEEDED: How could this be changed to address your concern?

What additional questions do you have after reading the Q&A?

IMPACT

PARENT/CAREGIVER

- **IF PARENT/CAREGIVER (VACCINATED CHILDREN)**, When you were deciding whether to vaccinate your child(ren) what information was important? Was there information you wish you had when you were making that decision? Why?
- **IF PARENT/CAREGIVER (NON-VACCINATED CHILDREN)**, What information in the Q&A would be the most helpful when deciding whether to vaccinate your child(ren)? Why?
 - What information would motivate you to get your child(ren) vaccinated? Why?
 - Has anything in this Q&A helped you decide get your child(ren) vaccinated for COVID in the near future?
 - **IF YES**, What helped you make this decision?
 - **IF NO**, What makes you hesitant to get the vaccine?
- **IF PARENT/CAREGIVER (VACCINATED AND NON-VACCINATED)**, What information in this Q&A would make you hesitant to get your child vaccinated? Why?

ADULT

- **IF VACCINATED ADULT**, What information was important when you were deciding whether to get vaccinated? Was there information you wish you had when you were making that decision? Why?
- **IF NON-VACCINATED ADULT**, What information in the Q&A would be the most helpful when deciding whether to get vaccinated? Why?
 - What information would motivate you to get vaccinated? Why?

- **ALL ADULTS**
 - What information in this Q&A would make you hesitant to get vaccinated? Why? How could this be changed to make you less hesitant to get the vaccine?
 - What are your thoughts about the information on fertility? Is this information clear and understandable? **IF YES**, What makes you say they are clear? **IF NO**, Can you say more about what isn't clear? How could this be changed to make this clearer?

- **FOR UNVACCINATED ADULTS** Has anything in this Q&A helped you decide to get vaccinated for COVID in the near future?
 - **IF YES**, What helped you make this decision?
 - **IF NO**, What makes you hesitant to get the vaccine?

BOTH GROUPS, How useful is this Q&A 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 Q&A are most useful to you?
- Why do you think FDA is telling you this information?

VIDEO (10 mins)

Now I am going to share my screen with you again. Do you see a video titled “[INSERT TITLE]?” This is a video that is currently posted on FDA’s website. Once it is done playing, I will ask you some questions about it.

PLAY VIDEO INTENDED FOR THE PARTICIPANT (PARENT OR ADULT)

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 VIDEO

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.

GENERAL IMPRESSIONS

In your own words, what is the overall, main message of what you've just watched?

- What is it asking you to do?

What are your overall thoughts about this video?

What do you like about it and why?

What don't you like and why?

Are there any words or phrases that confuse you or that you aren't sure of? If so, what and how would you suggest changing it to make it more clear?

How well do the visuals match the messages in the video?

Does anything you've seen in this video concern you? Why is that?

What additional questions do you have after watching the video?

Do you have suggestions for improving the video?

- Is there any additional information that you would like added to the video? **IF YES**, What information and why do you think it should be added?
- Is there any information that is NOT needed or can be removed? **IF YES**, What information and why do you think it is unnecessary?

How useful is this video 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 video are most useful to you?

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

CLOSING (2 mins)

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 to tell the FDA about the Q&A or video?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP RECORDING.