

# Asthma Factsheet

## 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 a fact sheet they created. The FDA is interested in getting opinions about the information I am about to discuss with you. You should have gotten a package in the mail for this study.

Do you have the package we mailed to you with you right now?

**IF YES, CONTINUE**

**IF NO BUT PACKAGE 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 R**

Please wait to open the packet until I tell you it is time to start. After you look at the material inside, 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 get \$35 e-rewards for your time. 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

Before we talk about the information I mailed to you, I have a few questions.

We are talking with you today because you said that [you and/or a child in your household] have asthma. Can you briefly describe for me how long [you and/or this child] have had asthma and how you manage this condition?

Have you talked with a healthcare provider about managing [your and/or your child's] asthma?

- **IF YES**, What have you and the healthcare provider discussed? **IF NEEDED**, Symptoms, medications, or other topics?
- **IF NO**, What has prevented you from talking with a healthcare provider? **IF NEEDED**, Do you not think the asthma is serious, the cost, or some other reason?

Now please open the envelope we sent you in the mail. Do you see a piece of paper titled "Asthma?" Please take a few minutes to look at it now. When you are done, I have some questions for you about the information.

**CHECK IN AFTER 3 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 the introductory text.
- 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 FACT SHEET ON SCREEN AS NEEDED TO AID DISCUSSION.

## RESEARCH QUESTIONS

Is the fact sheet clear and understandable?

What is the main message that participants get from the fact sheet?

Does the fact sheet provide useful information about treating asthma?

What topics covered in the fact sheet are of most interest?

Do participants indicate that any information in the fact sheet is new to them?

Do participants recognize the call to action of talking with their healthcare provider to create an asthma action plan and discuss clinical trials?

Do participants recognize the asthma medication devices shown in the picture?

Is the summary at the top of the page helpful?

Is the general layout appealing?

## INTRODUCTORY TEXT

Thank you for reading that information. Now I'm going to ask you some questions about it. I want you to know that I did not develop this fact sheet, so please give me your honest opinion about it—you will not hurt my feelings.

First, just tell me your overall thoughts about the fact sheet.

What do you like about it?

What don't you like?

How easy or difficult is it to understand this fact sheet? Is there anything confusing or unclear?

## DESIGN AND LAYOUT

What do you think of the way the fact sheet is set up?

- Is it easy to read? How is the size of the text for you?

- Does the order of the information make sense?
- Is the summary at the top of the page helpful?

What do you think about the picture? What is this a picture of?

- Do you think it goes with the information?

Would you say the amount of information in this fact sheet is too little, just right, or too much? What makes you say that?

## CONTENT

Now let's talk about what the fact sheet has to say.

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

- What, if anything, is it asking you to do? **IF TALK TO DOCTOR**, What is the fact sheet asking you to talk about with your healthcare provider?
- What is the most important message?
- 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 read in this fact sheet, what are the most important things to put at the top of the page?

Is any of this information new to you? Which parts?

Have you heard of clinical trials. What do you know about them? Why do you think clinical trials are mentioned on this fact sheet?

After reading this fact sheet, do you have any questions about asthma? **IF YES**, What are they?

After reading this fact sheet, do you have any questions about how this information relates to minority health? **IF YES**, What are they?

## IMPACT

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

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

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

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

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

- **IF IGNORE**, What would make this fact sheet more worth reading?

Do you think the fact sheet would or would not get people with asthma to join a clinical trial? Why or why not?

Would you share or discuss the fact sheet with anyone?

**IF YES**, Who?

**IF NO**, Why not?

If you had more questions about asthma, what would you do? **IF NEEDED**, Would you talk with your doctor, look for information online, or something else?

- Where would you look online? Would you visit any of the websites listed on the bottom of the page? Which ones and why?

## **WRAP-UP**

Do you have any other suggestions for improving the factsheet?

- Is there anything that is NOT needed or can be removed? **IF YES**, What?
- Is there any information that could be added? **IF YES**, What information?
- Is there anything that could be stated more clearly? **IF YES**, What could be stated more clearly?

**PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT R 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.**