

# BTOD Medication Guide

## 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 some prescription drug information they are creating. The FDA is interested in getting opinions about the information I am about to discuss with you.

You should have gotten [a packet in the mail/ an email] for this study. Do you have the [packet we mailed to you with you/email we sent you available] right now?

**IF YES, CONTINUE**

**IF NO BUT PACKET/EMAIL 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/email attachment] until I tell you it is time to start. After you look at the material inside the [packet/attachment], 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.

Have you ever heard of a Medication Guide?

**INTERVIEWER NOTE: Medication Guides are paper handouts that come with many prescription medicines and are also available online.**

- **IF YES**, Have you seen one? How would you describe a Medication Guide? What kind of information does it include? Where do you get a Medication Guide?
- **IF NO**, If you had to guess, what type of information do you think a Medication Guide might include? Where do you think you get a Medication Guide?

Now please open the [envelope we sent you in the mail/email I just sent you]. Do you see a [piece of paper/document] titled “Medication Guide” for Buprexil? This information is what you might find on the Medication Guide if you were prescribed a medicine that contains an opioid called buprenorphine. The drug name is made up, but the rest of the information is how the Medication Guide might look. 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 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 statements in the information.
- Any verbal expressions of acceptance, understanding, contentment, 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

Is the Medication Guide clear and understandable?

What is the main message that participants get from the Medication Guide?

Do participants recognize the call to action of seeking emergency medical care right away if they experience any of the listed symptoms, or if a child accidentally takes the medicine?

Do participants understand when naloxone should be used?

What information do participants find useful? Not useful?

What do participants understand from the information about how the medicine should, and should not, be taken?

What do participants understand from the information about how the medicine should be stored?

Is the general layout appealing?

## 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 this guide? Is there anything confusing or unclear? Do you think you would need your healthcare provider to help explain any parts of the guide?

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 are the main messages that this guide is trying to tell you? [Listen for 1) Accidental use of Buprexil by a child can result in death, 2) Buprexil may cause serious and life-threatening breathing problems, and 3) Serious symptoms or death can occur if you take Buprexil with the list of other types of medicine] IF NEEDED: What seems to be the most important or serious information?

- What is it asking you to do?

### IF SUBLINGUAL BUPRENORPHINE USER

- Is any of this information new to you? Which parts?
- Does anything you've read in this guide concern you? IF NEEDED: What?
  - o Why is that?

Based on this information, how should this medicine be taken? [Listen for "exactly as prescribed."] IF NEEDED: What about the dose or how often you take it?

- What is your understanding about using this medicine occasionally or "as needed?" IF NEEDED: What might happen if you did this?
- What is your understanding about changing the dose or changing how often you take this medicine from how it was prescribed by your healthcare provider? IF NEEDED: What might happen if you did this?
- How do you feel about the instruction to take this medicine exactly as prescribed? Does that instruction cause you any concern? Why?

What are things you should avoid or NOT do while using this medicine?

What would you say are the most serious risks of taking this medicine?

- Does the guide clearly explain what might happen to a child who accidentally uses this medicine?
  - o IF YES, Can you tell me what about the guide makes you say it was clear?
  - o IF NO, Can you say more about what wasn't clear?
  - o What would you do if a child accidentally took this medicine?
- The guide says the medicine "may cause serious and life-threatening breathing problems." What does that mean to you?
- Does the guide clearly explain what might happen if you take Buprexil with specific types of other medicines?
  - o IF YES, Can you tell me what about the guide makes you say it was clear?
  - o IF NO, Can you say more about what wasn't clear?
  - o Are there any types of medicines listed that you are unsure of? Which ones?
    - The second bullet mentions benzodiazepines. What are those, and can you name any?
    - The second bullet also mentions sedatives. What are those, and can you name any?

- How about antihistamines? What are those, and can you name any?

Toward the top half of page 1 it says that severe drowsiness, decreased awareness, breathing problems, coma, overdose, or death might occur if you take Buprexil with the other types of medicine listed.

- What would you do if you experienced any of these symptoms?

This medicine is called Buprexil, yet this guide says to talk to your healthcare provider about naloxone. Why is that?

- When should naloxone be used?
- Who should it be used with? **IF NEEDED**: The guide says naloxone is safe to give to children. Why would you give it to a child?
- Why do you think it says to get emergency help right away if naloxone is given?

How would you store this medicine?

- Did you notice that the guide says to store Buprexil securely?
- What does “securely” mean to you?
- Do you have any suggestions for a better way to explain how this medicine should be stored?

What additional questions do you have after reading this guide?

## DESIGN AND LAYOUT

What do you think of the way the guide is set up?

- Is it easy to read?
- Does the order of the information make sense?

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

## IMPACT

If your healthcare provider prescribed Buprexil for you and gave you this guide, what would you do with it? **IF NEEDED**, Throw it away, keep it for a day or two, keep it until finished with the prescription, keep it for future reference, etc. What is it about the guide that would make you do that?

- **IF THROW AWAY**, What would make this medication guide more worth keeping?

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

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

If you are ever prescribed Buprexil, will you do anything differently with this medicine compared to other types of medicine? **IF YES**, What would you do differently?

## **WRAP-UP**

Do you have any other suggestions for improving this guide?

- 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.**