

# Opioid Patient Counseling Guide

## Cognitive Interview Guide

### 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 pain reliever information. The FDA is interested in getting your opinion about the information we are about to show you.

They want to know that the information makes sense, is easy to understand, and that all people understand it the same way. If you agree to be interviewed, we will ask you about the item we sent you in the mail. After you look at the item, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

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

IF YES, CONTINUE

IF NO BUT GUIDE 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

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)**

# 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 any questions 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 confidential. Confidential means that we will not share your name or other information that could be used to figure out who you are. The interview will take about 45 minutes and you will get \$50 E-Rewards Currency for your time. We would like to record our conversation if you are okay with that. The recording helps us to 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. The recordings and our notes will be destroyed after we finish the project.

**IF FDA STAFF ARE ON THE PHONE:** I want you to know that some people from the FDA who work on this research project are listening to this interview to see if there are ways to make the information better.

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

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

You told us when you volunteered for this interview that you {have/have never} taken a prescription pain reliever. Have you heard about a type of pain reliever known as opioids?

- **IF NO**, Skip to next question
- **IF YES**, What do you know about them?
  - o IF NEEDED, What are the benefits of opioids? What are the risks?
  - o Have you ever talked with your doctor or other healthcare provider about taking an opioid?
    - **IF YES**, What, if anything, do you remember talking about? How helpful was that discussion?
    - **IF NO**, Skip to next question

Have you ever heard of a Medication Guide?

**INTERVIEWER NOTE: A “Medication Guide” is what patients receive at the pharmacy, different from the Patient Counseling Guide being tested here.**

- **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. Do you see a paper that says “What You Need to Know About Opioid Pain Medicines?” 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 images or statements in the information.

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

# RETROSPECTIVE GENERAL PROBES

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

## RESEARCH QUESTIONS

Is the guide clear and understandable?

Does the guide increase overall understanding of opioids and the associated risks?

Does the guide provide useful information about safe use of opioids?

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

Do participants recognize the call to action of talking with their doctor about opioids?

Are the images and general layout appealing?

Are participants familiar with Medication Guides, which is separate from the document being tested?

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

First, just tell me your overall thoughts about the guide.

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 doctor to help explain these parts?

## 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?

What do you think about the colors?

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

- Do you think it goes with the information?

- Do you think the guide needs more pictures or graphics, or are there enough? **IF NEEDED** What do you think should be added? Why?

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

## CONTENT

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

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

- What, if anything, is it asking you to do?
- 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 guide, what are the most important things to put on the front page?

Does the guide clearly explain what opioids are?

- **IF YES**, Can you tell me what about the guide makes you say it was clear?
- **IF NO**, Can you say more about what wasn't clear?
- **IF NOT MENTIONED**, The guide says that opioids are also known as narcotics. Does the word "narcotics" help explain this type of medicine to you?

Based on this information, what would you say are the most serious risks of taking opioids?

Does the guide clearly explain what it means to be addicted to opioids?

- **IF YES**, Can you tell me what about the guide makes you say it was clear?
- **IF NO**, Can you say more about what wasn't clear?
- **IF NOT MENTIONED**, What do you think about the blue box that lists risk factors? Is there anything confusing or unclear about these risk factors? What would you do if you thought you had a risk factor?

Can you tell me in your own words what the guide says is the difference between "tolerance" and "addiction?"

After reading this document, do you have any questions about opioids, addiction, or tolerance? **IF YES**, What are they?

**IF NOT MENTIONED, DIRECT R TO 1<sup>ST</sup> LINE**, What do you think about the second sentence that starts, "Keep this guide and the Medication Guide that comes with your medicine...?"

- Is it clear what the Medication Guide is?
- Where do you get the Medication Guide?

- Do you think it is the same or different than this Patient Counseling Guide? Do you think it is necessary to receive both the Medication Guide and this Patient Counseling Guide?

On page 2, the blue box explains what to do if you no longer need your opioid medicine. What do you think of this information?

- Did you know about these options for getting rid of extra opioid medicines? Are you surprised to see any of these options?
- **IF NOT MENTIONED:**
  - o What do you think about flushing opioids down the toilet?
  - o How likely are you to use a community drug take back program? How do you think you could find out more information about that type of program?

Does the guide clearly explain what naloxone (**pronounced nuh-LOX-own**) is? When should people use it?

- Let's say you were taking a prescription opioid and you had taken too much of it. How likely do you think you would be to take naloxone in that situation? **IF UNLIKELY**, Why is that?
- How likely would you be to give naloxone to a child who had accidentally taken an opioid medicine? **IF UNLIKELY**, Why is that?

**IF NOT MENTIONED, DIRECT R TO SENTENCE WITH "NALOXONE PACKAGE" AT BOTTOM OF PAGE 2**, What does "naloxone package" mean to you?

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

## **IMPACT**

If your doctor prescribed an opioid 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 you were prescribed opioids, how helpful would this guide be 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}?

After looking at this guide, what new information, if any, have you learned about taking opioids?

**IF EVER TAKEN PRESCRIPTION OPIOID [SCREENER Q3=C-H]**, If you are prescribed a prescription opioid in the future, will you do anything differently than you have in the past? **IF YES**, What would you do differently?

**IF NEVER TAKEN PRESCRIPTION OPIOID [SCREENER Q3=A, B, OR I (AND NOT C-H)],** When you were selected for this interview, you told us that you had taken [drug choice C-H], which is an opioid. If you are ever prescribed an opioid, will you do anything differently with that medication compared to other types of medication? **IF YES,** What would you do differently?

**IF NEEDED,** How would you store your opioid prescription?

**IF NEEDED,** What would you do if you had extra or unneeded opioids in your house?

If you thought you were addicted or tolerant to opioids, what would you do?

If you had more questions about opioids, 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 the website listed on the last page of the guide? Why?

## **WRAP-UP**

Do you have any other suggestions for improving the guide?

- Is there any information that is NOT needed or can be removed? **IF YES,** What information?
- 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.**