

Transmucosal Immediate Release Fentanyl (TIRF) Patient Prescriber Agreement Form (PPAF) 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 a type of prescription medicine for treating pain. 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 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 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

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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 45 minutes and you will receive \$50 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

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

[IF PATIENT] You told us when you volunteered for this interview that you take prescription medicines around-the-clock to treat pain. How long have you been taking these prescription medicines around-the-clock?

[IF CAREGIVER] You told us when you volunteered for this interview that you help manage medications for your [INSERT RELATIONSHIP] who has cancer and takes prescription medicines around-the-clock to treat pain. My questions for you today relate to the care that you provide this person. How long have you managing your [INSERT RELATIONSHIP's] medications?

Have you heard about a type of pain reliever known as Transmucosal Immediate Release Fentanyl (or TIRF)? TIRF medicines can come in the form of tablets, lozenges, films or sprays, and are also known as Abstral, Actiq, Fentora, Lazanda, Onsolis, or Subsys. Do any of these sound familiar?

- IF NO, Skip to text below
- IF YES:
 - o What do you know about TIRF medicines?
 - o Can you recall any risks of taking TIRF medicines? IF YES, What are they?

TIRF medicines contain fentanyl, a prescription opioid pain reliever. TIRF medicines are used to manage breakthrough pain in adults with cancer who are routinely taking other opioid medicines around-the-clock for pain. Breakthrough pain is pain that comes on suddenly for short periods of time and is not eased by a patient's normal pain management plan.

Now please open the envelope we sent you in the mail. Do you see a paper that says "Patient-Prescriber Agreement Form"? 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 FORM ON SCREEN AS NEEDED TO AID DISCUSSION.

RESEARCH QUESTIONS

Is the Patient-Provider Agreement Form clear and understandable?

What are the key messages that participants get from the form?

Do participants understand that TIRFs can cause their breathing to stop, which may lead to death?

Do participants understand that because of the serious risk of death, they have to follow certain safety rules?

Does the language about storing patient information in a database concern participants?

Do participants understand they can only get a TIRF medicine from a special pharmacy?

Do participants understand the information about the TIRF REMS program?

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

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

What do you like about it?

What don't you like?

How easy or difficult is it to understand this form? Is there anything confusing or unclear? Do you think you would need your [(doctor) OR (INSERT RELATIONSHIP'S doctor)] to help explain anything?

DESIGN AND LAYOUT

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

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

What are your thoughts about the signature lines on this form?

- **IF NEEDED**, Why do you think your [(doctor) OR (INSERT RELATIONSHIP'S doctor)] would ask you to sign this form?

CONTENT

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

In your own words, what is the overall, main message that the form 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?

Does the form clearly explain the risks of using TIRF medicines?

- **IF YES**, Can you tell me what about the form makes you say it was clear?
- **IF NO**, Can you say more about what wasn't clear?
- **IF NOT MENTIONED**, The form says that patients using TIRF medicines have to follow certain safety rules. What are those rules? **Listen for:**
 - o Patients must be opioid tolerant before taking TIRFs. Patients must continue to be opioid tolerant while taking a TIRF medicine.
 - o Patients must properly store and and dispose of TIRF medicines to avoid accidental overdose in others.
- Is there anything confusing about this?

What would you do if you thought someone had accidentally taken a TIRF medicine?

Listen for:

- o Call 911
- o Use Narcan

[IF PATIENT] What are your thoughts about item #10 on the second page?

- IF NEEDED, Does anything here concern you?

[IF CAREGIVER] “Personal information” in item #10 on the second page refers to your [INSERT RELATIONSHIP’S] information, not yours. What are your thoughts about item #10?

- IF NEEDED, Does anything here concern you?

Where would you expect to be able to fill a prescription for a TIRF medicine? How would you identify one of these pharmacies?

Does the form clearly explain the information about the TIRF REMS program at the bottom of page 2?

- IF YES, Can you tell me what about the form makes you say it was clear?
- IF NO, Can you say more about what wasn’t clear?

After reading this document, do you have any questions about taking TIRF medicines?
IF YES, What are they?

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

IMPACT

If a doctor prescribed a TIRF medicine for [(you) OR (your INSERT RELATIONSHIP)] and gave you a copy of this form, 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. Where would you keep it (on your refrigerator, in your medical files, near your prescription, or somewhere else)? What is it about the form that would make you do that?

If a doctor prescribed a TIRF medicine for [(you) OR (your INSERT RELATIONSHIP)], would you like a copy of it emailed to you or have it be available on your phone?

If [(you) OR (your INSERT RELATIONSHIP)] were prescribed a TIRF medicine, how helpful would this form 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}?
- IF NEEDED, Would this form help you and your [(doctor) OR (INSERT RELATIONSHIP’S doctor)] talk about the risks of using a TIRF medicine?

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- **IF NEEDED**, Would this form help you make a decision about whether or not to [(take the medicine) OR (give this medicine to your **INSERT RELATIONSHIP**)]? If a doctor prescribed this drug for [(you) OR (your **INSERT RELATIONSHIP**)], would you [(take it) OR (give it to him/her)? Why?

After looking at this form, what new information, if any, have you learned about using TIRF medicines?

WRAP-UP

Do you have any other suggestions for improving the form?

- 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.