

Attachment O-2 (Group 3 – All-Comers)

Label Comprehension Study

Assent for Participation in an Interview

Introduction and Purpose:

The purpose of this research study is to see if the label for a medicine is easy to understand and use. The medicine is only available now with a doctor's prescription or through a pharmacist or clinic, but it may become available on drugstore shelves. When it can be bought on a drugstore shelf, people will need to be able to understand from the label how to use the medicine so it is safe and effective. RTI International and their partner Concentrics Research are conducting this study sponsored by the US Food and Drug Administration (FDA).

You have been invited to take part in this study because you may have unique insights that will help us improve the label so it can be easily understood by people who use the medicine.

Before you take part in the study, you need to read this assent so that you understand what the project is about and what you will be asked to do. This form also tells you how we will protect your information and who you can call if you have questions. This form also tells you about the possible benefits of this study as well as the risks. Please ask the researcher to explain anything you do not understand. Your parent was provided with a parental permission form with similar information about the study, and he/she gave permission for you to take part in the study.

Procedures:

If you agree to participate, you will be asked to take part in a one-time individual, in-person interview. The discussion will last about 45 minutes. During the first part of the interview, we want to get an idea of what medical words you know. Next, you will be asked to review a copy of the label that will be on the medicine and answer some questions about it. We will audio-record your answers to the questions. This is so we can take notes on your answers to help us better understand why you feel the way you do.

If your parent/guardian said it was okay, some of the people working on the project may watch the interview from behind the one-way mirror or by live stream. We will let you know if this is the case. You can still participate in the study if you do not want other people to watch the interview. If you say no, these people will be asked to leave the observation room or to disconnect the live stream until the interview is over.

You will not be contacted in the future about this study after your participation ends.

Risk/Discomforts:

There are minimal risks to you from participating in this study.

1. Though unlikely, there is a small chance that you might feel embarrassed or upset by some of the questions asked in the interview. You can say you do not want to talk about any topic for any reason. You can also stop the interview at any time. Your participation is completely voluntary.
2. It is also possible that others may find out that you participated in this study. RTI and Concentrics will take several steps to keep your participation confidential.
 - The information that you give us will be combined with the responses of other participants in a summary report that will not identify you by name.
 - None of your answers to the screener or interview questions will be linked to your name or information that could identify, which means that no one will know what you said.
 - All notes taken during the interview will be kept in a locked file cabinet or on a password-protected computer. In addition, any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet separately from your answers to the screener or interview questions. Only authorized project staff will be able to see them.
 - We will also be audio recording our discussion. The audio files will be stored on password-protected computers at RTI, Concentrics, and FDA. During the interview, please do not tell us anything about yourself that could be used to identify you like your last name (it is okay to tell us your first name) or birthday. If you do share this kind of information with us during the interview, we will remove it from the transcripts and audio files before we give them to the FDA at the end of the study.
 - We will destroy all forms that have your name and contact information on them and the audio files at the end of the study.

Even with these steps, there is still a small risk that your privacy could be broken. There is also a small chance that there may be other unforeseeable risks.

Benefits:

This study will provide no direct benefit to you. The information that we gather during the study can benefit others by making sure that people understand from the label how to use the medicine so that it is safe and effective.

Payment:

You will receive \$40 [FORM TBD BY RECRUITMENT FIRM; CASH/CHECK ARE TYPICAL] at the end of the interview to reimburse you for your expenses related to participation.

Right to Refuse or Withdraw:

It is your choice to be in this interview. You can choose not to talk about any topic. You can stop the interview at any time without penalty and you will still get the \$40.

Persons to Contact:

If you have questions about the study, you can call the Project Director, Claudia Squire, at 919-541-6613. She can be reached between 9:00 AM and 5:00 PM Eastern Time Monday to Friday. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (toll-free number).

Your Assent:

STATEMENT OF ASSENT FOR THE INTERVIEW

I have read this assent form. The above document describing the benefits, risks and procedures for this research study has been explained to me. I had a chance to ask questions, and my questions were answered. I was given a copy of this assent form.

Do you assent to participate in the study now?

Yes

No

Participant signature

Date

Signature of person obtaining assent

Date

**PROCEED ONLY IF PARENT/GUARDIAN GAVE PERMISSION FOR THEIR
CHILD'S INTERVIEW TO BE OBSERVED**

STATEMENT OF ASSENT FOR THE INTERVIEW TO BE WATCHED BY STUDY STAFF

I understand that my interview may be watched by study staff.

I understand that my parent gave permission for the interview to be observed, but that I can still say no.

If I say no, I can still participate in the study.

Do you assent for study staff to watch the interview?

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Yes

No

Participant signature

Date

Signature of person obtaining assent

Date

YOU WILL BE GIVEN A COPY OF THIS PERMISSION FORM TO KEEP