

ATTACHMENT K1

LABEL COMPREHENSION STUDY TASK 3: GROUP 1-2, 4 (ADULT ALL COMERS, USERS AND ASSOCIATES) CONSENT FORM

Label Comprehension Study

Consent for Your Participation in an Interview

Introduction and Purpose:

The purpose of the research is to see if the planned 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 research sponsored by the US Food and Drug Administration (FDA).

You have been invited to take part in this research 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.

Procedures:

We are inviting you to take part in a one-time individual, in-person interview to collect this information. The discussion will last approximately 30 minutes. The study will be taking place at [INSERT LOCATION].

During the first part of the interview, we will ask you to read aloud some medical terms to get an idea of what medical words you are familiar with. Next, you will be asked to review the label on a medicine and answer some questions about the label. We will audio-record your answers to the questions. This is so we can take notes on your answers and better understand why you feel the way you do. If you do not want to be audio recorded, you will not be able to participate in the research.

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

Risk/Discomforts:

There are minimal risks to you for participating in this research.

1. While the discussion questions we ask are not meant to be sensitive, there is always a chance that you may feel uncomfortable with some of the questions. You do not have to answer any question that you don't want to answer and you can stop participating in the interview at any time. Your participation is completely voluntary. During the interview, do

not share any information about yourself that could be used to identify you like your last name or birthday. If you do share this kind of information with us during the interview, that part of the audio recording will not be transcribed.

2. It is also possible that others may find out that you participated in this research. RTI and Concentrics will take several steps to keep your participation secure to the extent provided by law:
 - 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.
 - We will assign a Participant ID number so that your answers to the screener or interview questions cannot be directly linked to your name and contact information.
 - All data collected during the interview will be kept in a locked file cabinet or on a password-protected computer. The data will not contain any information that could personally identify you. It will be destroyed within two years after the end of this research.
 - 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. These forms will be destroyed within one month after the research ends.
 - We will also be audio recording our discussion. The audio files will be stored on password-protected computers at RTI and Concentrics and will be transcribed. 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 tell us this information by mistake, that part of the audio recording will not be transcribed. The audio files and transcripts will be destroyed within 2 years after the research ends.

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 research will provide no direct benefit to you. The information that we gather during the research 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 be given a \$40 at the end of the interview as a token of appreciation for your time and travel expenses.

Right to Refuse or Withdraw:

It is your choice to participate in this interview. You can choose not to answer any questions. You can stop participating in the interview at any time with no penalty and you will still receive the \$40.

Circumstances under which your participation may be terminated:

Your participation will be terminated if you decide you do not want your interview to be audio recorded. If your participation is terminated for this reason, you will not receive the \$40. This

condition of participation was explained to you during screening at which time you agreed to be audio recorded.

Persons to Contact:

If you have questions about the research, you can call the Project Director, Claudia Squire, at 1-800-334-8571 ext. 26613 (a toll-free number). 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 Consent:

I have read this consent form. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to be in the research.

The above document describing the benefits, risks and procedures for this research study has been explained to me. I agree to participate.

Signature of Participant

Date

Signature of Person Obtaining Consent

Date

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