ATTACHMENT K3

LABEL COMPREHENSION STUDY
TASK 3: GROUP 3 (ADOLESCENT ALL-COMERS) – ADOLESCENT ASSENT FORM

Label Comprehension Study

Assent for Your 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 you can participate if he/she gives 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 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 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 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 study.

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. 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 study. 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 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 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 and Concentrics until they are destroyed within 2 years of the study end date. The audio files will be transcribed, and the transcripts will be given to FDA at the end of the study. 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, that part of the audio recording will not be transcribed.

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 at the end of the interview as a token of appreciation for your time and travel cost 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.

Circumstances under which your participation may be ended:
Your participation will end if you decide you do not want your interview to be audio recorded. If your participation ends for this reason, you will not receive the $40. This condition of participation was explained to you during screening at which team you agreed to be audio recorded.

Persons to Contact:
If you have questions about the study, 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 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**

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