Attachment M-2 (Group 4)

Label Comprehension Study
Consent Form

Introduction and Purpose:
You have been invited to take part in a research study. The purpose of the study 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 study sponsored by the US Food and Drug Administration (FDA).

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 45 minutes. During the first part of the interview, we want 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 for the purpose of taking notes on your answers so we can better understand why you feel the way you do. Some interviews may also be observed by study staff. We will let you know when you are being observed.

Risk/Discomforts:
There are minimal risks to you for participating in this study. 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.

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. All notes taken during the interview will be kept in a locked file cabinet or on a password-protected computer. 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. Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the study. The audio files will be stored on password-protected computers at RTI, Concentrics, and FDA. We will destroy all forms that have your name and contact

information on them and the audio files at the end of the study. However, there is still a small risk that your privacy could be broken. You will not be contacted in the future about this study after your participation in the interview ends.

Benefits:
This study will provide no direct benefit to you; however, you may find the discussion to be informative or interesting. 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 be given $50 [FORM TBD BY RECRUITMENT FIRM; CASH/CHECK ARE TYPICAL] at the end of the interview to reimburse you 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 $50.

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).

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 study.

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 (first name) **Date**

_____ _____
Signature of Person Obtaining Consent **Date**