

Attachment N (Group 3 – All-Comers)

Label Comprehension Study

Parental Permission for Your Child's Participation in an Interview

Introduction and purpose:

The purpose of the research 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).

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

Before your child takes part in the study, you need to read this parental permission so that you understand what the project is about and what your child will be asked to do. This form also tells you how we will protect your child's 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. Your child will be provided with an assent form with similar information at the time of the study.

Procedures:

If you agree to let your child participate, he/she will take part in a one-time individual, in-person interview. The discussion will last approximately 45 minutes. During the first part of the interview, we want to get an idea of what medical words your child is familiar with. Next, your child 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 child's answers to the questions. This is so we can take notes on your child's answers to help us better understand why he/she feels the way they do.

Study staff may also observe the interview from behind a one-way mirror or by live stream. We will let your child know when he/she is being observed. Your child can still participate in the study if you do not want the interview to be observed. Your child can also tell us if he/she does not want to be observed. If you or your child does not want the interview to be observed, the observers will be asked to leave the observation room and the live stream will be disconnected for the duration of the interview.

Your child will not be contacted in the future about this study after their participation in the interview ends.

Risk/Discomforts:

There are minimal risks to your child for participating in this study.

1. While the discussion questions we ask are not meant to be sensitive, there is always a chance that your child may feel uncomfortable with some of the questions. Your child does not have to answer any question that he/she doesn't want to answer and can stop participating in the interview at any time. Participation is completely voluntary.
2. It is also possible that others may find out that you child participated in this study. RTI and Concentrics will take several steps to keep your child's participation confidential.
 - The information that your child gives us will be combined with the responses of other participants in a summary report that will not identify your child by name.
 - None of your child's answers to the screener or interview questions will be linked to their name or information that could identify them, which means that no one will know what they 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 child's name or information that could identify them will be kept in a locked file cabinet separately from their answers to the screener or interview questions. Only authorized project staff will be able to see them.
 - We will also be audio recording the discussion. The audio files will be stored on password-protected computers at RTI, Concentrics, and FDA. During the interview, we will ask your child not to tell us anything about themselves that could be used to identify them like their last name or birthday. If your child does 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 child's 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 child's 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 your child. 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:

Your child will receive \$40 [FORM TBD BY RECRUITMENT FIRM; CASH/CHECK ARE TYPICAL] at the end of the interview as reimbursement to help defray expenses related

to participation.

Right to Refuse or Withdraw:

Your child's participation in this study is voluntary. Your child can choose not to answer any questions and can stop participating in the interview at any time without penalty. Your child will still receive the \$40 if they decide not to continue. You may withdraw your permission and stop your child's participation at any time.

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 child's rights as a participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (toll-free number).

Your Permission:

STATEMENT OF PARENTAL PERMISSION FOR THE INTERVIEW

I have read this parental permission 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 parental permission form.

By signing this form, you agree to allow your child to participate in our research study.

Child's name

Date

Printed name of parent or guardian

Date

Signature of parent or guardian

Date

STATEMENT OF PARENTAL PERMISSION FOR THE INTERVIEW TO BE OBSERVED BY STUDY STAFF

I understand that my child's interview may be observed, and that he/she can still participate if I do not or my child does not want others to observe the interview.

Revised 6/27/17

By signing this form, you agree to allow your child's interview to be observed.

Printed name of parent or guardian

Date

Signature of parent or guardian

Date

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