

ATTACHMENT B3

LABEL COMPREHENSION STUDY TASK 3: GROUP 3 (ADOLESCENT ALL-COMERS) – TELEPHONE SCREENER FOR RECRUITMENT FIRM

TELEPHONE RECRUITMENT SCRIPT

[Speaking to parent/guardian]

Hello, my name is _____ and I'm from [NAME OF RECRUITMENT FIRM]. I'm calling on behalf of RTI International and Concentrics Research about a research study that is being sponsored by the U.S. Food and Drug Administration (FDA). We are looking for teens to take part in a study to review a label for a medicine that may be available over-the-counter, meaning without a prescription. I am calling you because you have a teen between the ages of 15-17 who may qualify and be asked to participate in the study. FDA believes it is important to get feedback from many people, including teens, about this product label to help make sure that people understand from the label how to use the medicine so it is safe and effective. We are not selling or promoting any product.

The study involves participating in a one-time individual, in-person interview lasting no more than 30 minutes. During the first part of the interview, we will ask your child to read aloud some medical terms to get an idea of what medical words your child is familiar with. Then we will ask your child some questions about instructions for a medicine. The interview will be audio recorded. Your teen will be given \$40 at the end of the interview as a token of appreciation for their time and travel cost related to participation.

Before we can determine if your teen is eligible to be in the interview, we need to obtain your permission to ask your teen screening questions. This will include questions about their school grades, age, and race/ethnicity. If your child does qualify and is asked and decides to participate, I will need their email address and/or phone number to contact them to remind them about their appointment. If your child does participate, we will not tell you anything they say during the interview.

First, I want to confirm that you have [X] children between the ages of 15 and 17. Is that correct [YES/NO]? Are they all currently at home [YES/NO]? Can I speak to _____ **[oldest child who is at home]** to see if he/she is able to be in the study? **[NOTE: If that child does not**

want to come to the phone ask to speak to the next oldest.] We will not enroll anyone in the study who will be turning 18 before June 30, 2018 and all data will be deidentified within one month of the study end date (this means that any information that identifies your child will be destroyed within one month of the study end date). If he/she is able to be in the interview, we will need you to sign a parental permission form prior to his/her participation in the study. If your child qualifies for the study and decides to participate, I will ask to speak to you again at the end of the call so that I can give you more information. Will you provide permission for me to speak to your child?

SCREENER: DOCUMENT PARENTAL PERMISSION TO TALK TO CHILD:

----- YES, parent provides permission
 _____ No, parent declines; terminate call

| | | |
|------------|--|---|
| Yes | | ➔ CONTINUE |
| No/Refused | | ➔ TERMINATE (Thank parent for his/her time and end the call) |

[READ] Before we continue, I need to confirm a couple of things.

a. Are you this child's parent or legal guardian?

| | | |
|------------|--|---|
| Yes | | ➔ CONTINUE |
| No/Refused | | ➔ TERMINATE (Thank parent for his/her time and end the call) |

b. If your child qualifies for the study and decides to participate, the interview will be audio recorded. Can we audio record your child's interview?

| | | |
|-----|--|---|
| Yes | | ➔ CONTINUE |
| No | | ➔ TERMINATE (Closing Script and Contact Information Sheet) |

Thank you. Please give the phone to your child and give them privacy for the discussion. By privacy, I mean that you are not listening to our discussion in person (i.e., you are not in the same room as or within hearing distance of your child) or over the telephone.

[Speaking with adolescent]

My name is _____ and I'm from [NAME OF RECRUITMENT FIRM]. RTI International and Concentrics Research are doing a study that is being sponsored by the U.S. Food and Drug Administration (FDA). FDA is the government agency that protects the public health by reviewing new medicines. In these reviews, the FDA helps to make sure the medicines work and are safe before they are approved to be prescribed by health care providers and used by patients. We are looking for people to take part in a research study to review a label for a medicine that may be available over-the-counter soon, meaning without a prescription. What we learn from this study will help to make sure that people understand from the label how to use the medicine so it is safe and effective. We are not selling or promoting any medicine.

The study involves being in a one-time in-person interview lasting no more than 30 minutes. The session will include looking at a list of medical terms and answering some questions about instructions for the medicine. The interview will be audio recorded. 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. The interview will be audio recorded. You will be given \$40 at the end of the interview as a token of appreciation for your expenses related to study participation.

To see if you qualify for this study, I need to ask you some questions that will take a few minutes of your time. Your parent/guardian gave me permission to ask you these questions. This will include questions about your school grades, age, and race/ethnicity. If you qualify for the study and are asked to participate, you can decide if you want to be a part of the study. If you do qualify and are asked and decide to participate, I will need your email address and/or phone number to contact you to remind you about your appointment.

All of your answers will be kept private. We won't share any of your answers with your parents or tell them why you did or didn't qualify for the study. If you do participate in the study, we won't share anything that you say during the interview with your parents. Your contact information will be kept apart from your answers to these questions. If you feel uncomfortable at all, you can choose not to answer one or more questions or end the call at any time. However, without knowing your answers to some of the questions, we may not be able to tell if you qualify for this study. Also, just because your parent/guardian gave us permission to ask you these questions does not mean you must answer them.

c. Do you have any questions about the process?

| | |
|-----|--------------------|
| Yes | ➔ ANSWER QUESTIONS |
| No | ➔ CONTINUE |

- d. If you qualify for the study and are asked and decide to participate, the interview will be audio recorded. Is it okay if we audio record the interview?

| | | |
|-----|--|---|
| Yes | | → CONTINUE |
| No | | → TERMINATE (Closing Script and Contact Information Sheet) |

- e. Do you have privacy for the discussion? This means your parent/guardian is not listening to our conversation in person (i.e., he/she is not in the same room as you or within hearing distance) or over the phone.

| | | |
|-----|--|--|
| Yes | | → ANSWER QUESTIONS |
| No | | → SUGGEST THAT HE/SHE MOVES TO A PRIVATE AREA (A SEPARATE ROOM WITH A DOOR, IF POSSIBLE) OR ASKS THE PARENT/GUARDIAN TO HANG UP THE PHONE. |

- f. May I ask you my questions now?

| | | |
|-----|--|---|
| Yes | | → CONTINUE |
| No | | → TERMINATE (Thank adolescent for his/her time and end the call) |

PRESCREENING

1. How old were you on your last birthday?

| | |
|-------|---|
| _____ | Age 15 - 17 → CONTINUE Age 18+ → TERMINATE (Closing Script and Contact Information Sheet) Under Age 15 → TERMINATE (Closing Script and Contact Information Sheet) |
|-------|---|

1a. Will you turn 18 before June 30, 2018?

| | | |
|---------|--|---|
| Yes | | → TERMINATE (Closing Script and Contact Information Sheet) |
| No | | → CONTINUE |
| Refused | | → TERMINATE (Closing Script and Contact Information Sheet) |

2. Can you read, speak and understand English?

| | | |
|-----|--|---|
| Yes | | → CONTINUE |
| No | | → TERMINATE (Closing Script and Contact Information Sheet) |

3. Do you normally wear corrective lenses, contacts, or glasses to read?

| | | |
|---------|--|--|
| Yes | | → CONTINUE |
| No | | → CONTINUE |
| Refused | | → TERMINATE (Closing script and contact information script) |

4. Do you have any other problems with your eyes that would prevent you from being able to read?

| | | |
|-----|--|---|
| Yes | | → TERMINATE (Closing Script and Contact Information Sheet) |
| No | | → CONTINUE |

DEMOGRAPHIC QUESTIONS

5. What grade are you currently enrolled in?

| | | |
|------------------------|--|------------|
| 9 th grade | | → CONTINUE |
| 10 th grade | | → CONTINUE |
| 11 th grade | | → CONTINUE |
| 12 th grade | | → CONTINUE |
| Not enrolled in school | | → GO TO Q7 |

6. During the past 12 months, how would you describe the grades you mostly received in school?

| | | |
|-----------|--|---------------------------|
| Mostly As | | ➔ CONTINUE |
| As and Bs | | ➔ CONTINUE |
| Mostly Bs | | ➔ CONTINUE |
| Bs and Cs | | ➔ CONTINUE |
| Mostly Cs | | ➔ CONTINUE (LL indicator) |
| Cs and Ds | | ➔ CONTINUE (LL indicator) |
| Mostly Ds | | ➔ CONTINUE (LL indicator) |
| Mostly Fs | | ➔ CONTINUE (LL indicator) |

7. Are you Hispanic or Latino?

| | | |
|-----|--|------------|
| Yes | | ➔ CONTINUE |
| No | | ➔ CONTINUE |

8. What is your race? (Please select one or more from the following):

[READ LIST IF NECESSARY- ASSIGN RESPONSE TO ONE OR MORE GROUPS BELOW]

| | | |
|---|--|------------|
| American Indian or Alaska Native | | ➔ CONTINUE |
| Asian | | ➔ CONTINUE |
| Black or African American | | ➔ CONTINUE |
| Native Hawaiian or other Pacific Islander | | ➔ CONTINUE |
| White | | ➔ CONTINUE |
| | | |
| AIM FOR MIX | | |

9. What is your gender? [Do not read response categories.]

| | | |
|-----------------------------------|--|------------|
| Male | | ➔ CONTINUE |
| Female | | ➔ CONTINUE |
| | | |
| AIM FOR MIX OF MALE/FEMALE | | |