

ATTACHMENT J3

**LABEL COMPREHENSION STUDY
TASK 3: GROUP 3 (ADOLESCENT ALL-COMERS) – CLOSING
SCRIPT AND CONTACT INFORMATION SHEET**

VISIT INFORMATION

INTERVIEW APPT (MM/DD):

INTERVIEW APPT TIME:

RECRUITMENT INFO

RECRUIT DATE:

QUALIFIED (YES/NO):

ADOLESCENT CONTACT INFORMATION

FIRST NAME:

TELEPHONE:

EMAIL ADDRESS:

BEST TIME:

PARENT/GUARDIAN CONTACT INFORMATION

FIRST NAME:

TELEPHONE:

EMAIL ADDRESS:

BEST TIME:

This form should be stored in a locked filing cabinet in a separate location from screener

IF INELIGIBLE → **Closing for Ineligible Participants:** Thank you for answering our questions. At this time, you do not qualify to be in this research study. However, we appreciate your time and willingness to help us. Goodbye.

IF ELIGIBLE → **CONTINUE to Invitation Script:**

Invitation for Eligible Participants: Thank you for answering all of my questions. We would like to invite you to take part in the research study for a one-time, individual in-person interview. The interview will take place at **[ADDRESS]**.

The session will last no more than 30 minutes. No one will attempt to sell you anything, and no one will call you for other studies as a result of being a part of this study. The interview will be audio recorded. RTI and Concentrics will maintain copies of the audio files of sessions securely until they are destroyed within 2 years of the study end date. Any information that could identify you will be removed from written records before sending them to FDA. RTI, Concentrics, and FDA will maintain the written records of sessions securely until they are destroyed within 2 years of the study end date. If the audio file has any information that can identify you, that information will not be transcribed. The audio files will not be sent to FDA. Any forms related to the project that have your name on them will be kept in a locked file cabinet or on a password-protected computer. You will be given \$40 at the end of the interview to as a token of appreciation for time and travel costs related to participation. This is an important research effort and we hope that you will be part of it.

Are you interested in being in this study?

Yes → CONTINUE

No → [Thank respondent and end call]

Because you are under age 18, we will need a parent or guardian's permission for you to be in the study. You will need to have your parent email the signed form to us before the interview or you will need to bring it with you to the interview in order to be allowed to participate.

I'm glad that you will be able to join us. Right now, we have interview slots open on **[Day]**, **[Date]**, at **[Time]**. Would any of those times work well for you?

Yes → Document agreed upon date/time: _____

Contact Information for Adolescent

Thank you for your willingness to be in this study. I would like to collect some simple contact information for our reminder call and email.

[DO NOT RECORD ON THIS PAGE; RECORD ON PAGE 1 ONLY WHICH IS TO BE STORED SEPARATELY FROM THE SCREENER: FIRST NAME, PHONE NUMBER (FOR REMINDER CALL), EMAIL ADDRESS (FOR REMINDER EMAIL), AND BEST TIME TO CALL.]

You will get a reminder call and/or email the day before your appointment. We have you scheduled on **[Day]**, **[Date]**, at **[Time]**. The interview will be held at **[Address]**.

I also want to point out some details about the interview day:

- If you said that you needed glasses or contacts to read, please remember to bring them with you for your session.
- If you have any questions or if you need to reschedule your appointment, please call the number you just called **[PHONE NUMBER]** as soon as possible.

Do you have any questions about the study?

I am going to send you a copy of the study assent form by email with the reminder email so that you can review it prior to your appointment. The assent form includes information about the study procedures, as well as information about the risks and benefits of participating. The interviewer will discuss the form with you at the time of your appointment and answer any questions that you have. Then, if you agree to participate, you can sign the form at the interview. You can bring the form with you if you'd like, but we will also have copies available at the time of your interview.

Now, I would like to give your parent/guardian this information that I just gave you about the interview and the form that they will need to sign.

IF PARENT IS NOT AVAILABLE:

In order to participate in this study, we will need to speak with your parent to provide some additional information. Please call us back at **[PHONE NUMBER]** when your parent is around and able to speak with us.

IF PARENT IS AVAILABLE:

Your child is eligible to participate in the interview and has been scheduled to participate on **[DAY]**, **[DATE]** at **[TIME]**. Because your child is under 18, we must get written permission from

you in order for him/her to participate. We will be sending you a permission form to review and sign if you provide permission for your child's participation. You can return the signed form to us by email. If you will be accompanying your child to his/her session, you can also bring the signed form with you. Or, if you are unable to accompany your child, he/she must bring the signed form with him/her in order to participate.

We will also be sending you an assent form for your child's participation. Please remind your child to look over the form beforehand. Your child can bring that form to their interview but we will also have copies available at the time of his/her interview. Your child should not sign the form in advance, as he or she will sign it at the interview. If your child normally wears glasses or contact lenses to read, please remind them to bring those with them.

Contact Information for Parent/Guardian

We are asking for your contact information only for the purpose of sending you the form that you need to sign so your child can participate and so that we can make reminder calls. I am going to send you a copy of the permission by email with the reminder email. We need to have the form signed by you in order for your child to participate in the interview. We will destroy all contact information within one month of the study end date.

[DO NOT RECORD ON THIS PAGE; RECORD ON PAGE 1 ONLY WHICH IS TO BE STORED SEPARATELY FROM THE SCREENER]: *FIRST NAME, PHONE NUMBER (FOR REMINDER CALL), EMAIL ADDRESS (FOR REMINDER EMAIL), AND BEST TIME TO CALL.]*

Your child will get a reminder call and email the day before his/her appointment. We have him/her scheduled on **[Day]**, **[Date]**, at **[Time]**. The interview will be held at **[Address]**.

I also want to point out some details about the interview day:

- If you are bringing your child to the interview, please try to arrive at least 10 minutes before the starting time.
- If you have any questions or if your child needs to reschedule his/her appointment, please call [facility's phone number] as soon as possible.

Thank you. Goodbye.

REMINDER CALL

Hello this is [NAME] with a reminder call about an in-person interview you recently agreed to be in that is being conducted by RTI International and Concentrics Research for U.S. Food and Drug Administration (FDA).

I'm calling to remind you that you are scheduled for an interview on **[Day]**, **[Date]**, at **[Time]**. The interview will be held at **[Address]**. Please arrive 10 minutes prior to your interview time. If

you are more than 10 minutes late, we may need to give your interview slot to another person. If this happens, you may not be able to participate.

I also wanted to remind you that if need glasses or contacts to read, please remember to bring them with you for your appointment.

Do you have any questions or concerns that I can help you with about the study?

If you need to be in touch with us before your interview, you can call **[PHONE NUMBER]**.

Thank you. We greatly appreciate you being in this study.

REMINDER EMAIL (Subject line: "Products Label Study: Interview Appointment Reminder")

Dear [NAME]

Thank you for agreeing to be in the research study to review a medicine label that may be available over-the-counter soon, meaning without a prescription. RTI International and Concentrics Research are doing this study for U.S. Food and Drug Administration (FDA).

You are scheduled for a one-on-one interview on [Day], [Date], at [Time]. The interview will be held at [Address]. Please arrive 10 minutes prior to your interview time. If you are more than 10 minutes late, we may need to give your interview slot to another person. If this happens, you may not be able to participate.

Please remember that if need glasses or contacts to read, you should bring them with you for your appointment.

Finally, I have attached a copy of the assent form for the study. Please read it before your scheduled appointment. We will review it with you when you come for your appointment and will answer any questions that you have.

If you have any other questions, please let me know. If you need to reach us before your interview, you can reply to this email or call [PHONE NUMBER].

Thank you,

[NAME]

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