

# ATTACHMENT J1

## LABEL COMPREHENSION STUDY TASK 3: GROUP 1- 2 (USERS AND ASSOCIATES) – CLOSING SCRIPT

### VISIT INFORMATION

INTERVIEW APPT (MM/DD): \_\_\_\_\_ INTERVIEW APPT TIME: \_\_\_\_\_

### RECRUITMENT INFO

RECRUIT DATE: \_\_\_\_\_

QUALIFIED (YES/NO) \_\_\_\_\_

Indicate Eligibility for Group  
Number 1, 2, or both AND  
Category R or E: \_\_\_\_\_

RECRUITER INITIALS: \_\_\_\_\_

SUBJECT FIRST NAME: \_\_\_\_\_

SUBJECT TELEPHONE: \_\_\_\_\_ BEST TIME: \_\_\_\_\_

EMAIL ADDRESS: \_\_\_\_\_

**\*This form should be stored in a locked filing cabinet in the  
Project Director's Office in a separate location from  
screener\***

CLOSING SCRIPT

IF INELIGIBLE → **Closing for Ineligible Participants:** Thank you for answering our questions. At this time, you do not qualify to be in this study. However, we appreciate your time and willingness to help us. We will not keep any of the screening information that you provided.

Thank you. Goodbye.

IF ELIGIBLE BUT HOLDING → **Hold Script**

Thank you for answering all my questions. At this time, the section of the study you qualify for is full but we'd like to add you to a waitlist in case a spot opens up. Depending on the group of the study you fit best for you may get called sooner or later than others on the waitlist. If you would like to be added to the waiting list we will collect your contact information and keep it until the study ends on June 30<sup>th</sup>. Would you like to be added to the waitlist? (*If participant answers yes, go to the **Contact Information** questions.*)

IF ELIGIBLE → **CONTINUE to Invitation for Eligible Participants**

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

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. 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 a \$40 Visa gift card at the end of the interview as a token of appreciation for your time and travel expenses. 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 [SCHEDULE INTERVIEW and COLLECT CONTACT INFORMATION]

No → [Thank respondent and end call]

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: \_\_\_\_\_

Thank you for your willingness to be in this study. I would like to collect some simple contact information so that we can remind you of your appointment.

**Contact Information [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 SENDING CONSENT AND REMINDER EMAIL), AND BEST TIME TO CALL.*

We will send you a reminder email and a text message reminder a few days before your scheduled 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.
- Because of the nature of the study, children will not be allowed in the room during your visit. If you need to bring children with you on the day of your interview, you will need to bring another adult to supervise the children while you are in the interview.
- If you need to reschedule your appointment, please call the number you just called **[PHONE NUMBER]** to let us know at least 24 hours in advance so we can do our best to find an alternate time.

Do you have any questions about the study?

I am going to send you a copy of the study consent form by email after we finish this call so that you can review it prior to your appointment. The consent 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. You can bring the form with you if you'd like, but we will also have copies available at the time of your interview.

If you know someone else who may be interested in this study you can share the study phone line **[STUDY PHONE NUMBER]** or our website **[WEB ADDRESS]** if they want to see if they are eligible. You do not need to do this to be part of the study.

Thank you. Goodbye.

CONFIRMATION EMAIL SCRIPT TO SEND AFTER SCHEDULING AN APPOINTMENT USING THE TELEPHONE SCREENER AND TO SEND THE CONSENT FORM TO PARTICIPANTS

Thank you for scheduling an interview for the Product Label Study. Your appointment is on [DATE] at [TIME].

Please see the attached consent form for the Product Label Study. The consent 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. You can bring the form with you if you'd like, but we will also have copies available at the time of your interview.

**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 an individual, in-person 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. Because of the nature of the study, children will not be allowed in the room during your visit. If you need to bring children with you on the day of your interview, you will need to bring another adult to supervise the children while you are in the interview.

If you need to reach us before your interview, you can reply to this email or call [PHONE NUMBER]. If you need to reschedule your appointment please contact us 24 hours in advance so we can do our best to find an alternate time.

Thank you,

[NAME]

**GROUP ASSIGNMENT**

*Assign respondent to a group based on responses to the questions. If the person qualifies for both Group 1 and Group 2 (e.g., prescription opioid and heroin associate), assign them to a group based on whichever currently has fewer people.*

**Group \_\_\_\_\_**

R or E \_\_\_\_\_

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