

Attachment A-2
LABEL COMPREHENSION STUDY
GROUP 1 & 2 Closing Script and Contact Information Sheet

VISIT INFORMATION

INTERVIEW APPT (MM/DD)

INTERVIEW APPT TIME:

RECRUITMENT INFO

RECRUIT DATE:

QUALIFIED (YES/NO)

**Indicate Assignment to
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 information that you provided during our call. 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. Would you like to be added to the waitlist? (*If participant answers yes, take them to **Contact Information** questions.*)

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 study for a one-time, individual in-person interview. The interview will take place at [ADDRESS].

The session will last no more than 45 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, and project team members may listen to the interview over the telephone. Written records of the sessions and audio files will have any information that could identify you removed before sending to the FDA. RTI, Concentrics, and FDA will maintain the tapes and written records of sessions securely until they are destroyed at the end of the study. 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 \$50 Visa gift card at the end of the interview to reimburse you 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 for our reminder call and email.

Contact Information [RECORD ON PAGE 1 WHICH IS TO BE STORED SEPARATELY FROM THE SCREENER]

First Name: _____

Phone number (for reminder call): _____ Best time: _____

Email address (for reminder email): _____

You will get a reminder call and 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.
- 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.

Do you have any questions about the study?

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.

REMINDER CALL

Hello this is **[NAME]** with a reminder call about an individual, 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, we won't be able to give you the \$50 Visa gift card.

I also wanted to remind you that if need glasses or contacts to read, please remember to 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.

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

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, we won't be able to give you the \$50 Visa gift card.

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 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]

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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