

ATTACHMENT J2

**LABEL COMPREHENSION STUDY
TASK 3: GROUP 4 (ADULT ALL-COMERS) – Closing Script
and Contact Information Sheet**

VISIT INFORMATION

INTERVIEW APPT (MM/DD)

INTERVIEW APPT TIME:

RECRUITMENT INFO

RECRUIT DATE:

QUALIFIED (YES/NO)

RECRUITER INITIALS:

PARTICIPANT FIRST NAME:

PARTICIPANT TELEPHONE:

BEST TIME:

EMAIL ADDRESS:

***This form should be stored in a locked filing cabinet 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. 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 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 two years of the study end date. 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 as a token of appreciation for expenses 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 [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 [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.*

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.
- If you have any questions or if you need to reschedule your appointment, please call **[PHONE NUMBER]** as soon as possible.

Do you have any questions about the study?

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. 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 (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. 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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