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LABEL COMPREHENSION STUDY

GROUP 4 SCREENER

COHORT INFORMATION

GROUP 4	ALL COMERS	4
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LITERACY SUBGROUP INFORMATION

SUBGROUP A:	TARGETED LOW LITERACY (N=7-9)	A
SUBGROUP B:	PREGNANT (N=1-2)	B

VISIT INFORMATION

INTERVIEW APPT (MM/DD)

INTERVIEW APPT TIME:

RECRUITMENT INFO

RECRUIT DATE:

RECRUITER INITIALS:

QUALIFIED (YES/NO)

IF NO, DQ NO.:

SUBJECT NAME:

SUBJECT TELEPHONE:

BEST TIME:

EMAIL ADDRESS:

TELEPHONE RECRUITMENT SCRIPT

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 study that is being sponsored by the U.S. Food and Drug Administration (FDA). We're calling to recruit people to take part in a research study to evaluate the labeling for a healthcare product that will be available over-the-counter, or without a prescription. We are not selling or promoting any product.

The study involves participating in a one-time in-person interview lasting no more than 45 minutes and answering some questions about instructions for the product. As a thank you for your time, you will be given \$75.

To see if you are eligible for this study, I need to ask you a few questions that will take a few minutes of your time. All of your responses will be kept private. May I proceed with my questions?

Yes → CONTINUE [Thank respondent and proceed to Q1.]

No → [Thank respondent and end call.]

1. How old were you on your last birthday?

_____	Over Age 18 → CONTINUE Under Age 18 → TERMINATE
SCREEN FOR A MIX OF AGES <ul style="list-style-type: none"> • 18 – 29 years old • 30 – 49 years old • 50 – 64 years old • 65+ years old 	

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

Male	<input type="checkbox"/>	→ GO TO Q4
Female	<input type="checkbox"/>	→ CONTINUE
Other	<input type="checkbox"/>	→ GO TO Q4

SCREEN FOR MIX OF MALE/FEMALE

3. *[IF FEMALE]* Are you currently pregnant?

Yes	<input type="checkbox"/>	→ CONTINUE
No	<input type="checkbox"/>	→ CONTINUE

AIM FOR 1-2

4. What is the highest level of education you have completed?

_____ Degree

[DO NOT READ LIST – ASSIGN RESPONSE TO EDUCATION LEVEL BELOW]

Less than high school	<input type="checkbox"/>	→ CONTINUE
High school graduate (HS diploma or GED)	<input type="checkbox"/>	→ CONTINUE
Some college (no degree)	<input type="checkbox"/>	→ CONTINUE
College (2-year) degree (Associate degree)	<input type="checkbox"/>	→ CONTINUE
College (4-year) degree (e.g., BA, BS, AB)	<input type="checkbox"/>	→ CONTINUE
Some post-college	<input type="checkbox"/>	→ CONTINUE
Advanced or post-graduate degree (e.g., Masters, MD, PhD)	<input type="checkbox"/>	→ CONTINUE

5. How confident are you in filling out medical forms by yourself?

Extremely	<input type="checkbox"/>	→ TERMINATE UNLESS FEMALE AND PREGNANT FOR A MAXIMUM OF 2 PREGNANT WOMEN
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Quite a bit		→ TERMINATE UNLESS FEMALE AND PREGNANT FOR A MAXIMUM OF 2 PREGNANT WOMEN
Somewhat		→ CONTINUE
A little bit		→ CONTINUE
Not at all		→ CONTINUE

6. Can you read, speak and understand English?

Yes

→ **CONTINUE**

No

→ **TERMINATE**

7. Are you, or is anyone in your household, currently employed by any of the following?

A marketing or research company		→ TERMINATE
An advertising agency or public relations firm		→ TERMINATE
A pharmacy or pharmaceutical company		→ TERMINATE
A manufacturer of medicines		→ TERMINATE
A managed care or health insurance company		→ TERMINATE
A healthcare practice		→ TERMINATE
None of the above		→ CONTINUE

8. Have you ever worked for...? [Read the options below]

Department of Health and Human Services		→ TERMINATE
U.S. Food and Drug Administration		→ TERMINATE
RTI International		→ TERMINATE
Concentrics		→ TERMINATE

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Research		
None of the above		→ CONTINUE

9. Have you ever been trained or worked as a healthcare professional?

Yes

→ **TERMINATE**

No

→ CONTINUE

10. Have you participated in any market research study, product label study, or clinical trial in the past 6 months?

Yes

→ **TERMINATE**

No

→ CONTINUE

Don't know

→ **TERMINATE**

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

Yes

→ CONTINUE

No

→ CONTINUE

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

Yes

→ **TERMINATE**

No

→ CONTINUE

DEMOGRAPHIC QUESTIONS

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13. Please answer the next two questions about your ethnicity and race.

Are you Hispanic or Latino?

Yes

→ CONTINUE

No

→ CONTINUE

14. 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 / Alaska Native

Asian

Black or African American

Native Hawaiian / other Pacific Islander

White

Some other race

→ DOCUMENT:

SCREEN FOR MIX

IF INELIGIBLE → **Closing for Ineligible Participants:** Thank you for answering our questions. At this time you are not eligible 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 → 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 the Shugoll offices located at **[ADDRESS]**.

The discussion will last up to 45 minutes. No one will attempt to sell you anything, and no one will call you for other studies as a result of your participation in this study. You may be observed through a 1-way mirror and audio recorded during the course of the study. In appreciation for

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your time and effort, you will receive \$75 after completion of the interview. This is an important research effort and we hope that you will be part of it.

Are you interested in participating 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. We currently have interview slots available on **[Day]**, **[Date]**, at **[Time]**. Would any of those times be convenient for you?

Yes → Document agreed upon date/time: _____

Collect contact information for reminder call:

First Name: _____

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

Email address (for reminder email): _____

I also want to give you some information about the interview day:

- If you said that you needed glasses or contacts to read, please remember to bring them with you for your appointment.
- Because of the nature of the study, we will not be able to accommodate unattended small children during your visit. If you need to bring small children to the interview, you will need to bring another adult to supervise the child 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.

Thank you. Goodbye.

Reminder call script

Hello this is [NAME] calling from Shugoll about an in-person interview you recently agreed to participate in.

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]**. Do you need directions to our office?

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, we will not be able to

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accommodate unattended small children during your visit. If you need to bring small children to the interview, you will need to bring another adult to supervise the child while you are in the interview.

Do you have any other questions that I can address at this time?

Thank you [NAME]. We appreciate your participation in this study.