
Attachment A

LABEL COMPREHENSION STUDY

GROUP 1 & 2 SCREENER

TELEPHONE RECRUITMENT SCRIPT [Participant calls recruitment phone number]

Thank you for calling about the product label study. My name is _____. RTI International and Concentrics Research are doing a study that is being sponsored by the U.S. Food and Drug Administration (FDA). FDA is the government agency that protects the public health by reviewing new medicines. In these reviews, the FDA helps to make sure the medicines work and are safe before they are approved to be prescribed by health care providers and used by patients. We are looking for people to take part in a research study to review a label for a medicine that may be available over-the-counter soon, meaning without a prescription. We are not selling or promoting any medicine.

The study involves being in a one-time individual, in-person interview lasting no more than 45 minutes. The interview will include looking at a list of medical terms and answering some questions about instructions for a medicine. The interview will be audio recorded, and project team members may listen to the interview over the telephone. You will be given a \$50 Visa gift card at the end of the interview to reimburse you for your time and travel expenses.

To see if you qualify for this study, I need to ask you some questions that will take a few minutes of your time. Some of the questions are about whether you use certain prescription pain medicines or heroin, or have a family member or friend who does. If you qualify for the study you can then decide if you want to be a part of the study. If so, I will need your email address and/or phone number in order to contact you to remind you about your appointment.

The risk of others knowing your answers to the questions is minimal. To keep your information private, we will store your answers and contact information in separate, locked filing cabinets. This information will be destroyed at the end of the study. If you feel uncomfortable at all, you can choose not to answer a question or end the call at any time. Do you have any questions about the process? May I ask you my questions now?

PRESCREENING

1. How old are you?

_____	<p>Over Age 18 → CONTINUE</p> <p>Between Ages 15-17 → SWITCH TO ADOLESCENT SCREENER TO PROVIDE PHONE NUMBER FOR SCREENING [NOTE TO RIHSC: <i>Adolescents are not the subject of this review and will be reviewed separately.</i>]</p> <p>Under Age 15 → TERMINATE (Ineligible for the study)</p> <p>Don't know/refused → TERMINATE</p>
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2. Are you currently employed by [INSERT OPTIONS 1-6 BELOW]? (Check all that apply.)

1. A marketing or research company	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
2. An advertising agency or public relations firm	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
3. A pharmacy or pharmaceutical company	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
4. A manufacturer of medicines	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
5. A managed care or health insurance company	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
6. A healthcare practice	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
7. A hospital emergency room	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
8. None of the above	<input type="checkbox"/>	→ CONTINUE
9. Refuse	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)

3. Have you ever worked for [INSERT OPTIONS 1-4 BELOW]? (Check all that apply.)

1. Department of Health and Human Services	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
2. U.S. Food and Drug Administration	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)
3. RTI International	<input type="checkbox"/>	→ TERMINATE (Closing Script and Contact Information Sheet)

		Information Sheet)
4. Concentrics Research		→ TERMINATE (Closing Script and Contact Information Sheet)
5. None of the above		→ CONTINUE
6. Refuse		→ TERMINATE (Closing Script and Contact Information Sheet)

4. Have you ever been trained or worked as a healthcare professional? [*IF NEEDED: a health care professional (HCP) is defined as a trained person who deliver medical care to humans. Examples of HCP: nursing assistant, nurse, doctor, dentist, pharmacist, physician assistant. It is NOT a veterinarian, peer counselor, mental health counselor, or someone who is a caregiver for a family member or friend.*]

Yes		→ TERMINATE (Closing Script and Contact Information Sheet)
No		→ CONTINUE
Refused		→ TERMINATE (Closing Script and Contact Information Sheet)

5. Have you been in any research study in the past 12 months?

Yes		→ TERMINATE (Closing Script and Contact Information Sheet)
No		→ CONTINUE
Don't Know		→ TERMINATE (Closing Script and Contact Information Sheet)
Refused		→ TERMINATE (Closing Script and Contact Information Sheet)

SECTION 1: QUESTIONS TO ASSESS ELIGIBILITY AS USER (ADULT)

READ: NOW I'M GOING TO ASK YOU SOME QUESTIONS ABOUT DRUG USE. REMEMBER THAT YOUR ANSWERS WILL BE KEPT PRIVATE.

- Are you currently in treatment for [PRESCRIPTION OPIOIDS AND/OR HEROIN USE]? This could be individual therapy, an outpatient therapy group, or medication assisted treatment such as methadone or Suboxone. *[IF NEEDED: A prescription opioid is a pain medicine such as Vicodin, OxyContin, Opana, dilaudid, Percocet, oxycodone, or morphine]*

	Yes	No	DK	REF
1a. Prescription opioid				
1b. Heroin				

IF YES TO EITHER: CONTINUE TO Q3; IF NO TO BOTH OR DK OR REF: GO TO SECTION 1A

- Do you take methadone or Suboxone as part of your treatment program?

Yes	→ CONTINUE
No	→ CONTINUE
Don't know	→ CONTINUE
Refused	→ CONTINUE

- Have you been ordered by a judge to participate in treatment?

Yes	→ TERMINATE (Closing Script and Contact Information Sheet)
No	→ CONTINUE
Don't know	→ TERMINATE (Closing Script and Contact Information Sheet)
Refused	→ TERMINATE (Closing Script and Contact Information Sheet)

SECTION 1a: PRESCRIPTION OPIOID USE

- During the past 90 days, have you used any prescription opioid? An opioid is a prescription pain medicine such as Vicodin, OxyContin, Opana, dilaudid, Percocet, oxycodone, or morphine.

Yes	→ CONTINUE
No	→ GO TO SECTION 1b: HEROIN USE
Don't know	→ GO TO DK FOLLOW-UP

Refused		➔ GO TO SECTION 1b: HEROIN USE

DON'T KNOW FOLLOW-UP: DETERMINE IF IT IS BECAUSE HE/SHE DOESN'T KNOW IF THE MEDICINE IS AN OPIOID.

IF UNSURE WHETHER MEDICINE IS AN OPIOID, ASK: What is the name of the medicine you are taking?

Codeine (Fioricet w/ codeine, Fiorinal w/ codeine, Tylenol w/ codeine)		➔ CONTINUE
Fentanyl transdermal (Abstral, Actiq, Duragesic, Fentora, Ionsys, Lazanda, Sublimaze, Subsys)		➔ CONTINUE
Hydrocodone (Anexsia, Hysingla ER, Lortab, Norco, Reprexain, Vicodin, Vicoprofen, Zohydro ER)		➔ CONTINUE
Hydromorphone (Dilaudid, Dilaudid-HP, Exalgo)		➔ CONTINUE
Morphine (Astramorph PF, Duramorph PF, Embeda, Infumorph, Kadian, Morphabond, MS Contin)		➔ CONTINUE
Oxycodone (Oxaydo, Oxycet, Oxycontin, Percocet, Percodan, Roxicet, Roxicodone, Xartemis XR)		➔ CONTINUE
Oxymorphone (Opana, Opana ER)		➔ CONTINUE
Other (specify _____)		➔ CONTINUE IF DRUG NAME IS FOUND HERE: http://www.rxlist.com/script/main/hp.asp ; ELSE, GO TO SECTION 1b: HEROIN USE
Don't know		➔ GO TO SECTION 1b: HEROIN USE
Refused		➔ GO TO SECTION 1b: HEROIN USE

5. During the past 30 days, have you used any prescription opioid? *[IF NEEDED: An opioid is a prescription pain medicine such as Vicodin, OxyContin, Opana, dilaudid, Percocet, oxycodone, or morphine.]*

Yes		➔ CONTINUE
No		➔ GO TO SECTION 1b: HEROIN USE
Don't know		➔ GO TO SECTION 1b: HEROIN USE
Refused		➔ GO TO SECTION 1b: HEROIN USE

6. During the past 30 days, on how many days did you use a prescription opioid? *[IF NEEDED: An opioid is a prescription pain medicine such as Vicodin, OxyContin, Opana, dilaudid, Percocet, oxycodone, or morphine]*

_____ Days → CONTINUE

SECTION 1b: HEROIN USE

7. During the past 90 days, have you used heroin?

Yes	→ CONTINUE
No	→ GO TO SUMMARY OF SKIPS FOR NEXT STEP
Don't know	→ GO TO SUMMARY OF SKIPS FOR NEXT STEP
Refused	→ GO TO SUMMARY OF SKIPS FOR NEXT STEP

8. During the past 30 days, have you used heroin?

Yes	→ CONTINUE
No	→ GO TO SUMMARY OF SKIPS FOR NEXT STEP
Don't know	→ IF USED Rx OPIOIDS IN THE PAST 30 DAYS (SECTION 1a, Q6), GO TO SUMMARY OF SKIPS, OTHERWISE TERMINATE (Closing Script and Contact Information Sheet)
Refused	→ IF USED Rx OPIOIDS IN THE PAST 30 DAYS (SECTION 1a, Q6), GO TO SUMMARY OF SKIPS FOR NEXT STEP OTHERWISE TERMINATE (Closing Script and Contact Information Sheet)

9. During the past 30 days, on how many days did you use heroin?

_____ Days → SEE SUMMARY OF SKIPS FOR NEXT STEP

SUMMARY OF SKIPS

- If YES to either prescription opioid or heroin Treatment (Q2), Yes to Q6 (30-day opioid use), AND/OR Yes to Q9 (30-day heroin use), respondent is eligible as a USER → GO TO SECTION 3: FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS
- If NO to Q2, Q6, AND Q9, GO TO SECTION 2 to screen for eligibility as an Associate.
- If not a user and participant REF/DK to either Q6 and/or Q9, TERMINATE (Closing Script and Contact Information Sheet) as does not qualify for associate
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SECTION 2: QUESTIONS TO ASSESS ELIGIBILITY AS AN ASSOCIATE

1. Do you have a family member or friend who is currently in treatment for **[PRESCRIPTION OPIOIDS AND/OR HEROIN USE]**? This could be individual therapy, an outpatient therapy group, or medication assisted treatment such as methadone or Suboxone. *[IF NEEDED: A prescription opioid is a pain medicine such as Vicodin, OxyContin, Opana, dilaudid, Percocet, oxycodone, or morphine]*

	Yes	No	DK	REF
1a. Prescription opioid				
1b. Heroin				

NOTE: IF YES TO EITHER, GO TO SECTION 3: FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS; OTHERWISE, CONTINUE.

2. Do you have a family member or friend who uses **[PRESCRIPTION OPIOIDS AND/OR HEROIN]**? *[IF NEEDED: A prescription opioid is a pain medicine such as Vicodin, OxyContin, Opana, dilaudid, Percocet, oxycodone, or morphine]*

	Yes	No	DK	REF
2a. Prescription opioid				
2b. Heroin				

NOTE: IF YES TO EITHER GO TO SECTION 3: FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS. IF NO, DON'T KNOW, OR REFUSED FOR BOTH DRUGS, TERMINATE (Closing Script and Contact Information Sheet)

SECTION 3: FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS

1. How confident are you in filling out medical forms by yourself? Would you say...

Extremely		➔ CONTINUE
Quite a bit		➔ CONTINUE
Somewhat		➔ CONTINUE
A little bit		➔ CONTINUE
Not at all		➔ CONTINUE
Don't know		➔ CONTINUE IF LOW LITERACY REQUIREMENT IS MET
Refuse		➔ CONTINUE IF LOW LITERACY REQUIREMENT IS MET
At least 50% of the sample should answer "somewhat", "a little bit" or "not at all".		

2. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

Never		➔ CONTINUE
Rarely		➔ CONTINUE
Sometimes		➔ CONTINUE
Often		➔ CONTINUE
Always		➔ CONTINUE
Don't know		➔ CONTINUE
Refuse		➔ CONTINUE

3. Can you read, speak, and understand English?

Yes		➔ CONTINUE
No		➔ TERMINATE (Closing Script and Contact Information Sheet)
Refuse		➔ TERMINATE (Closing Script and Contact Information Sheet)

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

Yes		➔ CONTINUE
No		➔ CONTINUE
Refused		➔ TERMINATE (Closing Script and Contact Information Sheet)

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

Yes		➔ TERMINATE (Closing Script and Contact Information Sheet)
No		➔ CONTINUE
Refused		➔ TERMINATE (Closing Script and Contact Information Sheet)

6. What is the highest level of education you have completed? [DO NOT READ LIST - ASSIGN RESPONSE TO EDUCATION LEVEL BELOW]

Less than high school		➔ CONTINUE
High school graduate (HS diploma or GED)		➔ CONTINUE
Some college (no degree)		➔ CONTINUE
College (2-year) degree (Associate degree)		➔ CONTINUE
College (4-year) degree (e.g., BA, BS, AB)		➔ CONTINUE
Some post-college		➔ CONTINUE
Advanced or post-graduate degree (e.g., Masters, MD, PhD)		➔ CONTINUE
Refused		➔ CONTINUE

7. Are you Hispanic or Latino?

Yes		➔ CONTINUE
No		➔ CONTINUE
Refused		➔ CONTINUE

8. What is your race? (Check all that apply) [READ LIST IF NECESSARY]

American Indian / Alaska Native		➔ CONTINUE
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Asian		➔ CONTINUE
Black or African American		➔ CONTINUE
Native Hawaiian / other Pacific Islander		➔ CONTINUE
White		➔ CONTINUE
Other		➔ SPECIFY _____
Refused		➔ CONTINUE
AIM FOR MIX		

9. Was your total household income in 2016...?

Less than \$20,000		➔ CONTINUE
\$20,000 - \$34,999		➔ CONTINUE
\$35,000 - \$49,999		➔ CONTINUE
\$50,000 - \$74,999		➔ CONTINUE
\$75,000 - \$99,999		➔ CONTINUE
\$100,000 - \$149,999		➔ CONTINUE
\$150,000 or more		➔ CONTINUE
Don't know		➔ CONTINUE
Refused		➔ CONTINUE

10. What is your gender? [DO NOT READ RESPONSE CATEGORIES]

Male		➔ GO TO Closing Script and Contact Information Sheet
Female		➔ CONTINUE
Other		➔ SPECIFY _____ AND CONTINUE
Refused		➔ CONTINUE
AIM FOR MIX		

11. How did you hear about this study?

From the Hazelden Betty Ford Foundation		➔ CONTINUE
Posted flyers in the community		➔ CONTINUE

Posting on the internet		➔ CONTINUE
From a friend or family member		➔ CONTINUE
Other		➔ CONTINUE
Don't know		➔ CONTINUE
Refused		➔ CONTINUE

12. For study purposes, if you participate, the interview will be audio recorded. Are you okay with us audio recording the interview?

Yes		➔ CONTINUE
No		➔ TERMINATE (Closing Script and Contact Information Sheet)

NOTE: USE THE CLOSING SCRIPT AND CONTACT INFORMATION SHEET TO SCHEDULE AN INTERVIEW.

SECTION 4: TERMINATION DEMOGRAPHIC QUESTIONS

NOTE: THE GOAL OF THIS SECTION IS TO CONCEAL THE REASON FOR TERMINATION.

1. What is the highest level of education you have completed? **[DO NOT READ LIST - ASSIGN RESPONSE TO EDUCATION LEVEL BELOW]**

Less than high school		➔ CONTINUE
High school graduate (HS diploma or GED)		➔ CONTINUE
Some college (no degree)		➔ CONTINUE
College (2-year) degree (Associate degree)		➔ CONTINUE
College (4-year) degree (e.g., BA, BS, AB)		➔ CONTINUE
Some post-college		➔ CONTINUE
Advanced or post-graduate degree (e.g., Masters, MD, PhD)		➔ CONTINUE
Refused		➔ CONTINUE

2. Are you Hispanic or Latino?

Yes		➔ CONTINUE
No		➔ CONTINUE
Refused		➔ CONTINUE

3. What is your race? (Check all that apply) **[READ LIST IF NECESSARY]**

American Indian / Alaska Native		➔ CONTINUE
Asian		➔ CONTINUE
Black or African American		➔ CONTINUE
Native Hawaiian / other Pacific Islander		➔ CONTINUE
White		➔ CONTINUE
Other		➔ SPECIFY _____
Refused		➔ CONTINUE
SCREEN FOR MIX		

4. Was your total household income in 2016...?

Less than \$20,000	<input type="checkbox"/>	➔ CONTINUE
\$20,000 - \$34,999	<input type="checkbox"/>	➔ CONTINUE
\$35,000 - \$49,999	<input type="checkbox"/>	➔ CONTINUE
\$50,000 - \$74,999	<input type="checkbox"/>	➔ CONTINUE
\$75,000 - \$99,999	<input type="checkbox"/>	➔ CONTINUE
\$100,000 - \$149,999	<input type="checkbox"/>	➔ CONTINUE
\$150,000 or more	<input type="checkbox"/>	➔ CONTINUE
Refused	<input type="checkbox"/>	➔ CONTINUE

NOTE: AFTER THESE QUESTIONS, GO TO INELIGIBLE SCRIPT (CLOSING SCRIPT AND CONTACT INFORMATION SHEET).

APPENDIX 1: POTENTIAL ADDITIONAL QUESTIONS FOR CBOs WITH SPECIFIC REQUIREMENTS

1. Do you receive services or treatment at [NAME OF ORGANIZATION]?

Yes		→ GO TO SECTION 1A
No		→ CONTINUE
Don't know		→ TERMINATE
Refused		→ TERMINATE

2. Do you have a family member or spouse/partner who receives services or treatment at [NAME OF ORGANIZATION]?

Yes		→ CONTINUE
No		→ TERMINATE
Don't know		→ TERMINATE
Refused		→ TERMINATE

3. Are you involved in their treatment at [NAME OF ORGANIZATION]? This may mean that you went to a meeting with your family member or spouse/partner along with [NAME OF ORGANIZATION] staff to help plan their treatment, or that you come to counseling sessions with them, or provide support in some other way.

Yes		→ CONTINUE TO SECTION 2: QUESTIONS TO ASSESS ELIGIBILITY AS AN ASSOCIATE
No		→ TERMINATE IF REQUIRED BY CBO
Don't know		→ HOLD [PROBE TO DETERMINE INVOLVEMENT; DISCUSS WITH TEAM TO DETERMINE ELIGIBILITY]
Refused		→ TERMINATE