

ATTACHMENT B1

LABEL COMPREHENSION STUDY TASK 3: GROUP 1- 2 (USERS AND ASSOCIATES) – TELEPHONE 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. What we learn from this study will help to make sure that people understand from the label how to use the medicine so it is safe and effective. We are not selling or promoting any medicine.

The study involves being in a one-time individual, in-person interview lasting no more than 30 minutes. During the first part of the interview, we will ask you to read aloud some medical terms to get an idea of what medical words you are familiar with. Then we will ask you some questions about instructions for a medicine. The interview will be audio recorded. 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.

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 and are invited to participate you can 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 protect your privacy, you may want to go to a room by yourself to answer these questions. To keep your information

secure, we will store your answers and contact information in separate, locked filing cabinets and on password-protected computers that can only be accessed by project staff. This information will be destroyed within one month of the study's end date. If you feel uncomfortable at all, you can end the call at any time or choose not to answer one or more of the following questions. However, without knowing your answers to some of the questions, we may be unable to determine whether you are eligible for this study. Do you have any questions about the process? May I ask you my questions now?

PRESCREENING

1. How old are you?

_____	Age 18 or older → CONTINUE Under Age 18 → TERMINATE (Ineligible for the study) Don't know/refused → TERMINATE

2. What city are you calling from?

San Francisco, California	→ CONTINUE
Chicago, Illinois	→ CONTINUE
Charleston, WV or (ADD COUNTIES)	→ CONTINUE
Raleigh - Durham, North Carolina	→ CONTINUE
Vance County, North Carolina	→ CONTINUE
Other (Specify _____)	→ TERMINATE (Section 4: Terminate Demographic Questions)

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

Yes	→ CONTINUE
No	→ TERMINATE (Section 4: Terminate Demographic Questions)
Refused	→ TERMINATE (Section 4: Terminate Demographic Questions)

4. Are you currently employed by [INSERT OPTIONS 1-6 BELOW]? (Check all that apply.)

1. A marketing or research company		→ TERMINATE (Section 4: Terminate Demographic Questions)
2. An advertising agency or public relations firm		→ TERMINATE (Section 4: Terminate Demographic Questions)
3. A pharmacy or pharmaceutical company		→ TERMINATE (Section 4: Terminate Demographic Questions)
4. A manufacturer of medicines		→ TERMINATE (Section 4: Terminate Demographic Questions)
5. A managed care or health insurance company		→ TERMINATE (Section 4: Terminate Demographic Questions)
6. A healthcare practice		→ TERMINATE (Section 4: Terminate Demographic Questions)
7. A hospital emergency room		→ TERMINATE (Section 4: Terminate Demographic Questions)
8. None of the above		→ CONTINUE
9. Refused		→ TERMINATE (Section 4: Terminate Demographic Questions)

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

1. Department of Health and Human Services		→ TERMINATE (Section 4: Terminate Demographic Questions)
2. U.S. Food and Drug Administration		→ TERMINATE (Section 4: Terminate Demographic Questions)
3. RTI International		→ TERMINATE (Section 4: Terminate Demographic Questions)
4. Concentrics Research		→ TERMINATE (Section 4: Terminate Demographic Questions)
5. None of the above		→ CONTINUE
6. Refused		→ TERMINATE (Section 4: Terminate Demographic Questions)

6. 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 (Section 4: Terminate Demographic Questions)
No		→ CONTINUE
Refused		→ TERMINATE (Section 4: Terminate Demographic Questions)

7. Have you been in any research study in the past 12 months or an earlier phase of this study in the past two years?

Yes		➔ TERMINATE (Section 4: Terminate Demographic Questions)
No		➔ CONTINUE
Don't Know		➔ TERMINATE (Section 4: Terminate Demographic Questions)
Refused		➔ TERMINATE (Section 4: Terminate Demographic Questions)

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

Yes		➔ CONTINUE
No		➔ CONTINUE
Refused		➔ TERMINATE (Section 4: Terminate Demographic Questions)

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

Yes		➔ TERMINATE (Section 4: Terminate Demographic Questions)
No		➔ CONTINUE
Refused		➔ TERMINATE (Section 4: Terminate Demographic Questions)

10. 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 (Section 4: Terminate Demographic Questions)

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 SECURE.

1. Are you currently in treatment for any of the following? Treatment could be individual therapy, an outpatient therapy group, or medication assisted treatment such as methadone or Suboxone.

	Yes	No	DK	REF
a. Prescription pain relief medications (e.g., Dilaudid, Lortab, Opana, OxyContin, Percocet, Vicodin)				
b. Heroin				
c. Fentanyl that wasn't prescribed to you				

IF 1a, b, AND/OR c = YES, CONTINUE TO Q2

IF ALL = NO, DK, OR REFUSED, GO TO Q3

2. Have you been ordered by a judge to participate in this treatment?

Yes		➔ TERMINATE (Section 4: Terminate Demographic Questions)
No		➔ ELIGIBLE BASED ON TREATMENT STATUS (GO TO SECTION 3: FINAL ELIGIBILITY AND DEMOGRAPHIC QUESTIONS)
Don't know		➔ TERMINATE (Section 4: Terminate Demographic Questions)
Refused		➔ TERMINATE (Section 4: Terminate Demographic Questions)

3. During the past 90 days, have you used any of the following?

	Yes	No	DK	REF
a. Prescription pain relief medications (e.g., Dilaudid, Lortab Opana, OxyContin, Percocet, Vicodin)				
b. Heroin				
c. Fentanyl that wasn't prescribed to you				

IF Q3a = DK → GO TO Q3.1 TO DETERMINE IF IT IS BECAUSE HE/SHE DOESN'T KNOW WHAT SUBSTANCE THEY USE AND WHETHER IT IS AN ELIGIBLE PAIN RELIEF MEDICATION

→ IF UNSURE WHETHER MEDICINE IS pain relief medication, ASK: What is the name of the medicine you are taking?

3.1 [ASK IF Q3a = DK] Which of the following prescription pain relief medications have you used in the past 90 days?

SCREENER: Mark all that apply

Buprenorphine (Suboxone)		YES/NO
Codeine (Fioricet w/ codeine, Fiorinal w/ codeine, Tylenol w/ codeine)		YES/NO
Fentanyl (Abstral, Actiq, Duragesic, Fentora, Ionsys, Lazanda, Sublimaze, Subsys)		YES/NO
Hydrocodone (Anexsia, Hysingla ER, Lortab, Norco, Reprexain, Vicodin, Vicoprofen, Zohydro ER)		YES/NO
Hydromorphone (Dilaudid, Dilaudid-HP, Exalgo)		YES/NO
Methadone		YES/NO
Morphine (Astramorph PF, Duramorph PF, Embeda, Infumorph, Kadian, Morphabond, MS Contin)		YES/NO
Oxycodone (Oxaydo, Oxycet, Oxycontin, Percocet, Percodan, Roxicet, Roxicodone, Xartemis XR)		YES/NO
Oxymorphone (Opana, Opana ER)		YES/NO
Propoxyphene		YES/NO
Tramadol (Ultram, Ultracet)		YES/NO

None of the above (specify) _____		➔ CONTINUE IF DRUG NAME IS FOUND HERE: http://www.rxlist.com/script/main/hp.asp ; ELSE, GO TO Q4b (heroin)
Don't know		➔ GO TO 3b HEROIN
Refused		➔ GO TO 3b HEROIN

[THEN GO TO 3b (HEROIN)]

SUMMARY OF SKIPS

- i. If Q1a, b, and/or c = YES and Q2 = NO, eligible based on TREATMENT STATUS ➔ GO TO **SECTION 3 (FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS)**
- ii. If Q3a, b, and/or c = YES, eligible based on USER STATUS ➔ GO TO **SECTION 3 (FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS)**
- iii. If ALL of Q1 and Q3 = NO ➔ GO TO **SECTION 2 (QUESTIONS TO ASSESS ELIGIBILITY AS AN ASSOCIATE)**
- iv. If ALL of Q1 and Q3 = REF ➔ **TERMINATE (SECTION 4: TERMINATE DEMOGRAPHIC QUESTIONS)** as user status cannot be determined
- v. IF ALL OF Q1 = REF/DK and Q3a = DK and Q3b and c = NO/REF/DK and Q3.1 = REF/DK ➔ **TERMINATE (Section 4: Terminate Demographic Questions)** as user status cannot be determined
- vi. IF Q1b or C = NO, DK, or REF and Q3.1 = NONE OF THE ABOVE and specified pain relief medication is not listed on rxlist.com ➔ **TERMINATE (SECTION 4: TERMINATE DEMOGRAPHIC QUESTIONS)** as user status cannot be determined
- vii.

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 PAIN RELIEF MEDICATION AND/OR HEROIN USE]**? This could be individual therapy, an outpatient therapy group, or medication assisted treatment such as methadone or Suboxone.

Prescription pain relief medications include Dilaudid, Lortab Opana, OxyContin, Percocet, and Vicodin.

	Yes	No	DK	REF
1a. Prescription pain relief medication				
1b. Heroin				

IF Q1a AND/OR b = YES, ELIGIBLE BASED ON ASSOCIATE STATUS → GO TO SECTION 3 (FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS); ELSE, CONTINUE.

2. Do you have a family member or friend who uses **[PRESCRIPTION PAIN RELIEF MEDICATION AND/OR HEROIN]**?

Prescription pain relief medications include Vicodin, OxyContin, Percocet, Lortab, Dilaudid, and Opana.

	Yes	No	DK	REF
2a. Prescription pain relief medication				
2b. Heroin				

IF Q2a and/or b = YES, ELIGIBLE BASED ON ASSOCIATE STATUS → GO TO SECTION 3 (FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS); ELSE, TERMINATE (Section 4: Terminate Demographic Questions) BECAUSE ASSOCIATE STATUS CANNOT BE DETERMINED

SECTION 3: FINAL ELIGIBILITY & DEMOGRAPHIC QUESTIONS

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 graduate/GED		➔ CONTINUE
High school graduate or GED		➔ CONTINUE
Some college (no degree)		➔ CONTINUE
Postsecondary nondegree award (e.g., trade school diploma or certificate)		➔ CONTINUE
College (2 year) degree (Associate's degree)		➔ CONTINUE
College (4-year) degree (Bachelor's degree)		➔ CONTINUE
Master's or doctoral/professional degree		➔ CONTINUE
Refused		➔ CONTINUE

LL indicator = less than high school (priority) or high school graduate

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 or Alaska Native		➔ CONTINUE
Asian		➔ CONTINUE
Black or African American		➔ CONTINUE
Native Hawaiian or other Pacific Islander		➔ CONTINUE
White		➔ CONTINUE
Refused		➔ CONTINUE
AIM FOR MIX		

4. Was your total household income in 2017...?

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

LL indicator = Less than \$20k

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

Male		➔ CONTINUE
Female		➔ CONTINUE
Refused		➔ CONTINUE
AIM FOR MIX		

6. How did you hear about this study?

From a treatment center or other organization in the community where I get services		➔ 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

7. [IF PRESCREENING Q2 = RALEIGH-DURHAM, NC] Are you currently in treatment at SouthLight Healthcare or do you know someone who is receiving treatment at SouthLight Healthcare?

Yes	<input type="checkbox"/> CONTINUE
No	<input type="checkbox"/> CONTINUE (SCHEDULE DATA COLLECTION TO TAKE PLACE AT RTI)
Don't Know	<input type="checkbox"/> CONTINUE (SCHEDULE DATA COLLECTION TO TAKE PLACE AT RTI)
Prefer not to answer	<input type="checkbox"/> CONTINUE (SCHEDULE DATA COLLECTION TO TAKE PLACE AT RTI)

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 graduate/GED		➔ CONTINUE
High school graduate or GED		➔ CONTINUE
Some college (no degree)		➔ CONTINUE
Postsecondary nondegree award (e.g., trade school diploma or certificate)		➔ CONTINUE
College (2 year) degree (Associate's degree)		➔ CONTINUE
College (4-year) degree (Bachelor's degree)		➔ CONTINUE
Master's or doctoral/professional degree		➔ 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 or Alaska Native		➔ CONTINUE
Asian		➔ CONTINUE
Black or African American		➔ CONTINUE
Native Hawaiian or other Pacific Islander		➔ CONTINUE
White		➔ CONTINUE
Refused		➔ CONTINUE
SCREEN FOR MIX		

4. Was your total household income in 2017...?

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
Refused		➔ CONTINUE

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