

# ATTACHMENT A

## LABEL COMPREHENSION STUDY TASK 3: GROUP 1- 2 (USERS AND ASSOCIATES)– ONLINE SCREENER

### Screen 1

#### About the Product Label Study (heading)

Thank you for your interest in the Product Label Study. RTI International and Concentrics Research are carrying out this study which is 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 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 to reimburse you for your time and travel expenses.

(click NEXT)

### Screen 2

#### How to Find out if You Qualify (heading)

To see if you qualify for this study, we will ask you some questions that should take no more than 5 minutes to answer. Some of the questions are about whether you have used certain prescription pain medicines or heroin, or have a family member or friend who has. 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, we will need your email address and/or phone number in order to remind you about your appointment.

The risk of others knowing your answers to the questions is minimal. To keep your information secure, we will store your answers and contact information separately on a password-protected computer that can only be accessed by project staff. We are also recording IP addresses to help make sure people do not complete the screener more than once. IP addresses are not directly linked to your screener answers or contact information. All of this information will be destroyed within one month of the study’s end date. If you feel uncomfortable at all, you can close your browser window 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.

To help protect your privacy, we recommend that you take the screener in a secure location so that other people cannot see your answers on the screen. Another way to protect your privacy is to make sure that you close the browser window when you are done or if you decide to stop taking the screener after you already started. That will reduce the chance that someone will see your answers, especially if you are taking the screener in a public area. By clicking “Next” you agree to be screened for the study. (click NEXT)

If you do not want to complete the screening process, please close your internet browser.

**PRESCREENING**

1. How old are you?

_____	<b>Age 18 or older → CONTINUE</b> <b>Under Age 18 → TERMINATE (INELIGIBLE FOR THE STUDY)</b> Don't know/Prefer not to answer → <b>TERMINATE</b>

2. Please choose your city from the list below.

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

	<b>Demographic Questions)</b>
--	-------------------------------

3. 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. Prefer not to answer		→ TERMINATE (Section 4: Terminate Demographic Questions)

4. 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. Prefer not to answer		→ TERMINATE (Section 4: Terminate Demographic Questions)

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

**What is a health care professional (HCP)?** A trained person who deliver medical care to humans.

- **Examples of a HCP:** nursing assistant, nurse, doctor, dentist, pharmacist, physician assistant.
- **A HCP 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
Prefer not to answer		➔ TERMINATE (Section 4: Terminate Demographic Questions)

6. 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)
Prefer not to answer		➔ TERMINATE (Section 4: Terminate Demographic Questions)

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

Yes		➔ CONTINUE
No		➔ CONTINUE
Prefer not to answer		➔ TERMINATE (Section 4: Terminate Demographic Questions)

8. 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
Prefer not to answer		➔ TERMINATE (Section 4: Terminate Demographic Questions)

9. 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)**

**DISPLAY: THE NEXT FEW QUESTIONS ARE 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., Vicodin, OxyContin, Percocet, Lortab, Dilaudid, Opana)				
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	<b>→ TERMINATE (Section 4: Terminate Demographic Questions)</b>
No	<b>→ CONTINUE</b>
Don't know	<b>→ TERMINATE (Section 4: Terminate Demographic Questions)</b>
Prefer not to answer	<b>→ TERMINATE (Section 4: Terminate Demographic Questions)</b>

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 PRESCRIPTION PAIN RELIEF MEDICATION**

3.1 [ASK IF Q3a = DK] Which of the following prescription pain relief medications have you used in the past 90 days? (Mark all that apply.)

Buprenorphine (Suboxone)		Check Box
Codeine (Fioricet w/ codeine, Fiorinal w/ codeine, Tylenol w/ codeine)		Check Box
Fentanyl (Abstral, Actiq, Duragesic, Fentora, Ionsys, Lazanda, Sublimaze, Subsys)		Check Box
Hydrocodone (Anexsia, Hysingla ER, Lortab, Norco, Replexain, Vicodin, Vicoprofen, Zohydro ER)		Check Box
Hydromorphone (Dilaudid, Dilaudid-HP, Exalgo)		Check Box
Methadone		Check Box
Morphine (Astramorph PF, Duramorph PF, Embeda, Infumorph, Kadian, Morphabond, MS Contin)		Check Box
Oxycodone (Oxaydo, Oxycet, Oxycontin, Percocet, Percodan, Roxicet, Roxicodone, Xartemis XR)		Check Box
Oxymorphone (Opana, Opana ER)		Check Box
Propoxyphene		Check Box
Tramadol (Ultram, Ultracet)		Check Box
None of the above (specify)_____		→ CONTINUE [THIS FIELD WILL BE FLAGGED TO CHECK FOR SPECIFIED DRUG AT <a href="http://www.rxlist.com/script/main/hp.asp">http://www.rxlist.com/script/main/hp.asp</a> ]
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.

***What is a prescription pain relief medication?*** Prescription pain relief medications include Vicodin, OxyContin, Percocet, Lortab, Dilaudid, and Opana.

	Yes	No	DK	REF
1a. Prescription opioid				
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 USE]**?

***What is a prescription pain relief medication?*** Prescription pain relief medications include Vicodin, OxyContin, Percocet, Lortab, Dilaudid, and Opana.

	Yes	No	DK	REF
2a. Prescription opioid				
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?

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
Prefer not to answer		➔ CONTINUE

3. What is your race? (Check all that apply)

American Indian / Alaska Native		➔ CONTINUE
Asian		➔ CONTINUE
Black or African American		➔ CONTINUE
Native Hawaiian / other Pacific Islander		➔ CONTINUE
White		➔ CONTINUE
Prefer not to answer		➔ 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
Prefer not to answer		➔ CONTINUE

5. What is your gender?

Male		➔ CONTINUE
Female		➔ CONTINUE
Prefer not to answer		➔ CONTINUE

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
Prefer not to answer		➔ 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

**NOTE: AFTER THESE QUESTIONS, GO TO HOLD SCRIPT**

## 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?

Less than high school graduate/GED		→ CONTINUE
High school graduate (HS diploma or GED)		→ CONTINUE
Some college (no degree)		→ CONTINUE
Postsecondary nondegree award (e.g., trade school diploma or certificate)		→ CONTINUE
College (2-year) degree (Associate degree)		→ CONTINUE
College (4-year) degree (e.g., BA, BS, AB)		→ CONTINUE
Advanced or post-graduate degree (e.g., Masters, MD, PhD)		→ CONTINUE
Prefer not to answer		→ CONTINUE

2. Are you Hispanic or Latino?

Yes		→ CONTINUE
No		→ CONTINUE
Prefer not to answer		→ CONTINUE

3. What is your race? (Check all that apply)

American Indian / Alaska Native		→ CONTINUE
Asian		→ CONTINUE
Black or African American		→ CONTINUE
Native Hawaiian / other Pacific Islander		→ CONTINUE
White		→ CONTINUE
Other		→ SPECIFY _____
Prefer not to answer		→ CONTINUE

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
Prefer not to answer		➔ CONTINUE

NOTE: AFTER THESE QUESTIONS, GO TO **INELIGIBLE SCRIPT.**

**FINAL SCRIPT: TO DISPLAY ON SCREEN FOR PARTICIPANT**

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.

IF ELIGIBLE → **Hold Script**

Thank you for answering all of our questions and, based on your responses, you qualify for our study. If we still have space in our study, you will either receive an email within the next month from [healthproject@rti.org](mailto:healthproject@rti.org) inviting you to schedule an appointment for our study or a call from a member of our study team. If you would like to proceed we will ask you to enter your contact information. We will keep this information until the study ends on June 30<sup>th</sup>. Is this okay with you?

Yes → CONTINUE [Collect contact information]

No → TERMINATE; Thank you for your time.

Please enter your contact information below:

**Contact Information**

First Name: \_\_\_\_\_

Email address: \_\_\_\_\_

Phone number: \_\_\_\_\_

If we do send you an email invitation, we may follow-up by phone to make sure you received our email. Thank you.

IF ELIGIBLE → **Invitation email**

**Invitation for Eligible Participants (we will send the invitation a second time if someone does not respond within 48 hours): Subject line: “Product Label Study: Schedule your interview appointment”**

Hello, you recently completed an online screener for the Products Label study. We would like to invite you to take part in the study for a one-time, individual in-person interview. The interviews will take place from [DATE] at [LOCATION].

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 2 years of the study end date. Any information that could identify you will be removed from written records before sending them to the FDA. RTI, Concentrics, and FDA will maintain the written records of sessions securely until they are destroyed within 2 years of the study end date. If the audio file has any information that can identify you, that information will not be transcribed. 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 that only project staff have access to. You will be given a \$40 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.

If you schedule an interview with us, we will send you a reminder email and a text message reminder a few days before your scheduled appointment. Things to keep in mind on your 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 at least 24 hours in advance so we can do our best to find an alternate time.

If you are interested in being in this study, please click this **link** to schedule your appointment. And, if you have any questions, please contact us as 1-866-354-1076. Please note that if you don't sign-up for an appointment within 48 hours we may be unable to hold a space for you.

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.

Finally, I have attached a copy of the consent 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.

Thank you!

### **IF RTI CALLS TO SCHEDULE APPOINTMENT**

Hello, this is [NAME] from RTI International. You recently completed an online screener for the Products Label study. We would like to invite you to take part in the study for a one-time, individual in-person interview. The interviews will take place at [LOCATION].

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. Any information that could identify you will be removed from written records before sending to them. RTI, Concentrics, and FDA will maintain the written records of sessions securely until they are destroyed within 2 years of the study end date. Audio files that have any information that can identify you will not be transcribed. 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 a \$40 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]

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.

You will receive a reminder email and a text message reminder a few days 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?

I am going to send you a copy of the study consent form by email after we finish this call so that you can review it prior to your appointment. The consent form includes information about the study procedures, as well as information about the risks and benefits of participating. The interviewer will discuss the form with you at the time of your appointment and answer any questions that you have. You can bring the form with you if you'd like, but we will also have copies available at the time of your interview.

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.

#### CONFIRMATION EMAIL SCRIPT TO SEND AFTER SCHEDULING AN APPOINTMENT BY PHONE AND TO SEND THE CONSENT FORM TO PARTICIPANTS

Thank you for scheduling an interview for the Product Label Study. Your appointment is on [DATE] at [TIME].

Please see the attached consent form for the Product Label Study. The consent form includes information about the study procedures, as well as information about the risks and benefits of participating. The interviewer will discuss the form with you at the time of your appointment and answer any questions that you have. You can bring the form with you if you'd like, but we will also have copies available at the time of your interview.

**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 a one-time 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. 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 us know. If you need to reach us before your interview, you can reply to this email or call **[PHONE NUMBER]**.

Thank you,

**[NAME]**