

Attachment I

LABEL COMPREHENSION STUDY

GROUP 1 & 2 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. 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.

(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 use certain prescription pain medicines or heroin, or have a family member or friend who does. If you are qualified 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 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 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 study more than once. IP addresses are not linked to your screener answers or contact information. All of 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 close your browser window at any time.

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?

<p>_____</p>	<p>Over Age 18 → CONTINUE</p> <p>Between Ages 15-17 → A MESSAGE WILL DISPLAY ON THE SCREEN TELLING ADOLESCENTS THAT THEY MUST CALL THE STUDY'S TOLL-FREE TELEPHONE NUMBER AND HAVE A PARENT/GUARDIAN PRESENT TO BE SCREENED SINCE PARENTAL CONSENT IS REQUIRED [NOTE TO RIHSC: Adolescents are not the subject of this review and will be reviewed separately.]</p> <p>Under Age 15 → TERMINATE (INELIGIBLE FOR THE STUDY)</p> <p>Don't know/Prefer not to answer → 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		→ TERMINATE (Section 4)
2. An advertising agency or public relations firm		→ TERMINATE (Section 4)
3. A pharmacy or pharmaceutical company		→ TERMINATE (Section 4)
4. A manufacturer of medicines		→ TERMINATE (Section 4)
5. A managed care or health insurance company		→ TERMINATE (Section 4)
6. A healthcare practice		→ TERMINATE (Section 4)
7. A hospital emergency room		→ TERMINATE (Section 4)
8. None of the above		→ CONTINUE
9. Prefer not to answer		→ TERMINATE (Section 4)

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

1. Department of Health and Human Services		→ TERMINATE (Section 4)
2. U.S. Food and Drug Administration		→ TERMINATE (Section 4)
3. RTI International		→ TERMINATE (Section 4)

4. Concentrics Research		→ TERMINATE (Section 4)
5. None of the above		→ CONTINUE
6. Prefer not to answer		→ TERMINATE (Section 4)

4. 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)
No		→ CONTINUE
Prefer not to answer		→ TERMINATE (Section 4)

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

Yes		→ TERMINATE (Section 4)
No		→ CONTINUE
Don't Know		→ TERMINATE (Section 4)
Prefer not to answer		→ TERMINATE (Section 4)

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 PRIVATE.

1. 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.

What is a prescription opioid? 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

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

Yes		→ CONTINUE
No		→ CONTINUE
Don't know		→ CONTINUE
Prefer not to answer		→ CONTINUE

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

Yes		→ TERMINATE (Section 4)
No		→ CONTINUE
Don't know		→ TERMINATE (Section 4)
Prefer not to answer		→ TERMINATE (Section 4)

SECTION 1a: PRESCRIPTION OPIOID USE

4. During the past 90 days, have you used any prescription opioid?

What is a prescription opioid? A prescription opioid is a 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 5a

Prefer not to answer		→ 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.

5a. [If 5=Don't know] Below is a list of common prescription opioids. Have you taken any of these in the last 30 days?

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
Don't know		→ GO TO SECTION 1b: HEROIN USE
Prefer not to answer		→ GO TO SECTION 1b: HEROIN USE

5. During the past 30 days, have you used any prescription opioid?

What is a prescription opioid? A prescription opioid is a 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
Prefer not to answer		→ GO TO SECTION 1b: HEROIN USE

6. During the past 30 days, on how many days did you use a prescription opioid

_____ 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
Prefer not to answer		→ 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 (Section 4)
Prefer not to answer		→ IF USED Rx OPIOIDS IN THE PAST 30 DAYS (SECTION 1a, Q6), GO TO SUMMARY OF SKIPS FOR NEXT STEP OTHERWISE TERMINATE (Section 4)

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 (Section 4) as does not qualify for associate

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.

What is a prescription opioid? 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.

1. Do you have a family member or friend who uses **[PRESCRIPTION OPIOIDS AND/OR HEROIN]**?

What is a prescription opioid? 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 PREFER NOT TO ANSWER FOR BOTH DRUGS, TERMINATE (Section 4)

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
Prefer not to answer		→ CONTINUE

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
Prefer not to answer		→ CONTINUE

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

Yes		→ CONTINUE
No		→ TERMINATE (Section 4)
Prefer not to answer		→ TERMINATE (Section 4)

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

Yes		→ CONTINUE
No		→ CONTINUE
Prefer not to answer		→ TERMINATE (Section 4)

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

Yes		→ TERMINATE (Section 4)
No		→ CONTINUE
Prefer not to answer		→ TERMINATE (Section 4)

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

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
Prefer not to answer		→ CONTINUE

7. Are you Hispanic or Latino?

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

8. 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
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
Prefer not to answer		➔ CONTINUE

10. What is your gender?

Male		➔ CONTINUE
Female		➔ CONTINUE
Other		➔ SPECIFY _____ AND CONTINUE
Prefer not to answer		➔ CONTINUE

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
Prefer not to answer		➔ 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

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		→ 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
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 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
Prefer not to answer		➔ CONTINUE

5. 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
Prefer not to answer		➔ CONTINUE

NOTE: AFTER THESE QUESTIONS, GO TO INELIGIBLE SCRIPT.

FINAL 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. We will not keep any of the information that you provided during our call.

IF ELIGIBLE → **Hold Script**

Thank you for answering all of our questions and, based on your responses, you qualify for our study.

Please enter your contact information below:

Contact Information

First Name: _____

Email address: _____

Phone number: _____

If we still have space in our study, you will receive an email in the next 48 hours from **XXX scheduler** inviting you to schedule an appointment for our study. After sending your invitation email, we may follow-up by phone to make sure you received our email. Thank you.

IF ELIGIBLE → **Invitation email**

Invitation for Eligible Participants: Thank you for answering all of the 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 45 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, and project team members may listen to the interview over the telephone. Written records of the sessions and audio files will have any information that could identify you removed before sending to the FDA. RTI, Concentrics, and FDA will maintain the tapes and written records of sessions securely until they are destroyed at the end of the study. 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 \$50 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/or call 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.

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.

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!

REMINDER CALL

Hello this is **[NAME]** with a reminder call about a one time, individual 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, we won't be able to give you the \$50 Visa gift card.

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

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, we won't be able to give you the \$50 Visa gift card.

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

Thank you,

[NAME]