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LABEL COMPREHENSION STUDY GROUPS 1 - 3 SCREENER

COHORT INFORMATION

GROUP 1	PRESCRIPTION OPIOID USERS AND ASSOCIATES	1
GROUP 2	HEROIN USERS AND ASSOCIATES	2
GROUP 3	ADOLESCENT USERS AND ASSOCIATES	3

SUBGROUP INFORMATION

SUBGROUP A:	TARGETED LOW LITERACY (N=3)	A
SUBGROUP B:	NON-LOW LITERACY (N=6)	B
USER TYPE	PRESCRIPTION OPIOID/HEROIN USER OR IN-TREATMENT (MINIMUM N=3)	1
USER TYPE	ASSOCIATE (MINIMUM N=3)	2

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:

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
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TELEPHONE RECRUITMENT SCRIPT [Participant calls recruitment phone number]

Thank you for calling about Project CONFER. My name is _____. RTI International and Concentrics Research are conducting 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 conducting an independent review of new medicines to make sure they work and are safe before they are approved and can be prescribed by health care providers and used by patients. We are looking for people to take part in a research study to evaluate the labeling for a healthcare product that may 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 \$60.

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?

1. How old were you on your last birthday?

_____	<p>Age 15 – 17 → CONTINUE</p> <p>Age 18+ → CONTINUE</p> <p>Under Age 15 → TERMINATE</p>
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QUESTIONS TO ASSESS OPIOID/HEROIN USE

2. During the past 90 days, have you used any prescription opioid? An opioid is a prescription pain medication such as vicodin, oxycontin, opana, dilaudid, percocet, oxycodone, or morphine?

Yes	<input type="checkbox"/>	→ CONTINUE
No	<input type="checkbox"/>	→ GO TO Q5

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3. During the past 30 days, have you used any prescription opioid? *[IF NEEDED: An opioid is a prescription pain medication such as vicodin, oxycontin, opana, dilaudid, percocet, oxycodone, or morphine]*

Yes		→ CONTINUE
No		→ GO TO Q5
Don't Know		→ GO TO 3a

[Note: If respondents answers "don't know" determine if it is because he/she doesn't know if the medication is an opioid or if he/she doesn't know whether it was used in the past 30 days.]

- a. What is the name of the medication 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
Methadone (Dolophine, Methadose)		→ 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

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NOTE: IF DRUG MENTIONED IS NOT ON THE LIST YOU CAN LOOK IT UP AT:
<http://www.rxlist.com/script/main/hp.asp>.

IF OPIOID → CONTINUE; OTHERWISE GO TO Q5

4. During the past 30 days, on how many days did you use a prescription opioid? *[IF NEEDED: An opioid is a prescription pain medication such as vicodin, oxycontin, opana, dilaudid, percocet, oxycodone, or morphine]*

_____ Days → CONTINUE

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

Yes → CONTINUE
 No/Don't Know → GO TO Q7

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

_____ Days → CONTINUE

QUESTIONS TO ASSESS WHETHER OR NOT IN TREATMENT

7. Are you currently in treatment for prescription opioid or heroin use? This could be an outpatient therapy group or medication assisted treatment such as methadone or suboxone. *[IF NEEDED: A prescription opioid is a pain medication such as vicodin, oxycontin, opana, dilaudid, percocet, oxycodone, or morphine]*

Yes	→ GO TO Q10
No	→ IF YES TO PRESCRIPTION OPIOID USE (Q3) OR HEROIN USE (Q5), GO TO Q10 → IF NO PRESCRIPTION OPIOID USE (Q3) OR HEROIN USE (Q5), CONTINUE

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QUESTIONS TO IDENTIFY FAMILY/FRIENDS

8. Do you have a family member or friend who took prescription opioids during the past 30 days? An opioid is a prescription pain medication such as vicodin, oxycontin, opana, dilaudid, percocet, oxycodone, or morphine.

Yes		→ CONTINUE
No		→ CONTINUE
Not sure		→ CONTINUE

9. Do you have a family member or friend who took heroin during the past 30 days?

Yes		→ CONTINUE
No		→ CONTINUE IF YES TO Q8 [<i>friend/family in treatment for prescription opioid use</i>], OTHERWISE TERMINATE
Not sure		→ CONTINUE IF YES TO Q8 [<i>friend/family in treatment for prescription opioid use</i>], OTHERWISE TERMINATE

QUESTIONS TO ASSESS LOW LITERACY

[NOTE: DO NOT ASK THIS QUESTION IF RESPONDENT IS UNDER 18. GO TO Q11.]

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

Extremely		→ CONTINUE
Quite a bit		→ CONTINUE
Somewhat		→ CONTINUE
A little bit		→ CONTINUE
Not at all		→ CONTINUE
Not asked (Under 18 years old)		→ GO TO Q11

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At least 30% (n=3) of the sample should answer “somewhat”, “a little bit” or “not at all”.

OTHER

11. Can you read, speak and understand English?

Yes

→ CONTINUE

No

→ TERMINATE

12. 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

13. 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 Research		→ TERMINATE
None of the above		→ CONTINUE

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

- Yes → **TERMINATE**
- No → **CONTINUE**

15. Have you participated in any market research study, product label study, or clinical trial in the past 12 months?

- Yes → **TERMINATE**
- No → **CONTINUE**
- Don't know → **TERMINATE**

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

- Yes → **CONTINUE**
- No → **CONTINUE**

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

- Yes → **TERMINATE**
- No → **CONTINUE**

DEMOGRAPHIC QUESTIONS

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

_____ Degree

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[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

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

Are you Hispanic or Latino?

Yes

→ CONTINUE

No

→ CONTINUE

20. 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	<input type="checkbox"/>	→ CONTINUE
Asian	<input type="checkbox"/>	→ CONTINUE
Black or African American	<input type="checkbox"/>	→ CONTINUE
Native Hawaiian / other Pacific Islander	<input type="checkbox"/>	→ CONTINUE
White	<input type="checkbox"/>	→ CONTINUE
Some other race	<input type="checkbox"/>	→ DOCUMENT:

SCREEN FOR MIX

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

Male

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Female

Other

SCREEN FOR MIX OF MALE/FEMALE

SCREENER: COMPLETE TABLE ON LAST PAGE TO DETERMINE GROUP ASSIGNMENT.

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 SouthLight Healthcare 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 audio recorded during the course of the study. Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the interviews. RTI, Concentrics, and FDA will maintain the tapes and transcripts 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. In appreciation for your time and effort, you will receive \$60 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: _____

Thank you for your willingness to participate in this study. I would like to collect some minimal contact information for our reminder call and email.

Contact Information

First Name: _____

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

Email address (for reminder email): _____

You will receive a reminder call and email the day before your appointment. We have you scheduled on **[Day], [Date], at [Time]**. The interview will be held at **[Address]**.

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.

Do you have any questions about the study?

Thank you. Goodbye.

REMINDER CALL

Hello this is [NAME] calling regarding an in-person interview you recently agreed to participate 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]**.

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 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.

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Do you have any questions or concerns that I can address about the study?

If you need to be in touch with us before your interview, you can call **[PHONE NUMBER]**.

Thank you. We appreciate your participation in this study.

REMINDER EMAIL

Dear [NAME]

Thank you for agreeing to participate in the research study to evaluate the labeling for a healthcare product that will be available over-the-counter, or without a prescription. This study is being conducted by RTI International and Concentrics Research for U.S. Food and Drug Administration (FDA).

You are scheduled for an interview on **[Day], [Date], at [Time]**. The interview will be held at **[Address]**.

Please remember that if you need glasses or contacts to read, you should 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 have any further questions, please let me know. If you need to be in touch with us before your interview, you can call **[PHONE NUMBER]**.

Thank you,

[NAME]

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GROUP ASSIGNMENT

Assign respondent to a group based on responses to the questions. If the person qualifies for both Group 1 and Group 2 (e.g., uses opioids and heroin), assign them to a group based on whichever currently has fewer people.

GROUP	YES/NO
Group 1: Prescription Opioid User or Associate	
<u>User</u> <ul style="list-style-type: none"> • Q1 – age 18+ AND • Q3 – Yes [used opioids in past 30 days] 	
<u>In treatment</u> <ul style="list-style-type: none"> • Q1 – age 18+ AND • Q3 – Yes [used opioids in past 30 days] AND • Q7 – Yes [in treatment for opioid or heroin use] 	
<u>Associate</u> <ul style="list-style-type: none"> • Q1 – age 18+ AND • Q8 – Yes [family/friend used opioids in past 30 days] 	
Group 2: Heroin User or Associate	
<u>User</u> <ul style="list-style-type: none"> • Q1 – age 18+ AND • Q5 – Yes [used heroin in past 30 days] 	
<u>In treatment</u> <ul style="list-style-type: none"> • Q1 – age 18+ AND • Q5 – Yes [used heroin in past 30 days] AND • Q7 – Yes [in treatment for opioid or heroin use] 	
<u>Associate</u> <ul style="list-style-type: none"> • Q1 – age 18+ AND • Q9 – Yes [family/friend used heroin in past 30 days] 	
Group 3: Adolescent or Associate	
<u>User</u> <ul style="list-style-type: none"> • Q1 – age 15-17 AND • Q3 – Yes OR Q5 – Yes [used opioids or heroin in past 30 days] 	
<u>In treatment</u> <ul style="list-style-type: none"> • Q1 – age 15-17 AND • Q3 – Yes OR Q5 – Yes [used prescription opioids or heroin in past 30 days] 	

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<ul style="list-style-type: none">• Q7 – Yes <i>[in treatment for opioid or heroin use]</i>	
<u>Associate</u> <ul style="list-style-type: none">• Q1 – age 15-17 AND• Q8 – Yes OR Q9 <i>[family/friend used [prescription opioids or heroin in past 30 days]</i>	