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LABEL COMPREHENSION STUDY

ADULT QUESTIONNAIRE

POPULATION INFORMATION: CIRCLE THE CORRESPONDING NUMBER ON THE RIGHT

COHORT 1

GENERAL POPULATION OF ADULTS AND ADOLESCENTS 15+ [NOTE TO RIHSC: ADOLESCENTS ARE NOT THE SUBJECT OF THIS REVIEW AND WILL BE REVIEWED SEPARATELY]1		2
AGE SUBGROUP: CIRCLE THE CORRESPONDING NUMBER ON THE RIGHT		
ADULT, AGES 18+		
1 ADOLESCENT, AGES 15-17 [NOTE TO RIHSC: ADOLESCENTS ARE NOT THE SUBJECT OF THIS REVIEW AND WILL BE REVIEWED SEPARATELY]		2
OPIOID SUBGROUP: CIRCLE THE CORRESPONDING NUMBER ON THE RIGHT		
LITERACY SUBGROUP: CIRCLE THE CORRESPONDING NUMBER ON THE RIGHT		
NORMAL LITERACY		
1 LOW LITERACY		2

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INTERVIEWER

INTERVIEWER NAME:

INTERVIEWER INITIALS:

DATE: _____ **TIME STARTED:** _____ **AM/PM** **TIME ENDED:** _____ **AM/PM**
TOTAL MIN. _____

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INFORMED CONSENT**SUBJECTS MUST SIGN CONSENT FORM**

Before we get started I'm going to give you an informed consent form that describes the study and what you'll be asked to do in more detail. I'm going to give you two copies—one for you to sign for us and one for you to take home. Please take a few minutes to read the form. Once you are finished reading, we will talk through any questions you might have. Please do not sign anything until after I return to the room.

HAND THE SUBJECT THE CONSENT FORM AND LEAVE ROOM. ASK THE SUBJECT TO SIGNAL WHEN THEY ARE FINISHED BY OPENING THE DOOR.

ONCE THE SUBJECT IS FINISHED, REVIEW THE CONSENT FORM WITH HIM/HER. LET THE PARTICIPANT KNOW IF MEMBERS OF THE STUDY TEAM ARE LISTENING BY TELEPHONE, AND IF THEY DO NOT OBJECT¹,ASK THE FOLLOWING:

A. Do you have any questions about the consent form that you just read?

DISCUSS QUESTIONS	YES		1
CONTINUE	NO		2

B. Do you wish to participate in the study?

CONTINUE	YES		1
THANK AND TERMINATE	NO		2

ONCE ALL QUESTIONS ARE ADDRESSED AND SUBJECT AGREES TO PARTICIPATE, ASK SUBJECT TO SIGN THEIR FIRST NAME, AND DATE THE LAST PAGE. INTERVIEWER IS TO ENTER THE SUBJECT ID ON THE TOP OF EACH PAGE AND TO ALSO SIGN AND DATE THE LAST PAGE AS A WITNESS. GIVE SUBJECT A COPY OF THE CONSENT FORMFOR THEIR RECORDS.

¹ If the individual objects to being observed in-person or by live stream, the moderator will disconnect the live stream and ask the observers to leave the observation room before proceeding with the interview.

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REALM TEST

ADMINISTER REALM TEST AND PLACE SCORE IN THE BLANK BELOW.

Now, I would like to show you a word list of medical-related terms. These words are sometimes found on packages of medicines.

Please look at this list of words, beginning here **[POINT TO FIRST WORD]**. Say all of the words you know. If you come to a word you don't know, you can sound it out or just skip it and go on.

ENTER REALM SCORE:

INTRODUCTION

Once again, thank you for agreeing to participate in our study today. Your opinions are very important and we appreciate your time. I also wanted to share that there are some of my colleagues who are watching and listening today to help me take notes.

Today I will be showing you a label for a medicine that is currently available only by prescription, but may become available over-the-counter without a prescription. I would like for you to read the entire label and then I will ask you to answer some questions about what you have just read. We want to make sure that the label is clear and understandable even if this is something that you may or may not personally use.

Please read the label and take as much time as you need. When you are through, we will begin with the questions. During my questions, you will be able to refer back to the label as often as you like. I'm going to step out of the room now - please come to the door and let me know when you are finished.

HAND THE RESPONDENT THE LABEL.

LEAVE INTERVIEWING AREA AND WAIT FOR THE RESPONDENT TO LET YOU KNOW WHEN THEY HAVE FINISHED WITH THE LABEL.

RETURN TO THE INTERVIEWING AREA.

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IF RESPONDENT ASKS ANY QUESTIONS, RESPOND WITH: To make sure that each person is interviewed the same, I cannot give you any information other than what is on my script. Please keep in mind that I am testing the label and I am not testing you.

LABEL COMPREHENSION

Next, I would like you to answer some questions about what you have just read. My questions will not be about your previous knowledge or common sense, but from what you read on the label. I will first ask for your answer. Then I will ask you how you decided upon your answer.

I want to stress that I am testing the label and not testing you. There are no right or wrong answers.

Here is a booklet of questions for you to follow along as I read them aloud. Please do not skip ahead, but wait for me to tell you when to go to the next page. Keep in mind this is not a memory test, so you can refer back to the label as often as you would like during the interview.

HAND RESPONDENT THE BOOKLET OF SHOWCARDS.

FOR ALL QUESTIONS: INTERVIEWER CIRCLE THE NUMBER ON THE RIGHT-HAND SIDE OF THE PAGE THAT CORRESPONDS TO THE RESPONDENT’S ANSWER TO EACH QUESTION UNLESS OTHERWISE SPECIFIED.

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Please turn to Card A. **READ CARD ALOUD TO THE RESPONDENT.**

1a) According to the label, what is this product used for?

DO NOT READ LIST. MULTIPLE RESPONSES ALLOWED.

Correct	EMERGENCY TREATMENT (OR TO REVIVE FROM) OF OVERDOSE FROM DRUGS CALLED OPIOIDS SUCH AS MANY PRESCRIPTION PAIN MEDICATIONS AND STREET DRUGS SUCH AS HEROIN	1
Correct	EMERGENCY TREATMENT (OR TO REVIVE FROM) OF OVERDOSE FROM DRUGS CALLED OPIOIDS	2
Correct	EMERGENCY TREATMENT (OR TO REVIVE FROM) OF OPIOID OVERDOSE	3
Correct	OPIOID OVERDOSE	4
Correct	HEROIN OVERDOSE	5
Correct	OVERDOSE OF PRESCRIPTION PAIN MEDICATIONS	6
Partial Correct	DRUG OVERDOSE	7
Partial Correct	OVERDOSE	8
<i>Incorrect</i>	DON'T KNOW	9
	OTHER (SPECIFY)	10

1b) Why do you say that?

1c) Can you tell me more about that?

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Please turn to Card B. **READ CARD ALOUD TO THE RESPONDENT.**

2a) According to the label, if you suspect an overdose, what will the person look like or be doing?

DO NOT READ LIST.

Correct	WILL NOT WAKE UP, IS VERY SLEEPY OR NOT BREATHING WELL	1
Correct	WILL NOT WAKE UP	2
Correct	VERY SLEEPY	3
Partial Correct	NOT BREATHING WELL (E.G. BREATHING SLOWLY, SHALLOW, ETC.)	4
Correct	CAN'T AROUSE THE PERSON (OR OTHER SIMILAR RESPONSES)	5
<i>Incorrect</i>	DON'T KNOW	6
<i>Incorrect</i>	NOTHING	7
	OTHER (SPECIFY)	8

2b) Why do you say that?

The next few questions describe possible situations or scenarios that could occur to someone in real life. Also please assume that each question has all the information you need in order to make a decision. Please do not try to guess the answers to the questions – either refer back to the labeling for this product or simply say you don't know.

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Please turn to Card C. **READ CARD ALOUD TO THE RESPONDENT.**

- **Mark has a brother who abuses prescription pain medicines.**
- **His brother seems to be having trouble breathing and is very sleepy, but Mark is not sure if his brother is sleeping or is overdosing.**

3a) What, if anything, does the label say Mark should do?

DO NOT READ LIST.

Correct	CHECK: YELL WAKE UP, SHAKE THE PERSON GENTLY	1
Correct	YELL WAKE UP	2
Correct	SHAKE THE PERSON GENTLY	3
Correct	TRY TO WAKE THE PERSON UP	4
<i>Incorrect</i>	DON'T KNOW	6
<i>Incorrect</i>	NOTHING	7
	OTHER (SPECIFY)	8

3b) Why do you say that?

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Please turn to Card D. **READ CARD ALOUD TO THE RESPONDENT.**

4a) According to the label, what types of medicines or drugs are called opioids?

DO NOT READ LIST.

Correct	MANY PRESCRIPTION PAIN MEDICATIONS AND STREET DRUGS SUCH AS HEROIN	1
Partial Correct	PRESCRIPTION PAIN MEDICATIONS	2
Partial Correct	STREET DRUGS SUCH AS HEROIN	3
Partial Correct	HEROIN	4
<i>Incorrect</i>	DON'T KNOW	5
<i>Incorrect</i>	NOTHING	6
	OTHER (SPECIFY)	7

4b) Why do you say that?

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Please turn to Card E. **READ CARD ALOUD TO THE RESPONDENT.**

- **Mindy has a friend who is overdosing on heroin. Mindy has tried to wake her friend, but her friend won't wake up.**

5a) What, if anything, does the label say Mindy should do now?

DO NOT READ LIST.

Correct	GIVE 1ST DOSE	1
Correct	GIVE THE MEDICINE	2
Acceptable	CALL 911	3
<i>Incorrect</i>	DON'T KNOW	4
<i>Incorrect</i>	NOTHING	5
	OTHER (SPECIFY)	6

5b) Why do you say that?

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Please turn to Card F. **READ CARD ALOUD TO THE RESPONDENT.**

- **Mary just found her daughter who has overdosed on a prescription pain medicine.**
- **Mary has tried to wake her daughter, but she will not wake up.**
- **Mary has given a dose of this medicine..**

6a) What, if anything, does the label say Mary should do now?

DO NOT READ LIST.

Correct	CALL 911 IMMEDIATELY AFTER GIVING THE 1 ST DOSE	1
Correct	CALL 911	2
Partial Correct	GIVE ANOTHER DOSE IN 2-3 MINUTES UNTIL SHE WAKES UP	3
<i>Incorrect</i>	DON'T KNOW	4
<i>Incorrect</i>	NOTHING	5
	OTHER (SPECIFY)	6

6b) Why do you say that?

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Please turn to Card G. **READ CARD ALOUD TO THE RESPONDENT.**

- **Ryan gave his friend a dose of this medicine 30 seconds ago, but he hasn't woken up yet.**

7a) According to the label, Is it ok for Ryan to give his friend another dose right now?

DO NOT READ LIST.

Correct	NO	1
Correct	NO, WAIT 2-3 MINUTES	2
<i>Incorrect</i>	YES	3
<i>Incorrect</i>	DON'T KNOW	4
	OTHER (SPECIFY)	6

7b) Why do you say that?

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Please turn to Card H. **READ CARD ALOUD TO THE RESPONDENT.**

- Dre’s cousin is overdosing on a prescription pain medicine.
- Dre just gave him a second dose of this medicine and he still is not waking up.

8a) What, if anything, does the label say Dre should do now?

DO NOT READ LIST.

Correct	GIVE ANOTHER DOSE EVERY 2-3 MINUTES UNTIL THE PERSON WAKES UP	1
Correct	CONTINUE TO GIVE DOSES UNTIL THE PERSON WAKES UP	2
Acceptable	STAY WITH THE PERSON UNTIL THE AMBULANCE ARRIVES	3
<i>Incorrect</i>	DON'T KNOW	4
<i>Incorrect</i>	NOTHING	5
	OTHER (SPECIFY)	6

8b) Why do you say that?

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Please turn to Card I. **READ CARD ALOUD TO THE RESPONDENT.**

- Rodney’s friend is overdosing on a prescription pain medicine.
- Rodney gave his friend a dose of this medicine, and his friend woke up but is sweating and feeling angry.

9a) What, if anything, does the label say about this?

DO NOT READ LIST.

Correct	SOME PEOPLE MAY EXPERIENCE SYMPTOMS WHEN THEY WAKE UP, SUCH AS SHAKING, SWEATING, NAUSEA, OR FEELING ANGRY	1
Correct	SOME PEOPLE MAY EXPERIENCE SYMPTOMS WHEN THEY WAKE UP	2
Correct	<ul style="list-style-type: none"> • RESPONSES SIMILAR TO: THE DRUG IS MAKING THEM FEEL THIS WAY AND IT SAYS SO ON THE LABEL OR • IT SOUNDS LIKE IT IS A NORMAL REACTION –IT SAYS SO ON THE LABEL OR • IT’S A REACTION TO THE DRUG THAT IS STATED ON THE LABEL 	3
<i>Incorrect</i>	DON’T KNOW	4
<i>Incorrect</i>	NOTHING	5
	OTHER (SPECIFY)	6

9b) Why do you say that?

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Please turn to Card J. **READ CARD ALOUD TO THE RESPONDENT.**

- **Macy’s friend is overdosing on heroin**
- **Macy gave her friend 2 doses of this medicine, and he is starting to wake-up.**

10a) What, if anything, does the label say Macy should do now?

DO NOT READ LIST.

Correct	STAY WITH THE PERSON UNTIL THE AMBULANCE ARRIVES	1
Acceptable	STAY WITH THE PERSON	2
<i>Incorrect</i>	DON’T KNOW	3
<i>Incorrect</i>	NOTHING	4
	OTHER (SPECIFY)	5

10b) Why do you say that?

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Please turn to Card K. **READ CARD ALOUD TO THE RESPONDENT.**

11a) According to the label, is it safe to keeping giving doses of this medicine?

DO NOT READ LIST.

Correct	YES	1
<i>Incorrect</i>	NO	2
<i>Incorrect</i>	DON'T KNOW	3
	OTHER (SPECIFY)	4

11b) Why do you say that?

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Please turn to Card L. **READ CARD ALOUD TO THE RESPONDENT.**

- Tiana’s friend is overdosing on heroin.
- Tiana gave her friend one dose of this medicine and called 911.
- Her friend woke up, but is now very sleepy again.

12a) What, if anything, does the label say Tiana should do now?

DO NOT READ LIST.

Correct	GIVE ANOTHER DOSE IF THE PERSON BECOMES VERY SLEEPY AGAIN	1
Correct	GIVE ANOTHER DOSE	2
<i>Incorrect</i>	DON'T KNOW	3
<i>Incorrect</i>	NOTHING	4
	OTHER (SPECIFY)	5

12b) Why do you say that?

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Please turn to Card M. **READ CARD ALOUD TO THE RESPONDENT.**

13a) According to the label, can this medicine save a life?

DO NOT READ LIST.

Correct	YES	1
Correct	IT CAN REVERSE (TURN AROUND, CANCEL THE OVERDOSE)	2
<i>Incorrect</i>	NO	3
<i>Incorrect</i>	DON'T KNOW	4
<i>Incorrect</i>	NOTHING	5
	OTHER (SPECIFY)	6

13b) Why do you say that?

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14. QUALITATIVE QUESTION ADDED POST-INTERVIEW FOR FURTHER INSIGHT
(Questions will be related to the hypothetical scenarios. No personal questions will be asked):

15. QUALITATIVE QUESTION ADDED POST-INTERVIEW FOR FURTHER INSIGHT
(Questions will be related to the hypothetical scenarios. No personal questions will be asked):

16. QUALITATIVE QUESTION ADDED POST-INTERVIEW FOR FURTHER INSIGHT
(Questions will be related to the hypothetical scenarios. No personal questions will be asked):

17. Overall, would you say you had any trouble finding information on the label or following what to do or any confusion with the words or pictures?

<input type="checkbox"/> Identification issue (locating information)	<input type="checkbox"/> Navigation Issues (flow of words/concepts)
<input type="checkbox"/> Confusion with words	<input type="checkbox"/> Confusion with pictures
<input type="checkbox"/> None of the above	<input type="checkbox"/> Other

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Those are all of my questions. Thank you so much for your time.

DRAFT

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TO THE BEST OF MY ABILITY AND KNOWLEDGE, THE INFORMATION ENTERED INTO THE SURVEY IS COMPLETE AND CORRECT, AND THE SURVEY WAS CONDUCTED ACCORDING TO THE METHODOLOGY I WAS INSTRUCTED TO FOLLOW, ACCORDING TO THE STUDY PROTOCOL.

INTERVIEWER PRINT NAME: _____

INTERVIEWER SIGN NAME: _____

DRAFT

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ADULT REALM WORD LIST

List 1	List 2	List 3
fat	fatigue	allergic
flu	pelvic	menstrual
pill	jaundice	testicle
dose	infection	colitis
eye	exercise	emergency
stress	behavior	medication
smear	prescription	occupation
nerves	notify	sexually
germs	gallbladder	alcoholism
meals	calories	irritation
disease	depression	constipation
cancer	miscarriage	gonorrhea
caffeine	pregnancy	inflammatory
attack	arthritis	diabetes
kidney	nutrition	hepatitis
hormones	menopause	antibiotics
herpes	appendix	diagnosis
seizure	abnormal	potassium
bowel	syphilis	anemia
asthma	hemorrhoids	obesity
rectal	nausea	osteoporosis
incest	directed	impetigo