

OMB Control No. 0910-0847

Expiration date: 11/30/2020

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ATTACHMENT A

Focus Group Screening Questionnaire

Health Care Providers' Understanding of Opioid Analgesic Abuse-Deterrent Formulations: Focus Groups

Provider Segment	Primary Care Practice	Specialty Practice [each FG must have at least 3 different specialties]	Total Focus Groups
Physicians	3	3	6
Physician assistants	2	2	4
Nurse practitioners	2	2	4
Pharmacists	N/A	N/A	2
Total	8	8	16

Hello. We are recruiting healthcare professionals for a research study sponsored by the U.S. Food and Drug Administration. May I please speak to _____? [RESTATE FIRST SENTENCE IF THE FIRST PERSON YOU SPOKE TO IS NOT THE POTENTIAL PARTICIPANT.]

I work for [RECRUITMENT FIRM NAME], a market research firm. We are working with RTI International, a nonprofit research organization, conducting 90-minute focus groups to gather input from healthcare professionals nationwide.

May I ask you a few questions now to see if you qualify to be in the study?

- Yes - **Continue**
 No - **THANK AND END CALL**

1. Are you a physician, physician assistant, nurse practitioner, or pharmacist?

- Yes, physician → **Continue for physician segment**
 Yes, physician assistant → **Continue for physician assistant segment**
 Yes, nurse practitioner → **Continue for nurse practitioner segment**
 Yes, pharmacist → **Continue for pharmacist segment**
 No → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

2. Have you ever worked for ...? [READ LIST and obtain a response to each item]

- Any office, division, or agency within the Department of Health and Human Services (HHS) → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
 A pharmaceutical company → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
 A market research or marketing company → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
 RTI International → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
 None of the above → **CONTINUE**

3. In the last 6 months, have you participated in any focus groups or individual interviews about prescription opioid analgesics?

Yes - **THANK AND END CALL**

No - **Continue**

RECRUITER: CONTINUE IF PHYSICIAN, PHYSICIAN ASSISTANT, OR NURSE PRACTITIONER; IF PHARMACIST, SKIP TO Q14

4. Please indicate your area of practice [READ LIST AND RECRUIT EITHER TO PRIMARY CARE GROUP OR RECRUIT MIX OF SPECIALTIES FOR SPECIALTY GROUP]:

Primary care/family practice/general medicine/internal medicine → **Continue for primary care groups**

Rheumatology → **Continue for specialty groups**

Neurology → **Continue for specialty groups**

Anesthesiology → **Continue for specialty groups**

Pain Management → **Continue for specialty groups**

Emergency Medicine → **Continue for specialty groups**

Surgery → **Continue for specialty groups**

Orthopedics → **Continue for specialty groups**

Physical Medicine/Rehabilitation → **Continue for specialty groups**

Other → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

5. On average, what percentage of your time each month is spent on direct patient care?

50% or more → **Continue**

Less than 50% → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

6. In the past 30 days, for about how many patients have you prescribed opioid analgesics? _____ patients [Write down the number; recruit a mix]

Zero → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

7. In the past 30 days, for about how many of these patients have you prescribed opioids for chronic non-cancer pain that has lasted for longer than 3 months? _____ patients (Write down the number and ensure Q6≥Q7) [RECRUIT A MIX]

Zero → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

8. In the past 30 days, about how many prescriptions have you written for opioid analgesics?

----- [RECORD NUMBER AND RECRUIT A MIX]

Zero → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

9. In the past 30 days, about what percentage of the opioid prescriptions you prescribed fell into each of the following daily dose ranges? [RECORD PERCENTAGES AND RECRUIT A MIX OF 3 RANGES]

_____ 1-50 morphine milligram equivalents (MME) daily [IF NEEDED: for example, 50 MME daily is equivalent to 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300) or 33 mg of oxycodone (about 2 tablets of oxycodone sustained-release 15 mg)]

_____ 51-90 morphine milligram equivalents (MME) daily [IF NEEDED: for example, 90 MME daily is equivalent to 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325) or 60 mg of oxycodone (about 2 tablets of oxycodone sustained-release 30 mg)]

_____ 91 or greater morphine milligram equivalents (MME) daily [IF NEEDED: for example, 120 MME daily is equivalent to 120 mg of hydrocodone (12 tablets of hydrocodone/acetaminophen 10/325) or 80 mg of oxycodone (about 2 tablets of oxycodone sustained-release 40 mg)]

10. In the past 30 days, what percentage of the opioid prescriptions you prescribed were for chronic non-cancer pain that has lasted for longer than 3 months?

_____ % [RECORD NUMBER AND RECRUIT A MIX]

11. In the past 30 days, about how many prescriptions for abuse-deterrent opioid analgesics have you prescribed? Examples of abuse-deterrent opioid analgesics include OxyContin, Hysingla ER, MorphaBond ER, Xtampza ER, Arymo ER, and RoxyBond.

_____ [RECORD NUMBER, ENSURE Q10<Q7, AND RECRUIT A MIX]

12. In which medical setting do you practice most often? [RECRUIT A MIX]

- Private/small group practice (10 or fewer providers)
- Large group practice (11 or more providers)
- Community hospital
- Academic hospital
- Outpatient clinic
- Other outpatient setting (e.g., infusion center, dialysis clinic)
- Other (specify) _____

13. About what percentage of your patients are covered by each of the following types of health insurance? [DO NOT OFFER "DON'T KNOW" AS AN OPTION, BUT RECORD IF STATED SPONTANEOUSLY]

_____ Private health insurance → **CONTINUE TO Q18**

_____ Medicaid → **CONTINUE TO Q18**

_____ Medicare → **CONTINUE TO Q18**

_____ Other → **CONTINUE TO Q18**

_____ [DO NOT READ] Don't know → **CONTINUE TO Q18**

RECRUITER: CONTINUE IF PHARMACIST; FOR PRESCRIBERS, SKIP TO Q18

14. In the past 30 days, about how many prescriptions have you dispensed for opioid analgesics?

_____ prescriptions [Write down the number; recruit a mix]

Zero → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

15. In the past 30 days, for about how many patients have you dispensed prescriptions for opioid analgesics? _____ patients [Write down the number; recruit a mix]

Zero → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

16. In the past 30 days, for about what percentage of the patients for whom you dispensed opioid analgesic prescriptions did you provide patient education, such as talking with them about directions for use and advice on side effects?

_____ % [RECORD NUMBER AND RECRUIT A MIX]

17. In the past 30 days, about how many prescriptions for abuse-deterrent opioid analgesics have you dispensed? Examples of abuse-deterrent opioid analgesics include OxyContin, Hysingla ER, MorphaBond ER, Xtampza ER, Arymo ER, and RoxyBond.

_____ [RECORD NUMBER AND RECRUIT A MIX]

RECRUITER: CONTINUE FOR ALL SEGMENTS

18. How many years have you been in practice post-residency? If you did not do a residency, how many years have you been in practice? _____ years [Write down a number] [RECRUIT A MIX]

Less than 10 years

10-29 years

30 years or more

19. What is your gender? [RECRUIT A MIX]

Male

Female

20. What is your age? [RECRUIT A MIX]

25-34 years old

35-54 years old

55 or older

21. Are you Hispanic, Latino or of Spanish origin? [RECRUIT A MIX]

No

Yes

22. What is your race? [READ LIST ONLY IF NECESSARY AND RECRUIT A MIX]

White

Black or African American

Asian

Native Hawaiian or Other Pacific Islander

American Indian or Alaska Native

[DON'T READ] Other

23. Would you consider your primary practice location to be...? [RECRUIT A MIX]

Urban

Suburban

Rural

24. In what state do you practice most often? STATE: _____ [LIST]

REGION [DO NOT ASK; REFER TO LIST]: _____ [RECRUIT A MIX OF REGIONS]

Northeast: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania

South: Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, Washington D.C., West Virginia, Alabama, Kentucky, Mississippi, and Tennessee, Arkansas, Louisiana, Oklahoma, and Texas

Midwest: Illinois, Indiana, Michigan, Ohio, and Wisconsin, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota

West: Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming, Alaska, California, Hawaii, Oregon, and Washington

Closing Scripts

Ineligible - Closing Script

I'm sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

Eligible - Closing Script

Great! You qualify for our study.

In appreciation for your time, [you will receive \$300 [at the end of the session FOR IN PERSON GROUP]/in the mail 4-6 weeks after you participate FOR ONLINE GROUP].

The [online/in-person] focus group discussions will be held on [DATES] at [TIMES] and will last about 90 minutes. Which of those dates/times works with your schedule? [RECORD]

The discussion will be audio and video recorded, and project team members may observe the discussion.

Would you like to participate in the group discussion at [TIME] on [DATE] (to be determined based on the person's availabilities as noted above)?

- Yes → **Continue to informed consent instructions and verify contact info**
 No → **Continue**

25. What is your reason for not wanting to participate?

- Honorarium is too low → **Continue ONLY for specialists, Thank and end call for all others**
 Dates/times don't work with my schedule → **Thank and end call**
 Changed my mind → **Thank and end call**
 Other [RECORD] _____ → **Thank and end call**

[FOR SPECIALISTS ONLY] Would you be willing to participate if we increased the honorarium to \$400? [If no, ask] How much would you expect to receive for your participation? \$_____ Record answer _____

[If yes, say] You will receive this amount [at the end of the session for IN PERSON groups]/[IN THE MAIL 4-6 WEEKS AFTER YOU PARTICIPATE for ONLINE group]. Would you like to participate in the group discussion at [TIME] on [DATE]?

- Yes → **Continue to informed consent instructions and verify contact info**
 No → **Thank and end call**

Informed Consent Instructions

[FOR ONLINE GROUPS ONLY] We will send you two copies of an informed consent form that includes more information about the research study along with a reminder letter and instructions for the focus group. You MUST return a signed copy of this consent form before the date of the focus group to participate in the focus group. I can email the form to you so you can sign, scan, and email or fax it back, or send it by U.S. mail and you can mail it back. Which option do you prefer?

- Mail
 Email

[READ INSTRUCTIONS FOR THE OPTION SELECTED]

MAIL

OK, I will mail you two copies of the consent form along with a reminder letter and instructions for the focus group. Please read and sign one copy of the consent form and return it to us in the postage-paid envelope prior to [DATE OF FOCUS GROUP]. The other copy is for you to keep. Please remember that we must receive the signed consent form from you before the date of the focus group to participate in the group.

If you have any questions about the information in the consent form, you can contact the RTI project director, Brian Southwell, at (919) 541-8037 or bsouthwell@rti.org.

EMAIL

I will send you the consent forms by email to [email address]. Please send a scanned copy of the signed form to [EMAIL FOR RECRUITER] or fax a signed copy of the form to [FAX # for RECRUITER].

If you have any questions about the information in the consent form, you can contact the RTI project director, Brian Southwell, at (919) 541-8037 or bsouthwell@rti.org.

We will send you a confirmation letter with directions for attending the focus group scheduled on [DATE/TIME], so may I please have your mailing and/or e-mail address and telephone number? We will use this information to send you a reminder letter and to call and remind you of the focus group. We will destroy all contact information at the conclusion of the focus groups and none of this information will be shared with the FDA or RTI.

[VERIFY CONTACT INFORMATION]

****NOTE** THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUPS.**

NAME: _____

ADDRESS: _____

CITY: _____

ZIP CODE: _____

E-MAIL _____

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: _____

BEST PHONE NUMBER: _____

Is there another time and number we can try if we miss you?

ALTERNATE TIME: _____

ALTERNATE PHONE NUMBER: _____

Thank you. That's all the questions I have today. If you have any questions or find that you are unable to attend, please call [recruiter's phone number] as soon as possible so that we can try to find someone to replace you as a participant in this important research. Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].