FDA Opioids Communications Project Health Care Provider Screening Questionnaire

Introduction email

Subject: Interview for FDA Prescription Pain Medication Study

Hello, we are currently recruiting health care providers for an upcoming research study sponsored by the Food and Drug Administration. The purpose of this study is to gain health care providers' perspective about opioid use, misuse, and abuse.

RTI International, an independent, non-profit research institute, will be conducting one-on-one telephone interviews on this topic with providers nationwide. The interview will take up to 60 minutes. Interviews will be scheduled between DATE and DATE. You will receive an \$X* honorarium for your time. To see if you are eligible, please complete the brief survey linked below.

[Thank respondent and end call.]

1. Are you a medical or health professional?

| Yes | → CONTINUE |
|-----|-------------|
| No | → TERMINATE |

2. Have you ever worked for...?

| Department of Health and Human Services | → TERMINATE | |
|---|-------------|--|
| U.S. Food and Drug Administration | → TERMINATE | |
| Pharmaceutical company | → TERMINATE | |
| itracks | → TERMINATE | |
| RTI International | → TERMINATE | |

^{*}Honoraria will be based on provider type. Primary Care Physicians, Nurse Practitioners, and Physician Assistants will receive \$175. Specialists, such as anesthesiologists/pain specialists, and Dentists/Oral Surgeons will receive \$250.

3. Are you a...?

| Primary Care Physician (Family Practice, Internal Medicine, General Practitioner) | → CONTINUE |
|---|-------------|
| Advance Practice Practitioner in primary care, surgery, or pain management (Nurse Practitioner and Physician Assistant) | → CONTINUE |
| Surgeon (including oral surgeon) | → CONTINUE |
| Pain Medicine (pain specialist) | → CONTINUE |
| All Other Types | → TERMINATE |

SCREEN FOR A MIX OF THE FOLLOWING:

• PCPs: at minimum 10-12

• Mid-level: aim for 6

• Surgeon: aim for 6 (no more than 2 oral surgeons)

• Pain Medicine: aim for 6

Note: Over-recruit for each provider type to cover each category

4. How many hours a week do you practice medicine?

| At least 32 hours | → CONTINUE |
|--------------------|-------------|
| Less than 32 hours | → TERMINATE |

5a. [FOR PCPS AND ADVANCE PRACTICE PRACTITIONERS]: Did you prescribe opioids at least twice in the past 30 days?

| Yes | → CONTINUE |
|-----|---|
| No | → Ask follow-up question: Is this typical for your prescribing practices? |

| YES→ Terminate |
|--|
| NO→ Ask follow-up question: Do you typically prescribe opioids more or less often? |
| MORE OFTEN → CONTINUE |
| LESS OFTEN → Terminate |

5b. [FOR SURGEONS AND PAIN MEDICINE PROVIDERS]: Did you prescribe opioids at least once during the past 7 days?

| Yes | - | → CONTINUE |
|-----|---|---|
| No | | → Ask follow-up question: Is this typical for your prescribing practices? |
| | Y | /ES→ Terminate |
| | | NO Ask follow-up question: Do you cypically prescribe opioids more or less often? |
| | | MORE OFTEN → CONTINUE |
| | | LESS OFTEN → Terminate |

6. What percentage of the opioids that you prescribe are ER/LA opioids?

| Less than 10% | | → CONTINUE |
|--|--|------------|
| More than 10% | | → CONTINUE |
| SCREEN FOR AT LEAST 3 OF 30 PARTICIPANTS TO PRESCRIBE MORE THAN 10%. | | |

7. How long have you been practicing medicine?

| Less than 2 years | → CONTINUE |
|--------------------|------------|
| 2-5 years | → CONTINUE |
| 5-10 years | → CONTINUE |
| 10-15 years | → CONTINUE |
| More than 15 years | → CONTINUE |
| SCREEN FOR A MIX | |

8. How would you classify your practice?

| Solo | → CONTINUE |
|----------------------------------|------------|
| Small group practice (2-10 HCPs) | → CONTINUE |
| Large group practice (>10 HCPs) | → CONTINUE |

9. Is your practice part of an academic or healthcare system?

| Yes | → CONTINUE |
|-----|------------|
| No | → CONTINUE |

10. What percentage of your patient population is on Medicaid?

| < 20% | → CONTINUE |
|--------|------------|
| 20-60% | → CONTINUE |
| > 60% | → CONTINUE |

11. What is your gender?

| Male | | → CONTINUE | | |
|----------------------|--|------------|--|--|
| Female | | → CONTINUE | | |
| SCREEN FOR ½ OF EACH | | | | |

12. Would you consider your practice to be rural, suburban, or urban?

| Rural | | → CONTINUE | | |
|------------------|--|------------|--|--|
| Suburban | | → CONTINUE | | |
| Urban | | → CONTINUE | | |
| SCREEN FOR A MIX | | | | |

13. Are you Hispanic or Latino?

| Yes | → CONTINUE |
|------------------|------------|
| No | → CONTINUE |
| SCREEN FOR A MIX | |

14. Which of these groups best describes you? You may answer more than one.

| White | → CONTINUE |
|----------------------------|------------|
| | |
| Black / African American | → CONTINUE |
| American Indian or Alaskan | → CONTINUE |
| Native | |
| Asian | → CONTINUE |
| Native Hawaiian or Pacific | → CONTINUE |
| Islander | |
| Other | → CONTINUE |
| Two or more races | → CONTINUE |
| SCREEN FOR A MIX | |

15. In what state(s) are you currently practicing?

| | → CONTINUE |
|--|------------|
| | |

SCREEN FOR A MIX BASED ON THE FOLLOWING REGIONS:

Northeast: (1) New England (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont); **(2)** Mid-Atlantic (New Jersey, New York, and Pennsylvania)

South: (1) South Atlantic (Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, Washington D.C., and West Virginia); (2) East South Central (Alabama, Kentucky, Mississippi, and Tennessee); (3) West South Central (Arkansas, Louisiana, Oklahoma, and Texas)

Midwest: (1) East North Central (Illinois, Indiana, Michigan, Ohio, and Wisconsin); (2) West North Central (Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota)

West: (1) Mountain (Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming); **(2)** Pacific (Alaska, California, Hawaii, Oregon, and Washington)

Thank you for answering all of my questions. We would like to invite you to take part in the study.

Can we schedule you for an interview?

Yes → CONTINUE

No → [Thank respondent and end call]

OFFER AVAILABLE TIMES.

We will be sending you instructions for calling in, or for receiving a call from our system, for your interview so before we end the call, I'd like to confirm your contact information [Complete Participant Information on last page].

Finally, we will be sending you two copies of a consent form that includes more information about the research study. You MUST return a signed copy of this consent form in order to participate in study. I can either mail them to you and provide a postage-paid envelope for you to send a signed copy back to us, or I can email them to you and you can either email a scanned copy back to us or fax it to us. Which method do you prefer?

IF MAIL

OK, I will mail you two copies of the consent form. Please read and sign one copy of the consent form and return it to us prior to [DATE OF INTERVIEW]. We will provide a postage-paid envelope for you to send it to us. The other copy is for you to keep. Please remember that we must receive the signed consent form from you in order to participate in the interview.

If you have any questions about the information in the consent form, you can contact Lauren McCormack at 919-541-6277 or by email at Imac@rti.org

IF EMAIL

I will send you the consent forms by email to [email address].

Follow-up Email Text

Subject: Interview for FDA Prescription Pain Medication Study

Thank you for agreeing to participate in our study. In order to be able to participate in the interview we must receive a signed copy of this form from you prior to [DATE OF INTERVIEW]. Please keep a copy of the form for your records.

Instructions for Returning the Consent Form

- 1. You can send a scanned copy of the signed form to monica.grebe@itracks.com.
- 2. You can 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 Lauren McCormack at 919-541-6277 or by email at Imac@rti.org

Follow-up Mail Text

Dear [DR. NAME]:

Thank you for agreeing to participate in the interview for the FDA prescription pain medication study. I have included two copies of the consent form for this study. In order for you to be able to participate, we must receive a signed copy of this form from you before your interview scheduled on [DATE OF INTERVIEW]. Please return one signed copy of the form in the enclosed postage-paid envelope and keep the second copy for your records.

If you prefer, you can email a scanned copy of the signed form to monica.grebe@itracks.com or you can fax a signed copy to [FAX # for RECRUITER].

If you have any questions about the information in the consent form, you can contact Lauren McCormack at 919-541-6277 or by email at lmac@rti.org

Thank you,

RECRUITER

Closing for Ineligible Participants:

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.

Interview Call-In Information (email)

Subject: Telephone interview for FDA Prescription Pain Medication Research Study

Dear Dr. [FULLNAME]:

Thank you for agreeing to participate in our telephone interview for the FDA prescription pain medication study. Detailed in this email are some general instructions followed by specific information needed to participate in the interview.

The interview is scheduled to take place at the following date/time [STARTDATE].

You can either call in or you can opt to receive a phone call from our system at the time of your interview that will connect you to the interviewer. [PHONE PREFERENCES]

Your phone number is only accessible to the itracks IDI platform and is not shared with anyone including the interviewer.

The **interview is scheduled for 60 minutes**, therefore please be sure to allocate enough time in your schedule to accommodate the entire session.

As a token of our appreciation, a monetary incentive will be issued for participating in the interview. You can typically expect to receive a check in the mail within 4 to 6 weeks after you have completed the discussion.

Thank you and we look forward to your participation!

If you have any questions regarding this, please feel free to reply to this email.

To call in for your interview, dial the following phone number and enter the pin when prompted.

Phone Number: [CONFERENCEPHONE]

PIN: [CONFERENCEPIN]

If you have opted for us to call you, you will receive a phone call from our system at the time of your interview that will connect you to the interviewer.

Please respond to this email with your preference.

| 4 | ٠. | | 1.1 | | - 11 | • | • | | | |
|----|-----|-------|------|----|------|----|-----|------|------|----------|
| 1 |) I | would | IIKE | tΩ | call | ın | tor | mν | INTE | r\/I@\\/ |
| ъ, | , , | Would | 1111 | w | can | | 101 | 1119 | 1111 | |

| 2) | I would like to be called for my interview |
|----|--|
| | Phone Number: |

Confirmation Call

Hello this is [NAME] calling from itracks regarding an interview you recently agreed to do for the FDA prescription pain medication study.

I'm calling to make sure you received the instructions for the interview that we sent by email and that you are still willing to participate.

Have you received the instructions? [Wait for answer]

IF NO - Note in sheet and tell participant you will re-send.

And are you still planning on participating? [Wait for answer]

IF NO: Do you have a specific question or concern that I can address about the study? [IF NOT THANKK PARTICIPANT FOR THEIR TIME]

IF YES:

[CHECK TO SEE IF CONSENT FORM WAS RECEIVED. IF NOT REMIND PARTICIPANT TO SEND SAYING: I see you haven't returned a signed copy of the consent form to participate. Please send us that [in the postage-paid envelope provide before your interview or by email or fax]. You will not be able to participate in the study if we don't receive it.

Ending:

Great. Do you have any other questions at this time?

Thank you [NAME]. We appreciate your participation in this study.

Reminder Call: Consent

Initial reminder call to be made 3 days after the consent is sent if by email, 1 week if by mail. Additional follow-up calls to be made one day after the participant said they would send it.

After two reminder calls and/or 3 days prior to interview itracks and RTI will discuss whether to replace participant.

Hello this is [NAME] calling from itracks regarding an interview for the FDA prescription pain medication study that you recently agreed to participate in.

I'm calling because we have not received a signed copy of the study consent form yet. You will not be able to participate in the study unless we receive it before your scheduled interview on [DATE OF INTERVIEW].

Are you still planning to participate in the interview?

IF NO: Do you have a specific question or concern that I can address about the study? [IF NOT THANKK PARTICIPANT FOR THEIR TIME]

IF YES:

Will you be able to return it to us today? [IF NOT, ASK WHEN]. Will you be mailing it, sending it by email, or fax?

Great, I will make a note of when we can expect it.

Thank you [NAME]. We appreciate your participation in this study.

Reminder Calls

If participant has not called in/answered call for the interview 5 minutes after the start time.

When calling out to someone for reminders:

Hello this is [NAME] calling from itracks regarding the FDA prescription pain medication study that you recently agreed to participate in. We had you scheduled for an interview at [TIME].

Are you still able to complete the interview now?

IF YES – confirm phone # and tell participant that the interviewer will call them.

IF NO – [OFFER TO RESCHEDULE] IF NO: Well, thank you for your time.

*Honoraria will be based on provider type:

- Primary Care Physicians, Nurse Practitioners, and Physician Assistants will receive \$175.
- Specialists, such as anesthesiologists/pain specialists, and ral Surgeons, will receive \$250.

Participant Information (screener to collect on initial screening call)

| NAME: | | |
|------------------|---|---------------|
| ADDRESS: | | |
| CITY: | | |
| ZIP CODE: | | |
| EMAIL | | |
| What is the best | time to reach you? What is the best telephone number to reach you | at that time? |
| BEST TIME TO B | E REACHED: | |
| BEST PHONE NU | IMBER: | |
| Is there another | time and number we can try if we miss you? | |
| ALTERNATE PHO | DNE NUMBER: | |
| | | |
| Recruiter: | | |