

ATTACHMENT B
Focus Group Consent Form
Healthcare Providers Perspectives on Prescription Opioid Analgesics

Introduction and Purpose:

The purpose of this research is to gain healthcare providers' perspectives about opioid use, misuse, and abuse as part of a research study about prescription opioid analgesic medications. RTI International, a non-profit research organization in North Carolina, is conducting this study sponsored by the U.S. Food and Drug Administration (FDA).

You have been invited to take part in this research study because you told the study recruiters that you are a [HEALTHCARE PROVIDER WHO PRESCRIBES/A PHARMACIST WHO DISPENSES] opioids.

Procedures:

If you agree to participate, you will take part in a one-time [IN-PERSON/ONLINE] group discussion with about eight other [PHYSICIANS/NURSE PRACTITIONERS/PHYSICIAN ASSISTANTS/PHARMACISTS]. The discussion will last for 90 minutes. You are one of approximately 144 people from across the country being asked to participate in this study. You will not be contacted in the future about this research after your participation in the focus group ends.

Benefits:

This study will provide no direct benefit to you; however, what we learn from the focus groups may help FDA better communicate with healthcare providers about opioid medications.

Risk/Discomforts:

We do not expect that any of the focus group questions will make you uncomfortable; however, you can refuse to answer any question. Every effort will be made to protect your personal information, but this cannot be guaranteed. In addition to the steps listed below, we will ask the other participants not to disclose anything that was discussed in the group. However, we cannot control what other participants say after the group is finished.

Confidentiality:

Your identity and information will be kept secure to the extent provided by law. The RTI study team will not disclose your full name or your personal information, and this information will not be linked to any of your responses. The information you provide will be combined with the responses of other participants in your medical specialty in a summary report that will not identify you by name. Only RTI will have access to this signed consent form, and any information that includes your name or other personal information will keep in a locked file cabinet or on a password-protected computer that only authorized RTI project staff will be able to see.

Observation:

The focus group will be audio and video recorded and will be observed by study staff, including from the FDA. Only first names will be used during the groups, and any information that can identify you will be removed from the recordings and transcripts prior to sending them to FDA. The recordings and transcripts will be stored on password-protected computers at RTI and FDA for five years after the conclusion of this research project. Project staff may continue to analyze

the files during this period.

Right to Refuse or Withdraw:

It is your choice to participate in this focus group. You can choose not to answer any questions, and you can stop participating at any time and you will still receive an honorarium.

Honorarium:

To thank you for your time and participation, you will receive [\$300/\$400] [INSERT FORMAT E.G. CHECK/GIFT CARD] [IN THE MAIL 4-6 WEEKS AFTER THE FOCUS GROUP ENDS/AT THE CONCLUSION OF THE FOCUS GROUP].

Persons to Contact:

If you have questions about the research or the focus group, contact Dr. Brian Southwell, the RTI project director, at (919) 541-8037 between 9 AM and 5 PM Eastern Standard Time Monday - Friday. If you would like to speak with someone unrelated to the research; have questions about your rights as a research participant; want to report an injury from the study; or have questions, concerns, or complaints regarding the research study, contact RTI's Office of Research Protection toll-free at (866) 214-2043.

Your Consent:

I have read this consent form and agree to participate in the focus group. I was given a copy of this consent form.

Signature of participant _____ Date ___/___/___