

**Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications
Consent for Participation
Online Focus Group**

Introduction and Purpose:

You have been invited to take part in a research study. The purpose of the research is to gain a better understanding about prescription pain medications. RTI International, a non-profit research organization in North Carolina, is conducting this study sponsored by the US Food and Drug Administration (FDA).

Procedures:

We are inviting you to take part in an online focus group to collect this information. We will be conducting a total of 6 focus groups for this project. The focus group will be conducted online using audio only so no one will see you and you won't see other people. The focus group will last up to 90 minutes.

Risk/Discomforts:

There are minimal risks to you from being in this study. Some of the questions that we discuss will be related to prescription pain medication use. You can decline to talk about any topic for any reason. You can also stop being in the focus group at any time. Your participation is completely voluntary.

Benefits:

This study will provide no direct benefit to participants; however, what we learn from the focus groups will help the FDA better understand this issue and enable it to more effectively communicate with the public about prescription pain medications.

Confidentiality:

Your participation in this study will be kept confidential by RTI. The information that you give us will be combined with the responses of other participants in a summary report that will not identify you by name. All notes taken during the focus group will be kept in a locked file cabinet or on a password-protected computer. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. Only authorized project staff will be able to see them. We will also be audio recording our discussion. Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the focus groups. The audio files will be stored on password-protected computers at RTI and FDA. You will not be contacted in the future about this study after your participation in this group ends. We are conducting this focus group using an online platform where you can hear, but not see the other participants in order to help protect your privacy but, we cannot guarantee that what is said in the group will remain private. However, we will

take every precaution to protect your privacy. Participants will be asked not to share any information outside of the group.

Honorarium:

After the focus group has been completed, you will receive a \$75 check in the mail within 4-6 weeks in appreciation for your time.

Right to Refuse or Withdraw:

It is your choice to participate in this online focus group. You can choose not to talk about any topic. You can stop participating in the focus group at any time and you will not be penalized.

Persons to Contact:

If you have questions about the focus group, you can call Dr. Lauren McCormack, PhD, at (919) 541-6277 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. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to be in the focus group.

The above document describing the benefits, risks and procedures for this research study has been explained to me. I agree to participate.

Signature of participant _____ Date ___/___/___

Consent form: online focus group (general population and family/friends segments)

**Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications
Consent for Participation
Online Focus Group**

Introduction and Purpose:

You have been invited to take part in a research study. The purpose of the research is to gain a better understanding about prescription pain medications. RTI International, a non-profit research organization in North Carolina, is conducting this study sponsored by the US Food and Drug Administration (FDA).

Procedures:

We are inviting you to take part in an online focus group to collect this information. We will be conducting a total of 6 focus groups for this project. The focus group will be conducted online using a video and audio platform so you will be able to see and talk with other people in the group. The focus group will last up to 90 minutes.

Risk/Discomforts:

There are minimal risks to you from being in this study. Some of the questions that we discuss will be related to prescription pain medication use. You can decline to talk about any topic for any reason. You can also stop being in the focus group at any time. Your participation is completely voluntary.

Benefits:

This study will provide no direct benefit to participants; however, what we learn from the focus groups will help the FDA to better understand this issue and enable it to more effectively communicate with the public about prescription pain medications.

Confidentiality:

Your participation in this study will be kept confidential by RTI. The information that you give us will be combined with the responses of other participants in a summary report that will not identify you by name. All notes taken during the focus group will be kept in a locked file cabinet or on a password-protected computer. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. Only authorized project staff will be able to see them. We will also be audio recording our discussion. Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the focus groups. The audio files will be stored on password-protected computers at RTI and FDA,

and RTI will delete these files at the end of the project. You will not be contacted in the future about this study after your participation in this group ends. Because we are using an online platform, we cannot guarantee that what is said in the group will remain private. However, we will take every precaution to protect your privacy. Participants will be asked not to share any information outside of the group.

Honorarium:

After the focus group has been completed, you will receive 75 e-reward points credited to your account within 4-6 weeks in appreciation for your time.

Right to Refuse or Withdraw:

It is your choice to participate in this online focus group. You can choose not to talk about any topic. You can stop participating in the focus group at any time and you will not be penalized.

Persons to Contact:

If you have questions about the focus group, you can call Dr. Lauren McCormack, PhD, at (919) 541-6277 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. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to be in the focus group.

The above document describing the benefits, risks and procedures for this research study has been explained to me. I agree to participate.

Signature of participant _____ Date ___/___/___

Consent form: Individual phone interview (providers)

**Studies to Enhance FDA Communications Addressing Opioids and Other Potentially
Addictive Pain Medications
Consent for Participation
Individual Phone Interview**

Introduction and Purpose:

You have been invited to take part in a research study. The purpose of this interview is to gain health care providers' perspectives about opioid use, misuse, and abuse as part of a project to gain a better understanding about prescription pain medications. RTI International, a non-profit research organization in North Carolina, is conducting this study sponsored by the US Food and Drug Administration (FDA).

Procedures:

We are inviting you to take part in a telephone interview to collect this information. We will conduct a total of 30 interviews with health care providers across the country. The interview will last up to 60 minutes.

Risk/Discomforts:

There is no known physical risk to you from being in this study. You can decline to talk about any topic for any reason. You can also stop participating in the interview at any time. Your participation is completely voluntary.

Benefits:

This study will provide no direct benefit to participants; however, what we learn from the focus groups will help the FDA better understand this issue and enable it to more effectively communicate with the public about prescription pain medications.

Confidentiality:

Your participation in this study will be kept confidential by RTI. The information that you give us will be combined with the responses of other participants in a summary report that will not identify you by name. All notes taken during the interview will be kept in a locked file cabinet or on a password protected computer. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. Only authorized project staff will be able to see them. We will also be

audio recording our discussion. Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the interviews. The audio files will be stored on password-protected computers at RTI and FDA, and RTI will delete these files at the end of the project. You will not be contacted in the future about this study after your participation in this interview ends.

Honorarium:

After the interview has been completed, you will receive a \$175/\$250 check in the mail within 4-6 weeks in appreciation for your time.

Right to Refuse or Withdraw:

It is your choice to participate in this interview. You can choose not to talk about any topic. You can stop participating in the interview at any time and you will not be penalized.

Persons to Contact:

If you have questions about the focus group, you can call Dr. Lauren McCormack, PhD, at (919) 541-6277 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. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to be in the interview.

The above document describing the benefits, risks and procedures for this research study has been explained to me. I agree to participate.

Signature of participant _____ Date ___/___/___