Identifying Opioid Products

Consent to Participate in a Research Study

What Is the Purpose of This Study?

The purpose of this research study is to learn about how people identify prescription opioids in order to improve surveys and tools that ask people about their use of these medications.

If you take part in this research study, you will be one of about 100 people to do so. You are being invited to participate because your responses and insights will be helpful for creating surveys and tools that provide accurate and useful information about the use of opioid medications.

Who Is Leading the Study?

This research is being conducted on behalf of Inflexxion, a data and analytics company that specializes in behavioral health and substance use, and the U.S. Food and Drug Administration (FDA). RTI International, a nonprofit research institute, is conducting this study.

Do I Have to Take Part in This Study?

It is your choice to participate in this study. If you decide to take part in the study, it should be because you really want to volunteer. There will be no penalty and you will not lose any benefits or rights you would normally have if you choose not to volunteer. No one will be upset or treat you differently if you choose not to participate. Even if you decide to be part of the study now, you can stop participating at any time with no penalty, and you will still receive a token of appreciation.

What Will I Be Asked to Do?

We are asking you to take part in a research study that will be conducted entirely online and will last about 60 minutes, total.

- First, we will ask you to join a video conference call, so an RTI researcher can review this consent form with you and explain the study.

- If you consent to participate, we will then ask you to complete an online survey on your computer on your own. This survey will take about 45 minutes to complete.

- Next, we will ask you to rejoin the video conference call and participate in a 15-minute one-on-one online interview. During this interview, we will ask you about your thoughts and reactions to the survey questions and the language used in them.

We will audio record our discussion, during the interview, to make sure that your responses are captured accurately and to help us write a report, summarizing the interview discussion. If you do not want to be audio recorded, you will not be able to participate in the research.

After your participation in this research today, you will not be contacted in the future about this research study.

What Are the Possible Risks and Discomforts?

The risks associated with participating in this research are similar to those you would experience from seeing pictures of opioid medications, talking to people whom you do not know, and using the Internet.

1. As part of this study, you will be shown photos of opioid medications. While these questions are not meant to be sensitive, you may find seeing these photos or responding to some of the questions we ask to be upsetting or stressful. If you do, let either someone at your treatment facility or the researcher know so that we can help you find someone to talk with you about your feelings.

2. There is a chance your data could be seen by someone who should not have access to it. We are minimizing this risk in the following ways:

    - 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.

    - We will assign each participant a Participant ID number so that your answers to the screener, questionnaire, and interview questions cannot be directly linked to your name and contact information by members of the research team.

    - All data collected, during the study, will be kept on a password-protected computer. The data will not contain any information that could personally identify you.

Will I Benefit from Taking Part in This Study?

There is no direct benefit to you for being in this study. What we learn from this research study will help Inflexxion and FDA to improve their surveys and tools for collecting information about opioid use.

Who Will See the Information I Give?

The information collected will be secure to the extent permitted by law. When we analyze the results, your comments will be separated from the information that identifies you and combined with information from other people, taking part in the study. When we write up the study to share it with other researchers, we will write about the combined information. You will not be identified in any published or presented materials.

Your name will not be included with any of the data collected as part of this study. The information collected as part of this research will not be used or distributed for future research studies. All survey and interview data will be kept on a password-protected computer. Only authorized project staff at RTI and Inflexxion will be able to access them. Staff at your substance abuse treatment facility will not see any of your responses.

Will I Receive Any Payment or Reward for Taking Part in This Study?

In appreciation of your time and assistance with this study, you will receive a $25 gift card.

What If I Have Questions?

Before you decide whether or not to participate in the study, do you have any questions about this study or anything else I've talked about?

We will give you a copy of this document for your records. If you have questions about the study later on, you can call the project director Susana Peinado at 919-316-3190.

If you have any questions about your rights as a research participant, contact the RTI Office of Research Protection at 1-866-214-2043.

Verbal Consent to Participate Certification and Signature

Do I have your permission to continue with this study?
IF NO: I appreciate your time and consideration.

[STUDY STAFF WILL SIGN BELOW, INDICATING PARTICIPANT'S VERBAL CONSENT]

I certify "that the nature and purpose, the potential benefits, and possible risks associated with participating in this survey have been explained to the below-named individual" and that I fully and accurately answered his or her questions. A clean copy of the consent form will be sent to the participant.

_____
First Name of Participant

_____ _____
Signature of Person Obtaining Verbal Consent Date

_____
Printed Name of Person Obtaining Verbal Consent

[IF PATIENT CONSENTS TO PARTICIPATE IN STUDY, CONTINUE WITH CONSENT BELOW]

Consent to Allow Access to ASI-MV Data

What Is the Purpose of This Research?

Thank you for agreeing to complete the online survey and interview portion of this study. As part of the study, you are invited to give the research team access to some of your responses to an assessment you have already completed, during intake into your treatment program. This assessment is called the Addiction Severity Index-Multimedia Version or ASI-MV. The ASI-MV is used by your treatment program to collect information about patients' past drug use. Analyses that include your responses to this assessment will help us learn more about how people identify prescription opioids in order to improve surveys and tools that ask people about their use of these medications.

Do I Have to Take Part in This Research?

It is your choice whether or not to allow the research team to access your responses to the ASI-MV assessment. You can participate in this study, even if you do not agree to let the research team access your responses to the ASI-MV; you will not be penalized, and you will still receive the $25 gift card for completing the survey and interview.

What Will I Be Asked to Do?

If you give your consent, the research team will be able to access your responses to this assessment about your past drug use. If you consent, we will also ask you to fill out an authorization form, which your treatment clinic will mail to you if you are participating from your home or hand to you if you are participating at a treatment center. After you fill out the authorization form, we will ask you to hand it or send it back to your clinic contact, using the postage provided. We will not ask you any additional questions. If you do not give your consent today and authorization to the clinic, the research team will not access your ASI-MV records. Your consent and authorization only give us permission to access your responses to the ASI-MV and not any other health records.

What Are the Possible Risks and Discomforts?

The information collected will be secure to the extent permitted by law. There is a chance your data could be seen by someone who should not have access to it. We are minimizing this risk in the following ways:

- Your responses to the ASI-MV assessment will be kept on a password-protected computer. Only authorized project staff at RTI and Inflexxion will be able to access them.

- Your name will not be included with any of the data collected as part of this study. When we analyze your responses to the ASI-MV assessment, your responses in the assessment will be separated from the information that identifies you and combined with information from other people, taking part in the study.

- When we write up the study to share it with other researchers, we will write about the combined information. You will not be identified in any published or presented materials.

Will I Receive Any Payment or Reward for Allowing the Research Team to Access my Responses to the ASI-MV Assessment?

You will NOT receive an additional incentive for allowing the research team to access your responses to the ASI-MV assessment.

What If I Have Questions?

Before you decide whether or not to let the research team access your responses to the ASI-MV assessment, do you have any questions about this study or anything else I've talked about?

We will give you a copy of this document for your records. If you have questions about the study later on, you can contact Dr. Susana Peinado, the RTI project director, at 919-316-3190.

If you have any questions about your rights as a research participant, contact the RTI Office of Research Protection at 1-866-214-2043.

Verbal Consent for ASI-MV Data Access Certification and Signature

Do I have your permission to access your responses to the ASI-MV assessment?
IF NO: I appreciate your time and consideration. [STUDY STAFF CONTINUES WITH THE STUDY]

IF YES: Please remember to sign and return the authorization form given to you by your treatment clinic. [STUDY STAFF WILL SIGN BELOW, INDICATING PARTICIPANT'S VERBAL CONSENT, AND CONTINUE WITH THE STUDY]

I certify "that the nature and purpose, the potential benefits, and possible risks associated with allowing the research team to access my responses to the ASI-MV assessment have been explained to the below-named individual" and that I fully and accurately answered his or her questions. A clean copy of the consent form will be sent to the participant.

_____
First Name of Participant

_____ _____

Signature of Person Obtaining Verbal Consent Date

_____

Printed Name of Person Obtaining Verbal Consent