Informed Consent Form

CTN-0093: Validation of a Community Pharmacy-Based Prescription Drug Monitoring Program Risk Screening Tool

NCT03936985

Document created July 11, 2019

Information Sheet to Participate in Research
University of Cincinnati
Department: Department of Psychiatry and Behavioral Neuroscience
Principal Investigator: Theresa Winhusen, PhD

Title of Study
Validation of A Community Pharmacy-Based Prescription Drug Monitoring Program Risk Screening Tool (PharmScreen)

Introduction
You are being asked to take part in a research study. Please read the following carefully and ask questions about anything that you do not understand.

Who is doing this research study?
The people in charge of this research study are Theresa Winhusen, Ph.D. of the University of Cincinnati (UC) School of Medicine and Gerald Cochran, Ph.D. of the University of Utah School of Medicine. There may be other people on the research team helping at different times during the study.

What is the purpose of this research study?
The purpose of this research study is to understand the physical, mental, and behavioral health of pharmacy patients who are prescribed opioid medications.

Who will be in this research study?
Approximately 1,500 people will take part in this study. You may be in this study if you are:

- Prescribed a qualifying opioid medication
- 18 years of age or older
- Not receiving treatment for cancer
- Not previously enrolled in the study (meaning, taken the survey before)
- Not currently involved with the criminal justice system

What will you be asked to do in this research study, and how long will it take?
You will be asked to complete a one-time 35-45 minute survey that will ask about your physical health, mental health, medication use behaviors, and substance use. Your survey responses will also be confidentially linked to information about your prescription fill history from a national health care company. Your survey responses will not be shared with your health care providers or your pharmacy.

Are there any risks to being in this research study?
The research questions may make you uncomfortable. You can refuse to answer any question. As with any study, there is a potential risk of loss of confidentiality. To maintain participant

confidentiality, study records and data will be encrypted and stored in compliance with the International Conference on Harmonization (ICH) guidelines.

Are there any benefits from being in this research study?
You will probably not get any benefit from taking part in this study. But, being in this study may help researchers understand the physical health, mental health, medication use behaviors, and other behaviors of people at community pharmacies who are dispensed opioid pain medications.

What will you get because of being in this research study?
If you are qualified for this study and fill out and submit a completed survey, you will receive $50. The payment will be made to you with a prepaid, reloadable debit card, which will be mailed to your home address; please allow 14 days for receipt of the payment. The amount you receive may count as income and may affect your income taxes.

Do you have choices about taking part in this research study?
If you do not want to take part in this research study you may simply not participate.

How will your research information be kept confidential?
Only research staff will have access to the password-protected secured and encrypted computers. The data from this research study may be published; but you will not be identified by name.

Agents of the University of Cincinnati or the National Institutes of Health may inspect study records for audit or quality assurance purposes. The researcher cannot promise that information sent by the internet will be private. The identity of participants and information about them will be kept confidential. All researchers and agents involved in this study will use their utmost efforts to maintain the confidentiality and security of the information we collect.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if you report or the study staff deems that you may cause harm to yourself or others (such as suicidal thoughts/actions, child abuse or neglect, or violence). This information will be voluntarily reported to the authorities. Similarly, if you report or study staff deems that you are being harmed, that information will be voluntarily reported as required to the authorities.

What are your legal rights in this research study?
Nothing in this form waives any legal rights you may have. This form also does not release the investigator, the institution, or its agents from liability for negligence.

What if you have questions about this research study?
If you have any questions or concerns about this research study, you should contact Theresa Winhusen, Ph.D. at (513) 585-8292.

The UC Institutional Review Board reviews all research projects that involve human participants to be sure the rights and welfare of participants are protected.

If you have questions about your rights as a participant, complaints and/or suggestions about the study, you may contact the UC IRB at (513) 558-5259. Or, you may call the UC Research Compliance Hotline at (800) 889-1547, or write to the IRB, 300 University Hall, ML 0567, 51 Goodman Drive, Cincinnati, OH 45221-0567, or email the IRB office at irb@ucmail.uc.edu.

Do you HAVE to take part in this research study?
No one has to be in this research study. Refusing to take part will NOT cause any penalty, loss of benefits, or your ability to receive health or pain care that you would otherwise have.
You may start and then change your mind and stop at any time.

BY SELECTING CONTINUE, YOU GIVE YOUR CONSENT TO PARTICIPATE IN THIS STUDY. PLEASE PRINT OR SAVE A COPY OF THIS DOCUMENT FOR YOUR REFERENCE.

☐ **CONTINUE**

If you are not interested in participating in this project and wish to no longer be contacted, please check here __ __ and submit the form.