Opioid SMS R34 Phase 2

NCT05503186

IRB Approved Date: 09OCT2024

Wake Forest University
School of Medicine

MEDICATION SAFETY RESEARCH STUDY
Informed Consent Form to Participate in Research
Kathleen Egan, PhD, MS, Principal Investigator

SUMMARY

You are invited to participate in a research study. Research studies help scientists learn new information that may help other people in the future. The purpose of this research study is to understand how receiving text messages about prescription pain medication impacts the ways in which people keep medication in their home. We are inviting adults (18+ years of age) who have received a prescription for pain/opioid medication within the past 14 days to participate in this research study. About 485 people will participate in this research study. Participation in this study will involve completing three brief surveys online and receiving text messages to your cell phone about 1-2 times per week for 7 weeks.

All research studies involve some risks. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or psychological examinations. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be learning new information about medication safety.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You may choose not to take part,or you may leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

The remainder of this form contains a more complete description of this study. Please read this description carefully. Please take your time in making your decision if you would like to join. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted] or [redacted]

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means

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that you are put into a group by chance. It is like flipping a coin. If you take part in this study, you will be invited to complete three brief surveys and may be randomized to the group that receives text messages to your cell phone about 1-2 times per week for 7 weeks.

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

To opt out of receiving text messages, reply STOP to a text message. If you choose to opt of receiving a text message by replying STOP, you are also choosing to end all participation in this research study and will not be able to rejoin the study.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific meetings or published in scientific journals. Your identity and personal health information will not be disclosed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will You Be Paid for Participating?

You will be paid $25 for each of the three surveys that you complete with the possibility of being paid $75 if you complete all three surveys.

Who is Sponsoring this Study?

This study is being sponsored by the National Institute on Drug Abuse. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What About My Health Information?

In this research study, any new information we collect from you and information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes information about your prescription pain medication.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information on a password protected computer. Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. You can tell Dr. Kathleen Egan that you want to take away your permission to use and share your Protected Health Information at any time by sending an email to this address: [redacted] However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study. By clicking on "I agree to participate" at the end of this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Kathleen Egan at [redacted] or [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like

to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will have the opportunity to download a copy of this consent form after completion of the first survey.

AGREE TO PARTICIPATE

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have been provided with contact information to ask questions about being in this study and have those questions answered. By clicking on "I agree to participate" at the end of this form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.