Title: Veteran-Centered Lethal Means Safety Suicide Prevention Intervention

NCT Number: NCT06216327

IRB Approval Date: 30-July-2024

Department of Veterans Affairs	Informed Consent Form	COMIRB APPROVED For Use 30-Jul-2024
Version Date: 07.22.24	**R&D Stamp:** VA R&D	**COMIRB Approval Stamp/Date:**

Subject Name: _____ **Date:** _____

Title of Study: Household Medication and Firearm Storage Decisions after Clinical Care

Principal Investigator: [redacted] **VAMC:** 554

VA Investigator: [redacted] **COMIRB# 23-0023**

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by Veterans Health Administration - Health Services Research and Development (VHA HSR&D). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST? By doing this study, we hope to learn more about ways to promote medication and/or firearm safety. Your participation in this research will last about 4 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

This study is designed for the researcher to learn more about Veteran suicide prevention. There are no established benefits of participating in the study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Discomforts you may experience while in this study include becoming frustrated, tired, or distressed while completing study procedures. We will check in with you throughout each study visit to see how you are feeling. There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] at the Rocky Mountain Regional VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact [redacted] at [redacted].

DETAILED INFORMATION ABOUT THE STUDY

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

You are being asked to be in this research study because you are a Veteran who has received care in a VHA emergency care, mental health, women's health, or primary care setting. We are seeking to learn more about ways to promote medication and firearm safety after VHA healthcare encounters. This knowledge will be used to enhance VHA clinical care for Veterans.

Other people in this study

Up to 60 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will complete the following visits over the course of about four weeks.

Initial Visit: You will meet virtually (e.g., VA Webex) with a research team member. During that meeting, we will discuss ways to increase household safety and offer some options that you can consider. This meeting may also be audio recorded so that we can review and better understand the information you provide. Your name will not be identified in the transcriptions of these recordings. You will also be asked to complete some questionnaires about you, your health, and your medication and/or firearm access and storage practices. You may skip any question you would prefer not to answer. This visit will take approximately 45 minutes. At the conclusion of this visit, the team member may recommend up to two follow up intervention visits. These follow up visits will also be conducted virtually.

Follow Up Visit(s): A team member may also follow up with you to discuss your safety practices and address any questions you may have. These virtual contacts will last approximately 15-20 minutes.

Final Assessment: About 4 weeks from your first visit, a team member will follow up with you virtually to complete additional questionnaires and discuss your experience being involved in this study. This contact will last approximately 45 minutes.

This research study is expected to take approximately 8 weeks. Your individual participation in the project will take about 4 weeks, which will include up to 5 total visits: 1 today (to review this consent form), 1 initial study visit, up to 2 optional phone/virtual follow up meetings (if recommended), and a final phone/virtual meeting about 4 weeks from today.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Discomforts you may experience while in this study include becoming frustrated, tired, or distressed while completing study procedures. We will check in with you throughout each study visit to see how you are feeling. If you do experience any of these effects and would like to speak with someone, you can tell us today, or you may contact [redacted], the principal investigator of this study, at [redacted].

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in the consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about Veteran suicide prevention. There are no established benefits of participating in the study.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored by Veterans Health Administration- Health Services Research and Development (VHA HSR&D).

Will I be paid for being in the study?

You will be paid a total of $65 ($45 for intervention visit, $20 for follow-up assessment) via direct deposit for participating in this study. You will receive this payment after you complete the follow-up assessment call/virtual meeting (approximately 4 weeks after your first visit). It is important to know that payments from participation in a study are taxable income. Your SSN will be collected and used to report this taxable income to the IRS. You may also choose to not be compensated for participating in this study. We will access your medical record during the study to review your health data. If we are concerned that you are at risk of harming yourself, we may refer you back to emergency services or seek additional consultation regarding your care.

Will I have to pay for anything?

There will be no cost to you for participation in this study. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. The investigator may continue to review the data already collected prior to your withdrawal, but we cannot collect any further information once you withdraw from this study.

Can I be removed from this study?

The study team may decide to stop your participation without your permission, if the study team thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans in accordance with applicable federal regulations (38 CFR 17.85). Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call [redacted] at [redacted] during normal business hours, or if it is an emergency, dial 9-1-1.

Who do I call if I have questions?

The researcher carrying out this study at the VA is [redacted]. You may ask any questions you have now. If you have any questions, concerns, or complaints later you may call [redacted] at [redacted]. If you choose, you will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at [redacted]. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved or if you would like to obtain information or offer input, please contact the VA Research Office at [redacted].

How will my private information be protected?

Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information confidential to the extent allowed by law. Records about you will be kept on password protected files on VA computers behind the VA firewall and in locked filing cabinets within or research department. Only members of this study team will have access to this information.

Identifiers might be removed from the identifiable private information or data that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will include information about your study participation in your medical record.

Photography, Video, and Audio Recordings

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the researcher while you are participating in this study. The voice recording is intended for transcription for data analysis. You will be informed when voice recording will take place.

If you elect not to have study interactions audio-recorded, you can still consent to participate in the rest of the study.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

While this study is being conducted, you will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research Protections (OHRP), and the VA Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.
- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor VHA HSR&D (group paying for the study), study monitors or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee

I understand that by signing this consent form, a copy of limited data about me, restricted to all research data that is collected as part of this specific VA research study will be stored in the REDCap database (or Data Storage System) at the University of Colorado Denver's (UCD's) Colorado Clinical and Translational Sciences Institute (CCTSI). This data will be used solely for the purposes defined in this consent form and for this specific study. Data collected about me for this study placed on the CCTSI REDCap Database will not be accessed or used for any other study or purposes, and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Database is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado Denver.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to

participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

Agreement to be in this study

I have read this form or it has been read to me. A member of the research team has explained the study to me. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this form below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I will receive a copy of this consent after I sign it. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date: _____

Print name: _____

Witness's Signature: _____ Date: _____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____