Title: Examination of a Safety Aid Reduction Protocol for Treatment Resistant PTSD Among Veterans

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Department of Veterans Affairs	**RESEARCH CONSENT FORM** ***Version Date: 05/16/2025***

Participant Name: _____ Date:_____

Title of Study: Examination of a Safety Aid Reduction Protocol for Treatment Resistant PTSD Among Veterans

Principal Investigator: [redacted] VA Facility: SLVHCS

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?
We are asking you to choose whether or not to volunteer for a research study being funded by the Department of Veterans Affairs. The purpose of this study is to revise and extend an existing anxiety treatment for use among Veterans with posttraumatic stress disorder (PTSD). This treatment will then be tested for initial acceptability and feasibility. This initial information is designed to give you an overview of the study to help you decide whether to participate. We have included more detailed information after this page. Feel free to ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?
The purpose of this study is to revise and extend an existing anxiety treatment for use among Veterans with PTSD. This treatment will then be tested for initial acceptability and feasibility.

By doing this study, we hope to learn more about the treatment of PTSD. Your participation in this research will last between one hour and 14 hours (over the course of four months) depending on the phase of the study for which you are recruited.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
Although we cannot guarantee that you will benefit from this study, if the treatment is sucessful you may notice a reduction in your PTSD symptoms. Information gathered from this study will be used to improve our understanding of the treatment of PTSD and may help other Veterans in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
Risks in the proposed study are minimal. Nevertheless, you may experience some emotional discomfort when completing certain parts of the treatment. You may also encounter some privacy risks. As such, you may choose not to participate in this study. If this is your decision, there are other options including psychological (e.g., talk therapy) and pharmacological (e.g., medications) treatments for PTSD. You may discuss these options with your provider.

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 choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is [redacted], of the Southeast Louisiana Veterans Health Care System. If you have questions, comments, or concerns regarding this study or you want to withdraw from the study, her contact information is [redacted] ext. [redacted].

Participant Name: _____ Date:_____

Title of Study: Examination of a Safety Aid Reduction Protocol for Treatment Resistant PTSD Among Veterans

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to revise and extend an existing anxiety treatment for use among Veterans with PTSD. This treatment will then be tested for initial acceptability and feasibility. With this research, we hope to learn more about the treatment of PTSD.

HOW LONG WILL I BE IN THE STUDY?

A total of 70 Veterans will be recruited to participate in this study, which is expected to take approximately four years. Your individual participation in the project will take between one and 14 hours (over the course of four months) depending on the phase of the study for which you are recruited.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Phase 1:
Approximately, twenty Veterans will be recruited to take part in Phase 1 of the study. If recruited during Phase 1, you will be asked to take part in an individual in-person interview designed to gather your feedback on how to improve the treatment protocol and materials.

Phase 2:
Fifty Veterans will be recruited to take part in Phase 2 of the study. If recruited during Phase 2, you will a take part in a pilot trial designed to test initial acceptability and feasibility of the treatment protocol and materials refined in Phase 1. Before participating in a six to 10 week group-based treatment, you will be asked to complete a baseline appointment. After finishing the last group-based treatment session, you will be asked to complete a post-intervention appointment. Further, one-month after the last group-based treatment session, you will be asked to complete a follow-up appointment.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

Phase 1:
If recruited during Phase 1 of the study, you will be asked to take part in an audio-recorded individual in-person interview designed to gather your feedback on how to improve the treatment protocol and materials. This interview, which is expected to take one hour to complete, will be conducted by [redacted] in a private office in outpatient mental health.

Phase 2:
If recruited during Phase 2, you will a take part in a pilot trial designed to test initial acceptability and feasibility of the treatment protocol and materials refined in Phase 1. Before participating in this pilot trial, you will be asked to complete a baseline appointment. During the baseline appointment, which is expected to take 90 minutes to complete, you will answer questions about your mental health via clinical interviews and self-report questionnaires. In particular, you will be asked about a range of emotional experiences from your feelings of anxiety to depression, including suicidal ideation and behaviors, to trauma. After the baseline appointment, you will

participate in a six to 10 week group-based treatment (see below for a description of the treatment). Treatment sessions will be conducted by [redacted] once weekly, over the course of six to 10 weeks, with each visit lasting between 60 and 90 minutes. After finishing the last group-based treatment session, you will be asked to complete a post-intervention appointment. During this post-intervention appointment, which is expected to take 60 minutes to complete, you will answer questions about your mental health via self-report questionnaires. Finally, one-month after the last group-based treatment session you will be asked to complete a follow-up appointment. During this follow-up appointment, which is expected to take 90 minutes to complete, you will answer questions about your mental health via clinical interviews and self-report questionnaires. All appointments and group treatment sessions will take place in a private office or group room in outpatient mental health.

Treatment: Although the START-PTSD protocol will be revised based on feedback from Veterans in Phase 1, it is expected that it will last between six to 10 weeks and involve group-based sessions, delivered once weekly, with each visit lasting between 60 to 90 minutes. Consistent with the original treatment protocol, main components will include: 1) education about anxiety; and 2) correction of anxiety maintaining behaviors via the identification and reduction of safety aids. Known safety aids to be included are cognitive avoidance (e.g., using mental distractions to avoid trauma-related images), situational avoidance (e.g., avoiding crowded market places), checking behaviors (e.g., checking doors, windows, locks, and perimeters more often than necessary), use of companions (e.g., relying on someone to attend a social gathering), and use of alcohol and certain substances (e.g., consuming alcohol to reduce anxiety). You will be taught to monitor and track your use of safety aids, as well as specific strategies to fade out your use of safety aids. Finally, the last session will involve a review of skills learned throughout treatment. Time will also be spent discussing myths about recovery (e.g., "I should never be anxious again") and factors that contribute to relapse (e.g., adopting new safety aids).

We expect that you keep your study appointments. If you have to miss an appointment, please contact the Principal Investigator ([redacted]) or Research Coordinator ([redacted]) to reschedule as soon as you know you will miss the appointment. We also expect that you will complete the self-report questionnaires as instructed. However, you are free to skip any questions that you prefer not to answer. While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

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.

Risk Associated with Questionnaires and Treatment:
You may experience some psychological risks by participating in this study. In particular, you may experience some emotional discomfort when answering questions about your mental health. Further, some parts of the treatment, including fading out safety aids (e.g., going to a crowded store, not checking perimeters more often than necessary), may cause distress initially. However, this distress usually goes down over time with repeated fading. If for any reason, you wish not to answer specific questions or you wish to end participation, you will be able to do so.

Risks Associated with Privacy/Confidentiality:
You may encounter some privacy/confidentiality risks by participating in this study. In particular, it is possible that your data may be breached. To lower this risk, all appointments will take place in a private office or group room in outpatient mental health. Further, you will be assigned a unique code. This code will be used in place of your personally identifiable information (like your name) on all study materials. All hardcopy data will be kept in a locked office, in a locked cabinet, to which only the Principal Investigator and Research Coordinator have a key. All electronic data will be kept on a secure VA server (behind the VA firewall) on a network drive that can only be accessed via a password protected computer. Only approved personnel who have completed the required VA trainings in Privacy and Information Security will have access to the data.

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 this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

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 research team while you are participating in this study. The said voice recording is intended for the following purposes: to capture exact wording and opinions and views on the treatment. Digital recorders containing the voice recordings will be kept in a locked office, in a locked cabinet, to which only the Principal Investigator and Research Coordinator have a key. The Principal Investigator and Research Coordinator will transcribe each recording directly from the digital recorder removing any personal identifiers (e.g., names). De-identified electronic copies of the transcriptions will be saved on a secure VA server (behind the VA firewall) on a network drive that can only be accessed via a password protected computer. Recordings will be erased from the digital recorder following NIST 800-88 and VA 6500.1 Sanitization Guidelines immediately upon completion of each transcription. No recordings will be backed up or saved after transcriptions are completed.

The study team has also explained that you will not receive any payment, 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 stop being recorded and may take back your consent for up to a reasonable time before the voice recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?
We do not know if you will get any benefits from taking part in this research study. If the treatment is useful, you may notice a reduction in your PTSD symptoms. Information gathered from this study will be used to improve our understanding of the treatment of PTSD and may help other Veterans in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?
You may choose not to participate in this study. If this is your decision, there are other choices including psychological (e.g., talk therapy) and pharmacological (e.g., medication) treatments. You may discuss these with your provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?
Taking part in this study will involve the study team collecting private information about you. This information will be protected in the following ways:

Your research results will be kept confidential to the extent allowed by law. All appointments and group treatment sessions will take place in a private office or group room. Further, all subjects will be assigned a unique code. This code will not have any personally identifiable information and will be used in place of your name on all relevant study materials. The hardcopy data will be kept in a locked office in a locked cabinet, to which only the Principal Investigator and Research Coordinator will have a key. All electronic data will be kept on a secure VA server (behind the VA firewall) on a research network drive that can only be accessed via a password protected computer. Only approved personnel who have completed the required VA trainings in Privacy and Information Security will have access to the data. Further, all study personnel will only have access to the minimum information necessary to complete the study. The data collected for research purposes are not a part of the VA medical record. However, we will include information about your study participation in your medical record.

Health Information Portability and Accountability Act (HIPAA)
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 release 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 your mental health diagnoses 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 the Institutional Review Board (IRB), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the CSR&D Centralized Data Monitoring Committee.

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 take back this authorization, in writing, at any time. To take back 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 take back the authorization. Your request will be valid when the Release of Information Office receives it. If you take back 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 benefits outside of the study.

If you take back this authorization, [redacted] and her research team can continue to use information about you that was collected before receipt of the withdrawal. The research team will not collect information about you after you take back 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 taken back before that time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?
You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Payment for Participation:
You will reimbursed by study personnel for your time, travel, and effort in completing research activities. Compensation will be provided in the form of a voucher. Vouchers can be turned in to the SLVHCS Financial Operations office for immediate cash payment. You will be compensated only for those phases/portions of the study for which you are recruited and complete.

- Phase 1: $50 for the individual in-person interview (60 minutes)
- Phase 2: $75 for the baseline appointment (90 minutes); $50 for the post appointment (60 minutes); $75 for the follow-up appointment (90 minutes)

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
If you are injured as a result of being in the study, the VA will provide treatment for research-related injury in accordance with applicable federal regulations (38 CFR 17.85). Compensation may be payable under Title 38 USC 1151 or under the Federal Tort Claims Act. The right to

compensation will be controlled by provisions of Title 38 USC 1151 or of the Federal Tort Claims Act.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

During the Day: [redacted]

After Hours: Emergency Department at [redacted]

IF YOU ARE EXPERIENCING A MENTAL HEALTH CRISIS, PLEASE CALL THE 24-HOUR VETERANS CRISIS LINE AT 1-800-273-8255. THE CRISIS LINE IS OPEN 7 DAYS A WEEK.

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?
Taking part in this research is completely voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you chose to take part but later change your mind, you may withdraw at any time without any penalty or loss of benefits and will continue to receive the same standard of care that you would otherwise have received. There are no major adverse consequences to withdrawal. Of note, data already collected before your withdrawal may continue to be reviewed by the PI but no further information can be collected, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION
Study personnel may have to end your participation in this study under the following condition(s): 1) If they believe it is in your best interest; 2) If a physical health complication impedes your ability to participate in the study; 3) If you experience a study-related injury; or 4) if your symptoms significantly worsen requiring immediate attention. The Principal Investigator will notify you in person if you are withdrawn and work with your provider to find the best alternate care.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?
Questions, complaints, and concerns about the research or related matters can be answered by the Principal Investigator, [redacted]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the IRB. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the IRB at [redacted] if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

Participant Name: _____ Date:_____

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WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

New findings discovered during the course of the research that may affect your willingness to continue participation will be provided to you. If you decide to withdraw from the study, the Principal Investigator will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. The Principal Investigator could also decide it to be in your best interest to withdraw you from the study. If so, she will explain the reasons and arrange for your usual medical care to continue.

FUTURE USE OF DATA AND RE-CONTACT

De-identified electronic data will be kept after the study for future use. The electronic data will be kept on a secure VA server (behind the VA firewall) on a network drive that can only be accessed via a password protected computer. Only approved personnel who have completed the required VA trainings in Privacy and Information Security will have access to the data.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date