Participant Name: _____ Date:_____

Title of Study: Evaluating the Use of Peer Specialists to Support Suicide Prevention

Principal Investigator: Anne Klee, PhD VA Facility: VA Connecticut Healthcare System

Principal Investigator for Multisite Study: Matthew J. Chinman, PhD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by RR&D Small Projects in Rehabilitation Research. 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 current approaches to suicide prevention in the Veterans Health Administration, or VA. Your participation in this research will last approximately 3 months.

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

You might want to be a part of this study so that you provide information that can help improve Veteran services for suicide prevention. *For a complete description of benefits, refer to the Detailed Information section of this consent.*

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

You might not want to be a part of this study because it might be uncomfortable or difficult for you to discuss suicide prevention efforts. *For a complete description of risks, refer to the Detailed Consent and/or Appendix.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to participate in this 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 Anne Klee, PhD, at the VA Connecticut Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is 203-640-1727.

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to develop, and pilot test a peer-to-peer approach to support Veterans following a suicidal crisis. If this approach is shown to be helpful, the VA may expand its use of Peer Specialists to reach the goal of zero Veteran suicides.

In this research project, we hope to learn whether Peer Specialists can lower the number of Veteran suicides. This study will be done in 3 phases. This informed consent form is only for the second part of this study, which is to find out how easy or hard it is to have Peer Specialists help out with suicide prevention efforts in the VA, and what Veterans think about these efforts.

HOW LONG WILL I BE IN THE STUDY?

You are being asked to regularly meet with a Peer Specialist for approximately 3 months. You will also be asked to meet with research staff for study assessment visits at the beginning of the study, after 3 months (after all of your visits with the Peer Specialists), and at approximately the 6-month mark. You will also be invited to participate in a 1-time, in-depth qualitative interview that will last about an hour.

The whole research study is expected to take approximately two years.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to take part in this study:

- A researcher will reach out to you and help you complete this Informed Consent form over the phone or in-person. If you complete this over the phone, you will sign it once you have had it explained to you, and you will return it to the study team in the envelope provided. You will also have the option of completing the Informed Consent form in-person.

- A researcher or Peer Specialist will call you and set up a time for your study visits or Peer Specialist visits. You need to have access to a phone or device you can use for video calls for the study or be able to attend an in-person visit.

- You will meet with a Peer Specialist (either in-person, by phone, or by video call) for approximately an hour at a time per the following schedule. All visits will be recorded for research purposes to make sure the visits follow the PREVAIL model:

- Weeks 1 and 2: two times a week (total of 4 visits)
- Weeks 3-8: once a week (total of 6 visits)
- Weeks 9-12: once every other week (total of 2 visits) with an additional 3 visits during this same time frame.

- You will meet with research staff 3 times over the course of 6 months to answer questions about how you are doing, about your life, and any symptoms you may be experiencing.

- You are invited to participate in a 1-time interview to talk about what it was like working with a Peer Specialist, what you liked or didn't like, and any recommendations you may have. You will not need to provide any identifying information about yourself and your responses will be kept anonymous.

- Your interview will be recorded and transcribed (with your personal health or personal identifiable information removed) and the information you provide will be kept secure in a VA protected electronic file.

- If you have worries or concerns after the interview, the interviewer will provide a number you can call to discuss these concerns and what your next steps should be.

Do you agree to participate in this 1-time interview?

_____ Yes (*make note of this in the study database and continue with the remainder of the form*)

_____ No (*make note of this in the study database and continue with the remainder of the form*)

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, we ask that you:

- Keep your study visits. If you miss your scheduled study visits, please contact the Peer Specialist or research staff to reschedule as soon as you know you will miss the visit.
- Ask questions as you think of them.
- Tell the investigator or research staff if you believe you might be pregnant or might have gotten your partner pregnant.

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

Your participation in this project is voluntary and your decision not to participate does not impact your employment or the VA benefits to which you are entitled.

Even though the risk is minimal as shown in previous studies, there is the possibility that participating in this phase of the study may result in the worsening of your mental health and/or an increase in suicidal thoughts or behaviors. You will be provided with a phone number to call if you wish to discuss these thoughts.

Another potential risk is the loss of confidentiality related to the information you provide during the study visits and interviews with research staff and meetings with Peer Specialists. We will do everything we can to keep your study information strictly confidential. However, research staff will need to break confidentiality if they find out about any of the following:

- Threat of harm to yourself
- Threat of harm to others
- Suspected child abuse
- Suspected elder abuse
- Possession of a weapon on VA property

Please note that information about your encounters with Peer Specialists and research staff will be entered into your medical record.

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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Although there are no direct or personal benefits to you from your taking part in this study, it is possible that Veterans meet with a Peer Specialist regularly, may benefit from an improved sense of hope and belonging. Additionally, the information we get from your participation will help the study team better develop a peer-led program that might help other Veterans who experience a suicidal crisis.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you do not want to participate, you can continue to receive all your usual care at the VA, and all your regular benefits. You do not have to participate.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will store any electronic or hard/paper copies of the information about you in a safe place and will keep any copies that contain information like your name, address, or date of birth separate from any information that does not contain identifiers. Only those individuals who are allowed will be able to review your information.

If you agree to take part in the one-time interview, the audio will be deleted from the secure recording device after the interview is transcribed. Any identifying information will be removed from the interview transcript. The content of your interview or information from your study visits will not be used in or distributed for future studies. We will include information about your study participation in your medical record. However, what you say during the interview and study visits will *not* be included in your medical record.

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 website at any time

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Health Information Portability and Accountability Act (HIPAA)-*does not apply to Veterans who have a Conservator. The Conservator must sign Form 10-0493.*

There are rules to protect your private information. Federal and state laws and the federal medical 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 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. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

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.

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.

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, Anne Klee, PhD, and her 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.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

Costs to Participants

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 Offered for Participation

You will be paid for your time and participation in the study. You will be paid $25 after each research visit, for a total of up to $75. You will also be paid $25 if you choose to participate in a one-time research interview. Veterans will receive these payments via Electronic Funds Transfer (EFT), debit card, or canteen books. Your social security number will be needed to process the payments, and if you are not already enrolled, bank account information is also required to register for EFT. If you are paid via EFT, this payment will be made directly to your bank account. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you whether to take part in this study or not. If you decide to take part, you may still leave the study at any time. You may withdraw your permission to participate at anytime by calling Anne Klee, PhD, at 203-640-1727 or Joshua Bullock, PhD, at 203-516-8013.

If you leave early, you will not lose any of your VA benefits. If you don't take part, you can still receive all the usual care that is available to you. Your decision will not affect the relationship you have with your doctor or other staff. Your decision will not affect the usual care you receive as a patient.

If you leave the study, the investigator may continue to review the information already collected for the study. If you leave, no further information can be collected, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Describe foreseeable circumstances under which the participant's participation might be terminated by the investigator without regard to the participant's consent.

If the investigator might terminate participation of a participant, possible reasons should be listed and the procedures for an orderly termination of participation described. Include a description of any adverse effects on the participant's health or welfare that may result, or any additional follow-up that may be requested after the participant is withdrawn from the active portion of the study.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have a general question about this research study, or if you have any concerns or complaints, you may call Anne Klee, PhD, at 203-640-1727 or Joshua Bullock, PhD, at 203-516-8013.

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 VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Record Retention: Your research records will be kept in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: April 4, 2022

LSI Approval Date: NA

LSI Verification Date: April 6, 2022

Participant Name: _____ Date:_____

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Someone from the research 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/the Veteran. 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 or give permission for the Veteran named below, to participate in the study, and authorize the use and disclosure of your/the Veteran's health information in 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
If Veteran has a conservator of person: I give permission for the above-named Veteran to participate in this study (this signature is for consent only-a separate form for HIPAA authorization, Form 10-0493, must be signed)		
_____ Conservator's Name	_____ Conservator's Signature	_____ Date

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