**Study Title:** Caring Cards to and from Veterans: Feasibility and Acceptability of a Peer Approach to Suicide Prevention and Recovery

**Principal Investigator:** [redacted]

**VA Facility:** VA San Diego Healthcare System

| Participant Name: | Date: |
|---|---|
| | |

## STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

***WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?***

This study about creating opportunities for Veterans to help other Veterans who share similar mental health experiences. Caring Cards is a project where Veterans with lived mental health experience create handmade, one-of-a-kind cards that are sent to Veterans who may be in need of extra support. It is being funded by Department of Veterans Affairs, Rehabilitation Research and Development. By doing this study, we hope to learn if Caring Cards can be done with Veterans and if Veterans like it. We also hope to learn if Caring Cards can help make improvements in Veterans' lives, such as improvements with social connection and reduced suicidal thinking/behaviors.

***WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?***

You will be asked to attend a weekly Caring Cards group. Each group will last two hours. Groups will meet for a total of 6-months. In addition to participating in these groups, you will be asked to complete two sets of questionnaires to help us determine your satisfaction with making these cards and how your participation in this group made you feel. Each set of questionnaires take about 30-45 minutes to complete. The first set will be completed at the start of the study, soon after you enroll, and the other at the end of the study, approximately 7-months after you enroll. You may complete these assessments either in person, which can be scheduled at your convenience, or by phone, WebEx, VA Video Connect, or online.

From start to finish, your total participation in this research will last about 7-months.

You will also be invited to attend one or more monthly, two-hour meet-up groups at the San Diego VA (La Jolla). These groups are completely optional, and <u>you do not have to attend them as part of your participation in this study</u>. These groups are meant to give Veterans who created the cards the opportunity to meet the Veterans who receive the cards. A total of four meet-up groups will be offered over the course of four months (one per month). Again, if COVID-19 precautions are in effect and these groups cannot meet in person, they will be held via WebEx or VA Video Connect.

***WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?***
There is no guaranteed direct benefit to Veterans who participate in this study. However, benefits to the individual participants may include increased social connectedness and sense of purpose. Participants' suicide risk and related behaviors may also decrease.

***WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?***
There are minimal risks to participating in this study. Some potential risks include becoming bored or fatigued when completing the assessments. During the baseline assessment and follow-up assessments, participants may experience feelings of anxiety or discomfort while talking about themselves and/or symptoms. In addition, card makers may experience some discomfort drawing upon their lived mental health experience to create caring cards for other Veterans in need. Participation is voluntary and the only alternative is to not participate. A complete description of risks is included in the Research Details Study Risks section. A complete description of alternate treatment/procedures is provided in the Research Details Alternatives section.

***WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?***
The person in charge of the study is [redacted] of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted]

## RESEARCH DETAILS

***WHO IS CONDUCTING THIS RESEARCH AND WHY?***

[redacted] PI is asking for your consent to this research. This study is being sponsored by the Department of Veterans Affairs, Rehabilitation Research and Development.

The purpose of the research is to evaluate a new intervention called Caring Cards. Caring Cards is a group-based program that offers Veterans an opportunity to help other Veterans who share similar mental health experiences.

Specifically, in Caring Cards, Veterans with lived mental health experience create handmade, one-of-a-kind cards that are sent to Veterans who may be in need of extra support. By doing this study, we hope to learn if Caring Cards is feasible to do with Veterans and if Veterans like it. We also hope to learn if Caring Cards can help make improvements in Veterans' lives, such as improve social connection and reduce suicidal thinking/behaviors.

You are being asked to participate because you have been identified as someone with a history of elevated suicide risk (i.e., inactive high-risk flag for suicide). Approximately 80 people will take part in this research at this facility. With 30 serving as card makers and 50 as card recipients.

***FOR HOW LONG WILL I BE IN THE STUDY?***

Your individual participation will take about 7-months from start to finish.

***WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?***

As a ***card maker***, you will be asked to attend a weekly Caring Cards group. Each group will last two hours. Groups will consist of approximately 10 Veterans and will meet for a total of 6-months. During these groups, you will be asked to create caring cards for other Veterans in need of mental health support. You will be asked to draw upon your personal experiences to create these cards. For example, you may be asked to consider a time when you were struggling with mental health, perhaps, thoughts of suicide. If someone sent a you a card during this time, what would have been helpful for you to read or see?

**Caring Cards groups** are largely unstructured and laid-back, meaning, you can create these cards at your own pace, in a supportive and comfortable environment. The groups will be facilitated by a mental health provider, who is supervised by [redacted] All art supplies will be provided to you. You and your fellow group members can work on these cards together. If groups are able to meet in person, we will hold groups at the main VA hospital in La Jolla and at the Rio Clinic, which is located in the Mission Valley area. We will do our very best to see you at your preferred location; however, this will depend on available space. If COVID-19 precautions are in effect and these groups cannot meet in person, they will be held via WebEx or VA Video Connect and we will mail you all art supplies needed to create these cards from home.

In addition to participating in these groups, you will be asked to complete two sets of **questionnaires** to help us determine your satisfaction with making these cards and how your participation in this group made you feel. You can skip any question that makes them uncomfortable and can stop at any time. Each set of questionnaires take about 30-45 minutes to complete. An example of a question that may be asked is, “These days, people in my life would be better off if I were gone.”

The first set of questions will be completed at the start of the study (within one month of initial contact/screening), and the other at the end of the study, approximately 7-months after you enroll (within one month of your last group meeting). You may complete these assessments either in person, which can be scheduled at your convenience, or by phone, WebEx, VA Video Connect, or online.

For quality assurance, the groups and assessments will be **audio recorded**. [redacted] will reviewed these tapes each week and will stored them in a locked filing cabinet that only [redacted] will have access to. All data will be handled according to the current RSC-10 Record Control Management guidelines.

You will also be invited to attend one or more monthly, two-hour **optional meet-up groups** at the San Diego VA (La Jolla). <u>These groups are completely optional, and you do not have to attend them as part of your participation in this study</u>. These groups are meant to give Veterans who created the cards the opportunity to meet the Veterans who receive the cards. A total of four meet-up groups will be offered. Again, if COVID-19 precautions are in effect and these groups cannot meet in person, they will be held via WebEx or VA Video Connect.

In addition to your responses to the questionnaires, we will also collect basic information about your demographic background including, age, race and ethnicity, sex, sexual orientation, military branch, and marital status. We will also collect your contact information, including email address, telephone number, and mailing address. If sessions are completed remotely, we will also collect the names and contact information for any people who will be present during your sessions and an emergency contact (if applicable). We will also have access to your medical records (CPRS).

You are welcome to continue to participate in other VA mental health care while you are involved in this study. If you desire additional mental health support or referrals after the end of the study, the research team can discuss this with you and place an appropriate consult.

If you are interested in learning about the results of this study, please let us know and we would be happy to share clinically relevant research results, including individual research results.

Below is a list of responsibilities and expectations of you, as the participant.

- Keep your study appointments, this includes all assessment and group appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- 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.

***WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?***

The procedures done for research are the Caring Cards groups and questionnaires. These are not part of standard care.

***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.

**Disclosure or Identification of Suicidal Ideation or Intent to Harm Self**: During structured interviews concerning suicide or discussion with rater or other staff, you may disclose a level of risk of harming themselves that would require a higher level of care. Further, during the intervention, you may experience an increase in suicidal ideation beyond that which you reported at baseline.

**Assessments**: The questionnaires are non-invasive clinical assessments associated with minimal risk. All measures are physically non-invasive. Responding to these questions will require time and attention. You may become bored or fatigued completing the evaluation. You may also become distressed during the psychiatric evaluation, which requires you to discuss current symptoms.

**Intervention Period**: Risks involved in participating in this group are minimal. Card makers may experience some discomfort drawing upon their lived mental health experience to create caring cards for other Veterans in need.

Participants do not have to answer any assessment question they do not want to and can decide at any time to withdrawal from the study.

**Confidentiality**: As with any research study, a risk of disclosure of personal material exists.

**Audiotaping**: 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: quality assurance.

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 voice recording is used.

If the recording is an optional part of the study, such that a participant could refuse to be recorded but still be an active participant in the study, also insert the following:

Signature: _____ Date: _____

Inclusion of Women of Childbearing Potential: The policy of the NIH, and other Federal agencies regarding the research participation of women with childbearing potential has changed substantially in the past few years. Studies are now mandated to include such women unless there is a clear and justifiable reason to exclude them.

***WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?***

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions. You may also experience enjoyment from your participation in this study.

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

You may choose not to participate in this study. If this is your decision, there are other choices such as other VA mental healthcare. You may discuss these options with your doctor.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**

While you are a participant in this study, you will be notified if any important new information is found that may affect your willingness to continue. If the results of this research might influence your mental health care after you complete participation, the investigators will contact you to let you know these results.

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

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: your medical provider, VA San Diego Healthcare [redacted] or 911 if you are in urgent need of medical care.

DURING THE DAY:

Dr./Mr./Ms._____at _____ and

AFTER HOURS:

Dr./Mr./Ms._____at _____

***DO I HAVE TO TAKE PART IN THIS STUDY?***

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

If you choose to withdrawal after you enroll in the study, the investigator may continue to review the data that was already collected prior to your withdrawal; however, the investigator cannot collect further information, except from public records, such as survival data.

***RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION***

Although we do not anticipate termination of your participation, the investigator reserves the right to terminate your participation without regard to your consent under any of the following circumstances:

- Being violent or threatening violence towards others involved in the study (i.e., group members, facilitator, research team).
- Causing significant disruption to the group (participants and/or facilitator) or assessments (e.g., making inappropriate sexual, derogatory, or racist remarks or gestures).

If any of the above is observed, [redacted] will be immediately notified. You will be informed that the observed behavior may result in your termination from the research study. [redacted] will invite you and any other parties involved to have a discussion about the concerning behavior and a Disruptive Behavior Report (DBR) will be filed. A DBR is an official document that identifies concerning behavior. It becomes part of your medical record. As part of the DBR process, the Disruptive Behavior Committee will meet with you to inform you the report was filed and if any restrictions have been placed on you (e.g., restricted to only being seen in La Jolla). [redacted] may also consult with the Disruptive Behavior Committee about any concerning behaviors observed.

In situations where active violence is being perpetuated, VA or local police will be contacted first, followed by [redacted]

Adverse effects on your health or welfare that may result include legal action taken against you for perpetrating or threatening violence towards a research team member or fellow participant, and possible hospital restrictions at the discretion of the Disruptive Behavior Committee.

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

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact [redacted]

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

***WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?***

You will be paid a total of $120 to complete the baseline and follow-up assessments ($60 for each assessment completed). These payments will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation. You will not be compensated for your group appointments or any options meet-up groups you participate in.

Note: VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care. Any payment offered should be commensurate with the time and inconvenience of the participant incurred by the participant that they otherwise would not have incurred, as well as to cover travel expenses.

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

If you have any questions, complaints, or concerns about the research or other related matters, you may contact [redacted] at [redacted]

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at [redacted] VA Research Service at [redacted] VA Regional Counsel at [redacted] or the VASDHS Institutional Review Board at [redacted] This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study related questions or concerns you can contact the research team at [redacted]

***FUTURE USE OF DATA AND RE-CONTACT***

Your deidentified data may be retained after the study for future research; the data will be stored behind the VA firewall on secure computers, and only members of the research team will have access to these data.

If the research team believes you may qualify or be interested in participating in future studies, you may be re-contacted by a VA provider via telephone in the future.

Please check and initial below if you agree or disagree to be contacted for future research.

☐ **Yes, I may be contacted for future research opportunities as described**. _____ (initial)

☐ **No, I do not wish to be contacted for future research opportunities as described**. _____ (initial)

***HOW WILL MY PRIVATE INFORMTION BE PROTECTED?***

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. The Veterans who receive the cards will not know your identity and you will not know theirs. If you choose to attend one of the optional meet-up groups, you may meet other study participants.

Your interactions with research team members will be documented in the VA Computerized Patient Record System. The research includes collecting the subject's SSN for CPRS review and for payment. Similarly, data collected via audio recording during periods the groups, which are used for quality control, and data collected through online surveys (if applicable), will also be stored.

Any presentations or publications from this information will not identify you.

We will keep confidential all research and medical records that identify you to the extent allowed by law. Paper copies of your data will be kept in a locked file cabinet and in a locked office in [redacted] the VA San Diego. Electronic data will be stored on a restricted access computer network. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, VA Office of Research and Development and federal compliance officers may look at or copy portions of records that identify you.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

We will include information about your study participation 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.

This study 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.

Any presentations or publications from this information will not identify you.

***AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY***

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

The study coordinator has explained the study to me. I have been told of 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 document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

**I agree to participate in this research study as has been explained in this document.**

_____ _____

Participant's Signature Date

A copy of this document will be provided to the research participant.

**Study Title:** Caring Cards to and from Veterans: Feasibility and Acceptability of a Peer Approach to Suicide Prevention and Recovery

**Principal Investigator:** [redacted]

**VA Facility:** VA San Diego Healthcare System

_____ _____

Or Signature of Legally Authorized Representative | Legally Authorized Representative (print)

_____ _____ _____

Signature of Researcher obtaining consent | Name (print) | Date

A copy of this document will be provided to the research participant.

**Study Title:** Caring Cards to and from Veterans: Feasibility and Acceptability of a Peer Approach to Suicide Prevention and Recovery

**Principal Investigator:** [redacted]

**VA Facility:** VA San Diego Healthcare System

## 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 document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. They may also collect other information including your name, address, suicide risk status (i.e., high-risk flag, suicidal behaviors), date of birth, email address, telephone number, and social security number.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. Other VA entities may include the Institutional Review Board, Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

Your health information disclosed outside the VA as described in 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 may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address: [redacted]

If you revoke this authorization, [redacted] 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.

While this study is being conducted you will have access to your research-related health records.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study; any study information that has been placed into a repository to be used for future research will expire 5 years following publication.

***AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION***

**Study Title:** Caring Cards to and from Veterans: Feasibility and Acceptability of a Peer Approach to Suicide Prevention and Recovery

**Principal Investigator:** [redacted]

**VA Facility:** VA San Diego Healthcare System

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records. A copy of this signed document will also be put in my medical record.

| _____ | _____ | _____ |
|---|---|---|
| Participant's Signature | Last 4 of SSN | Date |

| _____ | _____ |
|---|---|
| Signature of Legally Authorized Representative | Date |

_____
Legally Authorized Representative (print)

A copy of this document will be provided to the research participant.

**Study Title:** Caring Cards to and from Veterans: Feasibility and Acceptability of a Peer Approach to Suicide Prevention and Recovery

**Principal Investigator:** [redacted]

**VA Facility:** VA San Diego Healthcare System

## EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at [redacted] or [redacted] You may leave an anonymous comment at the VASDHS research compliance hotline at [redacted]

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.