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

NCT04486677

November 22, 2022

Human Protocol (Version 1.12)

General Information

***Please enter the full title of your study::**

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

***Please enter the Study Number you would like to use to reference the study:**

Caring Cards RR&D SPiRE
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Add departments

and Specify Research Location:

Is Primary?	Department Name
◉	**VASDHS** - VASDHS

Assign key study personnel(KSP) access to the study

***Please add a Principal Investigator for the study:**

Treichler, Emily B., PhD

3.1 If applicable, please select the Research Staff personnel

A) Additional Investigators

Depp, Colin A., PhD
Co-Investigator
Doran, Neal M., PhD
Co-Investigator
Ehret, Blaire C., PhD
Co-Investigator
Granholm, Eric L., PhD
Co-Investigator

B) Research Support Staff

Chalker, Samantha A., PhD
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Martinez Ceren, Camila
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Study Coordinator
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Study Coordinator

***Please add a Study Contact**

Treichler, Emily B., PhD

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

VASDHS IRB
Human Subjects Protocol
v20190121

Section 1 - Preliminaries

Principal Investigator:

Emily B. Treichler, PhD

Protocol Title:

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

IRB Protocol Number:

H200125

Protocol Nickname:

Caring Cards RR&D SPiRE

Form Template Version:

v20150115

Date Prepared:

11/22/2022

Please be advised that this protocol application form has changed as a result of the 2018 Common Rule. There are new questions and sections, and you may be required to provide additional information to previous sections.

1a) Is this study considered human research?

- (•) Yes
- ( ) No
- ( ) I don't know

1b) Please select:

(•) This is an application for a NEW human subject research protocol
( ) This is a revision of an existing protocol

Section 2 - Research Subjects

2a) What is the total planned number of VA-consented subjects?

Include the total number of subjects who will prospectively agree to participate in the study (e.g., documented consent, oral consent, or other).

80

2b) What is the total number of VA subjects who WILL NOT be consented?

Include the total number of subjects that will be included without consent (e.g., chart review). *Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still should enter the number of charts as your "planned subjects."*

200

Section 2.1 Consented Subject Groups

2.1) For each of the subject categories listed below, indicate whether or not these subject groups will participate in the study:

2.1a) Children under the age of 18
Note: If neonates or children will be involved in this study, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.

( ) Yes (•) No

2.1b) Pregnant women

(•) Yes ( ) No

2.1c) Individuals with cognitive/decisional impairment

( ) Yes (•) No

2.1d) Non-English-speaking individuals

( ) Yes (•) No

2.1e) Prisoners of War (explicitly targeting this group)

( ) Yes (•) No

2.1f) Non-Veterans (Note: Justification for inclusion of non-Veterans will be required)

( ) Yes (•) No

2.1g) Incarcerated individuals (Note: VA CRADO approval will be required)

( ) Yes (•) No

2.1h) VA employees - including VA paid, IPA, or WOC (Note: Union review and authorization may be required)

( ) Yes (•) No

2.1i) Students of the institution (e.g., resident trainees) or of the investigator

○ Yes ◉ No

2.1j) Patients with cancer (or high cancer risk) [explicitly targeting this group]

○ Yes ◉ No

Section 2.2 Subject Categories without consent

2.2) Indicate if data or specimens only will be used without enrollment consent for each category listed below:

2.2a) Non-Veterans

○ Yes ◉ No

2.2b) Prisoners

○ Yes ◉ No

2.2c) Neonates or Children
Note: If neonates or children will be involved, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.

○ Yes ◉ No

Section 3 - Study Features (these items default to "No" for convenience)

3) This section consists of several Yes/No questions addressing protocol characteristics. Click on *Save and Continue*.

Section 3.1 Protocol Basics

Select all that apply

3.1a) The research **intends to change** the participant.

◉ Yes ○ No

3.1b) **Interactions** with living participants to collect data or specimens with no intent to change them.

○ Yes ◉ No

3.1c) This is a study that **never** has any **subject contact and does not collect subject identifiers**

○ Yes ◉ No

3.1d) This is a **chart review** study involving retrospective or prospective medical records.

○ Yes ◉ No

3.1e) This is a **multi-site** study occurring in-part or in-full at other locations.

○ Yes ◉ No

3.1f) There is an **international** component to this research. *International research includes sending or receiving human derived data or specimens (identifiable, limited data set, coded, or deidentified) to or from an international source. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator.*

○ Yes ◉ No

3.1g) This study includes **off-station activity** (not including VA-leased space or CBOC clinics) conducted under VASDHS IRB approval. *Note: this does not include research conducted by a collaborator at their home institution under their institutional approval.*

(•) Yes ( ) No

3.1h) VA subjects will **participate** in part or in full **at other locations** (not including VA-leased space or clinics) under VASDHS IRB approval. *Note: if this study involves remote participation of subjects, please indicate "no" and describe their remote participation in section 9 of the application. This question is intended to understand whether participants must physically go to a non-VA location to participate in this VA research study.*

(•) Yes ( ) No

Section 3.2 Specimen Use and Data Repository

Indicate whether or not each of the following applies to this protocol

3.2a) Involves specimens that are left over from pathological or diagnostic testing (**non-research specimens**)

( ) Yes (•) No

3.2b) Involves **specimens collected for research** purposes **only**

( ) Yes (•) No

3.2c) This study includes **specimen banking** (specimens are retained for use outside of the purposes of this protocol)

( ) Yes (•) No

3.2d) The study involves **DNA** genotyping or other **genetic analysis**

( ) Yes (•) No

3.2e) Biological **specimens/material** will be sent outside of the VA.

( ) Yes (•) No

3.2f) A **data repository** is maintained (data are retained after completion of the protocol for other uses, IMPORTANT: see **?** before checking "yes")

( ) Yes (•) No

3.2g) **Data will be shared outside** of the VA (identifiable, coded, limited data set, or deidentified)

( ) Yes (•) No

Section 3.3 Treatment and Clinical Trials

Indicate whether or not each of the following applies to this protocol

3.3a) Includes a **treatment** component (a research treatment)

(•) Yes ( ) No

3.3b) Study is a **clinical trial.** *Note: A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.*

(•) Yes ( ) No

3.3c) Has a data safety monitoring board (**DSMB)** or data safety monitoring committee.

( ) Yes (•) No

3.3d) Has a **data safety monitoring plan** (but not a DSMB) (this is not the data security plan, it is a safety plan).

(●) Yes ( ) No

Section 3.4 Drugs and Devices

Indicate whether or not each of the following applies to this protocol

3.4a) **Drugs** that require **FDA** action such as an Investigational New Drug (IND) approval or exemption or 510 (k) approval.

( ) Yes (●) No

3.4b) Other drugs, supplement, etc. that **do not require FDA** action for inclusion in the study.

( ) Yes (●) No

3.4c) Medical **devices requiring FDA** IDE approval or waiver

( ) Yes (●) No

3.4d) **Other** medical **devices**

( ) Yes (●) No

Section 3.5 Risk and Hazards

Indicate whether or not each of the following applies to this protocol

3.5a) Study places subjects at **greater than minimal risk** (do not include risks that are due to standard care)

( ) Yes (●) No

3.5b) Human subjects are exposed to **radioisotopes** (do not include standard care).

( ) Yes (●) No

3.5c) Subjects have other **radiation exposure** (e.g., x-rays) (do not include standard clinical use).

( ) Yes (●) No

3.5d) Target population has psychiatric diagnosis, behavioral complaint, or chronic pain.

(●) Yes ( ) No

Section 3.6 Clinical Facilities and Standard Care

Indicate whether or not each of the following applies to this protocol

3.6a) Study **uses VA clinical services** (e.g., adds required tests run in the VA lab for study purposes; research procedures concurrent with clinical care)

(●) Yes ( ) No

3.6b) Includes procedures or drugs that will be considered **part of standard care.**

( ) Yes (●) No

3.6c) Involves **lab tests done for research** purposes.

( ) Yes (●) No

Section 3.7 Subject Expenses and Compensation

Indicate whether or not each of the following applies to this protocol

3.7a) There may be expense or added **costs to the subject** or the subject's insurance.

○ Yes ◉ No

3.7b) This is a **qualifying cancer treatment trial** and subjects may be billed for study drugs or procedures.

○ Yes ◉ No

3.7c) This is a cancer treatment trial but **subjects will not be billed** for study drugs or procedures.

○ Yes ◉ No

3.7d) Subjects will be **compensated** (either in cash or other means such as a gift certificate).

◉ Yes ○ No

Section 3.8 Subject Activities

Indicate whether or not each of the following applies to this protocol

3.8a) Involves **surveys or questionnaires** completed by subjects

◉ Yes ○ No

3.8b) Includes the use of **recruitment materials** such as flyers, advertisements, or letters

◉ Yes ○ No

3.8c) Involves facial **photographs** or audio or video **recordings** of **patients**

◉ Yes ○ No

Section 3.9 Sponsors and Collaboration

Indicate whether or not each of the following applies to this protocol

3.9a) This research is a funded research project **(commercial (industry) sponsor, NIH, VA, other).**

◉ Yes ○ No

3.9b) Other **commercial (industry) non-financial support** is provided (e.g., drugs or supplies).

○ Yes ◉ No

3.9d) The protocol has **Department of Defense** involvement (e.g., subjects or funding).

○ Yes ◉ No

3.9c) The PI or other study staff member has a financial interest or other **real or potential conflict** related to this study.

○ Yes ◉ No

3.9e) This study involves **collaborative** research activities (research conducted at other institutions under the authorities or approvals of the other institution/s). *Note: this may include other VA and/or non-VA institutions, but does not include off-site VA research.*

○ Yes ◉ No

Section 4 - Estimated Duration

4) What is the estimated duration of the entire study? (From IRB approval to IRB closure)

2 years; 12/01/2020-12/01/2022

Section 5 - Lay Language Summary

5) Provide a summary or synopsis of the proposed study using non-technical language (not more than 1 paragraph)

Veteran suicide is a national problem; social disconnection is an important contributor to suicide risk. This study will recruit Veterans to take part in a peer-centered group called Caring Cards (CC). CC gives Veterans who have a history of increased suicide risk the opportunity to make cards that are then sent to Veterans who are currently at high-risk for suicide. CC is an innovative group that was developed at VA San Diego and piloted over the past two years. Since its inception, several CC groups have started in various clinics at the VASDHS, as part of standard clinical care. This project will directly benefit Veterans and contribute to the quality of services provided by VA San Diego by creating a safe, creative space for Veterans with lived experience related to suicide risk to join together to provide messages of hope, community, and resilience to their peers at risk for suicide. Helping Veterans support one another provides a bridge for social connection, which may help prevent Veteran suicide. This intervention may also improve Veterans' satisfaction with VA healthcare and engagement with mental health treatment.

Section 6 - Specific Aims

6) Provide a statement of specific aims and hypotheses that serve as the basis for this protocol. Emphasize those aspects that justify the use of human subjects.

Aim 1: Establish the feasibility and acceptability of Caring Cards for Veteran card makers and recipients (i.e., 70% average group attendance, > 75% average satisfaction with group participation and card receipt, and 70% average follow-up response). Establish feasibility and acceptability for optional meetup groups (i.e., 70% average meetup group attendance [feasibility] and > 75% average satisfaction with meetup groups [acceptability]).

Aim 2: Evaluate pre/post changes in thwarted belongingness and perceived burdensomeness among card-makers and recipients.

Aim 3: Evaluate pre/post changes in social connectedness and suicide risk among card makers and recipients.

Section 7 - Background and Significance

7) Provide a succinct discussion of relevant background information to justify performing the proposed study.

Veteran suicide is an epidemic; from 2005-2016, suicide rates have risen 26% despite increased prevention efforts. Suicide prevention is VA's highest priority. Efforts to expand and develop innovative services are required to address this ever-growing problem. Thwarted belongingness and perceived burdensomeness are potent transdiagnostic social risk factors for suicide. Unfortunately, few interventions have directly targeted these constructs to reduce suicide risk. The overarching goal of this project is to refine and evaluate Caring Cards, an innovative peer-centered intervention that aims to reduces suicide risk by promoting social recovery among Veterans. Inspired by caring contacts for suicide prevention and the recovery model, Caring Cards employs a novel approach to social recovery by leveraging Veterans' lived experience with mental health conditions. In Caring Cards, Veterans compose messages of hope and unity by handmaking one-of-a-kind cards in outpatient groups. These cards are then sent to their anonymous peers who identified to be at elevated risk for suicide.

In a recent pilot study conducted by Ehret and colleagues (IRB #H190032), preliminary data indicate Caring Cards is highly feasible and acceptable to both Veteran card makers and recipients. These data also suggest Caring Cards benefits both Veteran card makers and

recipients by providing card makers with a safe, creative space to connect with others for a common purpose (targeting belongingness and perceived burdensomeness), and card recipients peer developed cards that facilitate connection to others with similar experiences (targeting thwarted belongingness). Caring Cards is a scalable and low intensity, intervention that bi-directionally targets suicide prevention and promotes social recovery among two at-risk Veteran populations.

Our pilot study did not have any adverse events; all (100%) of the card recipients said receiving the card was a positive experience. A total of 14 (77.8%) said the card had an impact on their experience following discharge and recovery; all "yes" responses for this item were positive. A total of 16 (88.9%) Veterans denied any negative aspects to receiving the card; however, one Veteran mentioned uncertainty about privacy (i.e., asked if the card makers knew who they were; interviewer confirmed their anonymity) and another mentioned they felt some negative emotions, as receiving the card reminded them of their hospitalization.

In addition, when surveyed, all group members (100%) said they would recommend this group to other Veterans. When asked if the group has positively impacted their lives, the majority (90%) said "yes," one Veteran did not answer this question; none said "no." The majority (90%) said they believed this group should be a permanent clinic offering. When asked how long they would like to stay in this group, the majority (50%) said "other," (four Veterans wrote in an undetermined amount of time [e.g., "forever," "ongoing"] and one said, "not sure"). Other Veterans indicated they would like to participate in the group for "more than 6 months" (10%), "4-6 months" (10%), and "1-3 months" (30%). No Veterans said they would like to stay in the group for "less than 1 month."

Provided the positive feedback we received from our two cohorts of Veterans (card recipients and makers), Caring Cards is a minimal risk intervention that is highly acceptable to Veterans at elevated risk for suicide.

This simple, yet potentially powerful intervention may help to meaningfully reduce suicidal ideation, attempts, and completions, as well as psychiatric hospital readmissions, contact with psychiatric emergency services among Veterans at increased risk for suicide. We successfully established feasibility and acceptability of Caring Cards with Veterans discharging from the VASDHS' inpatient psychiatry unit (pilot project described above). In an effort to understand if Caring Cards is feasible and acceptable with other groups of Veterans at risk for suicide, we aim to examine Caring Cards with a new group of at-risk Veterans, those with inactive high-risk flags (card makers) and those with current high-risk flags (card recipients).

Prior to assessing the impact Caring Cards has on VASDHS' Veterans' suicide risk within these two new populations, noted above, two important initial steps should be taken: 1) determine if it is feasible for Veterans with inactive high-risk flags to make these cards, and to send these cards and collect Veterans with active high-risk flags feedback, and 2) determine if these groups of Veterans find making and receiving these cards acceptable (i.e., satisfaction). The current project aims to address these initial steps, as well as preliminary examine the impact Caring Cards has on suicide risk and social connectedness-related constructs (i.e., thwarted belongingness, perceived burdensomeness, perceived rejection, lonliness, and emotional support) within these two groups.

Last, based on Veterans' feedback from our pilot project, we will be inviting participants to attend optional meet-up groups, as an opportunity to socially connect with one another. Because this type of group has not been examined yet, feasibility and acceptability of these groups will also be investigated.

Section 9 - Design and Methods

9) Describe the research design and the procedures to be used to accomplish the specific aims of the project. Provide a precise description of the planned data collection (include what systems or databases will be used/accessed to gather data), analysis and interpretation. For chart review studies, include the timeframe of collection. Address sample size, inclusion of women and minorities. Define in clear terms exactly what will be done to the human subjects.

We plan to recruit a total of 80 participants- 30 Veterans with inactive high-risk flags (HRFs) for suicide will be recruited to serve as the Caring Cards group members (i.e., card makers), and 50 Veterans with active HRFs will be recruited to serve as as our card recipients. We have developed a targeted/planned enrollment specifically to ensure the inclusion of **women** and racial/ethnic **min orities**. The VA San Diego serves a diverse population of Veterans, including by gender, ethnicity,

age/era and mental health and physical diagnoses. Recent data indicate that 15% of the Veterans accessing the clinic were females and 14% were African-American and 11% were Hispanic/Latino. We will systematically monitor the gender and ethnic composition of the screened and recruited sample and contrast proportions with known gender and ethnic composition of Veterans on the inactive and active high-risk for suicide list. Should substantial discrepancies present (>10%) in regard to the rate of those screened or enrolled compared to the anticipated rate, our investigative team will review procedures and identify potential remedies. Children (persons under the age of 18) will not be recruited into the study.

Recruitment: The VASDHS keeps record of all Veterans with inactive and active HRFs. A waiver of HIPAA authorization will be obtained in order to extract CPRS contact information (i.e., mailing address and telephone number) of Veterans with inactive and active HRFs. The study coordinator will mail a letter to prospective participants introducing the study (see letter attached to protocol submission). Per standard protocol, two weeks after the letter is sent, the study coordinator will contact the prospective participants by phone and invite them to be screened for potential study enrollment.

For inpatient prospects, the study coordinator will consult with the PI and/or the Veteran's treating inpatient teams to determine the appropriate timing of approaching Veteran on the unit. If appropriate, the study coordinator will conduct screening on the unit, and if agreeable to participate, consent and baseline assessments may be completed prior to or following discharge.

In our original protocol, we were approved to recruit participants by mailing them an introductory letter followed by a telephone call two weeks after the letter.

We would like to amend our approach by including recruiting participants via their providers. Specifically, we would like to approach VA healthcare providers/clinics (e.g., Primary Care Mental Health Integration, Center of Recovery Education, Mood Clinic, PTSD Clinic), with information about the study, asking them to share this information with their Veterans.

Providers will share study information verbally and/or via study flyer (see below) with Veterans during their standard clinical interactions. If a Veteran is interested in learning more about the study, providers will ask their permission to have our study personnel reach out to them to discuss screening/enrollment. Providers will alert study personnel to interested Veterans via encrypted VA email or adding them as additional signers to Veterans' CPRS progress notes.

Last, providers will inform Veterans that they can directly reach out to our study personnel if they are interested in participating. Contact information for personnel will be provided on our study flyer described below.

To facilitate recruitment via providers, we would like to share a study flyer with providers/clinics so they can distribute to their Veterans. Please see attached for a draft of our flyers – one for card makers and one for card recipients. Moreover, we have an information flyer for providers, which we have included as well.

Screening: As noted above, Veterans with inactive and active HRFs will be introduced to the study via a letter and subsequent phone call. The study coordinator will screen potential participants based on the following inclusion/exclusion criteria.

Inclusion criteria for card-makers: (1) VASDHS Veteran with an inactive high-risk flag, (2) 18 years of age or older, (3) access to transportation to attend the group, and (4) decisional capacity. *Inclusion criteria card recipients*: (1) VASDHS Veteran with an active high-risk flag, (2) 18 years of age or older, and (3) decisional capacity. *Exclusion criteria for card makers and recipients:* (1) the absence of a mailing address, working phone number, and email address, (2) inability to read and write in English, (3) previous or current experience as either card maker or recipient, and (4) currently employed by the VA San Diego. If COVID-19 precautions are in effect, Veterans will also be screened for access to reliable computer, tablet, or smartphone with camera and internet access, as well as the willingness to participate in this study remotely. Participants' decisional capacity for informed consent in order to meet eligibility for this study will be assessed during consent (separate from screening call) via the University of California San Diego Brief Assessment of Capacity to Consent (UBACC) will be collected by the study coordinator.

Given that we will likely be conducting at least some of our groups via telehealth, we would like to amend our inclusion criteria for card makers by distinguishing between in person groups vs. telehealth groups for criterion #3, which will be amended to (3) access to transportation to attend the group (if being held in person).

We would also like to amend our exclusion criteria for card makers by adding (5) if participating in group via telehealth, the absence of access to reliable computer, tablet, or smartphone with camera and internet access.

Enrollment- Consent and Baseline Assessment: Following the screening procedures outlined above, Veterans will be invited to participate as either a card maker or recipient (depending on their HRF status). Consent and baseline assessments will be completed either via phone, VA Video Connect (VVC), WebEx, or in-person. If consent is obtained via phone or VVC, or WebEx, we will adhere to current approved guidelines (i.e., use My Health-e-Vet, using MS Azure, have Veteran send signed consent form via email, have Veterans fax, or have the study coordinator take a screen shot of the signed consent during their VVC or WebEx session).

Following consent, Veterans will complete a baseline assessment battery that consists of the following questionnaires: Beck Scale for Suicidal Ideation (BSS), Columbia-Suicide Severity Rating Scale (C-SSRS), Interpersonal Needs Questionnaire (INQ-15), and NIH Toolbox Adult Social Relationship Scales.

If a Veteran is conserved, the study coordinator will obtain their conservator's consent for study enrollment, as well as the assent of the conserved Veteran.

Caring Cards Groups (Veteran card makers with inactive HRFs): Our study will include three groups, each with 10 Veterans; they will meet separately for 120 minutes once per week at the VASDHS for six months. If groups are unable to take place in-person due to COVID-19 precautions, groups will take place using the VA-approved virtual platform, WebEx. Groups will be facilitated by a post-doctoral or intern-level therapist supervised by the PI, who is a licensed clinical psychologist. If groups are unable to meet in-person, art supplies and cards will be mailed to the group members at their mailing address. If groups take place remotely, this may increase recruitment; however, due to the scope of this pilot project, enrollment will be capped at 10 Veterans per group (a total of 30 card makers). Group members will be assessed for suicide risk at enrollment and follow-up. In addition, the groups' facilitator will remind Veterans at the start of each group to please let them know before the end of group if they are experieicing any thoughts of suicide or homicide. If group is conducted virtually, the Veteran may ask the facilitator to call them after the group has concluded. If suicide is reported, the group's facilitator will further assess their risk by completing a C-SSRS; if the Veteran's C-SSRS is positive, the facilitator will contact the PI for further risk assessment and Safety Planning.

Sending Caring Cards (Veteran card recipients with active HRFs): A total of six cards, one per month, for six months will be mailed. Veterans recruited from psychiatric inpatient care will be mailed a card within the week following their discharge; cards will be sent on a monthly basis thereafter. This is consistent with post-discharge caring contacts recommendations. The study coordinator will contact Veterans via phone two weeks after the card was sent to confirm they received it. Because card-recipients are receiving regular contact by VA Suicide Prevention Coordinators and will receive formal suicide risk assessment at enrollment and follow-up, they will not be directly assessed for suicide risk following the mailing of each card.

Optional Meet-Up Groups (card makers and recipients): All study participants will be invited to attend one or more monthly, 120-minute optional, unstructured meetup groups at the VASDHS facilitated by a therapist. A total of four meet-up groups will be offered throughout the study's duration. Again, if COVID-19 precautions are in effect and these groups cannot meet in person, they will be invited to meet via WebEx. Meet-up groups will begin with an introduction to the purpose of the group (i.e., the facilitator will explain that this is an opportunity for the card makers and recipients to meet one another) followed by a review of basic group rules (i.e., limits of confidentiality will be reviewed, group members will be informed that they are free to come and go as they please, meaning they can arrive later than the designated start time and leave earlier than the end time, and the facilitator will be available if anyone has any questions or concerns). The facilitator will remind meet-up group attendees that if they are having thoughts of suicide or homicide, they should speak directly to them. If group is conducted virtually, the Veteran may ask the facilitator to call them after the group has concluded. If suicide is reported, the group's facilitator will further assess their risk by completing a C-SSRS; if the Veteran's C-SSRS is positive, the facilitator will contact the PI for further risk assessment and Safety Planning.

Follow-up Assessments: All follow-up assessments will be collected in-person or via remote methods described above by the study coordinator.

Follow-up assessment battery includes: Beck Scale for Suicidal Ideation (BSS), C-SSRS "Since Last Contact," Interpersonal Needs Questionnaire (INQ-15), NIH Toolbox Adult Social Relationship Scales, and Intervention Satisfaction Questionnaire (developed by PI).

Card makers: Veterans are expected to participate in the Caring Cards groups for six months. Follow-up assessments will be collected within one month of the last group meeting. If a card maker drops out prior to the group's end date, follow-up will be collected within one month the last group meeting they attended. **Card recipients**: Follow-up assessments will be collected within one month after the delivery of the final card. If a card recipient drops out prior to this, follow-up will be collected within one month after the last card they received.

Feasibility & Acceptability: Feasibility for card makers will be assessed by the proportion of enrolled Veterans who attend all scheduled Caring Cards groups. Feasibility for recipients will be assessed by the ratio of cards sent and received. For all participants, feasibility will be measured by the proportion of Veterans 1) referred for screening, 2) determined eligible, 3) enrolled /completed baseline, and 4) complete follow-up assessments. Feasibility of the optional meet-up groups will also be evaluated based on average attendance. Acceptability for all participants will be assessed by the Intervention Satisfaction Questionnaire, a measure that will be developed by the research team to assesses Veterans' satisfaction with their participation in the Caring Cards and meet-up groups (if attended), as well as asks for feedback about Caring Cards and assesses reasons for study dropout or non-attendance to meet-up groups.

Participant Compensation: Participants will be paid a total of $120 to complete the baseline and follow-up assessment ($60 each). No recruitment will take place year two. We would like to pay participants $120 at baseline, or $60 at each assessment (baseline and follow-up).

Fidelity: For groups, Caring Cards is a manualized intervention and the facilitator (trained by the PI) will run the groups. The PI will review audiotapes of treatment delivery using a fidelity rating scale, and feedback will be shared in weekly supervision. To assess fidelity for sending cards, quantity, timing, and receipt of the cards will be recorded by the study's research assistant. The study coordinator will monitor the accuracy of this record.

In our original protocol we were approved to use VA-approved audio recording devices to record the groups to ensure fidelity. Given that some groups are likely to take place via telehealth, we would like to amend our protocol to include recording groups via WebEx. VA WebEx has a recording features and for all telehealth groups, we propose to use this feature to record the sessions. The recordings of these WebEx groups will be stored via within the VA WebEx account used to facilitate the group. These recordings will be stored via password protection behind VA firewall and encrypted VA-specific WebEx account (i.e., veteransaffairs.webex.com). Only study personnel will have access to these recordings.

12.15.21 Amenment Meet-up Groups for Former Participants: We plan to invite former study participants - i.e., those who have completed thier follow-up assessments, to participate in our optional meet-up groups. As noted above, we plan to hold 120-minute optional, unstructured meetup groups at the VASDHS (Rio or LJ clinics) facilitated by a therapist/research personnel. One to four meet-up groups may be offered throughout the study's duration. Meet-up groups will begin with an introduction to the purpose of the group (i.e., the facilitator will explain that this is an opportunity for the card makers and recipients to meet one another) followed by a review of basic group rules (i.e., limits of confidentiality will be reviewed, group members will be informed that they are free to come and go as they please, meaning they can arrive later than the designated start time and leave earlier than the end time, and the facilitator will be available if anyone has any questions or concerns). The facilitator will remind meet-up group attendees that if they are having thoughts of suicide or homicide, they should speak directly to them. If group is conducted virtually, the Veteran may ask the facilitator to call them after the group has concluded. If suicide is reported, the group's facilitator will further assess their risk by completing a C-SSRS; if the Veteran's C-SSRS is positive, the facilitator will contact the PI for further risk assessment and Safety Planning.

Former participants who agreed at consent to be re-contacted will be called via telephone and invited to join these optional meet-up groups. See telephone script. In addition feasibility and acceptability data will be collected from those who join. Specifically, we will record attendance (feasibility) and one to two weeks following the final meet-up group offered, former participants will be called and invited to answer follow-up questions based on their participation the meet-up groups (acceptability). See script.

Section 9.8 Questionnaires & Surveys

9.8) Provide the name and a reference for questionnaires/surveys that are standard or identify them here and attach a copy of the questionnaire/survey. ***Questionnaires or surveys that are not clinical standard references must be uploaded. Reference the help link for additional information related to surveys administered to VA personnel and approved platforms for web-based surveys.***

1) University of California San Diego Brief Assessment of Capacity to Consent

Jeste DV, Palmer BW, Appelbaum PS. A new brief instrument for assessing decisional capacity for clinical research. Archives of general psychiatry. 2007;64(8):966-974.

2) Columbia-Suicide Severity Rating Scale (C-SSRS)

Posner K, Brent D, Lucas C. Columbia-suicide severity rating scale (C-SSRS). New York, NY: Columbia
University Medical Center;2008.

3) Beck Scale for Suicide Ideation (BSS)

Beck, A. T., Kovacs, M., & Weissman, A. (1979). Assessment of suicidal intention: the Scale for Suicide Ideation. Journal of consulting and clinical psychology, 47(2), 343.

4) Interpersonal Needs Questionnaire (INQ-15)

Van Orden KA, Cukrowicz KC, Witte TK, et al. Thwarted belongingness and perceived burdensomeness:
Construct validity and psychometric properties of the Interpersonal Needs
Questionnaire. Psychological assessment. 2012;24(1):197-215.

5) NIH Toolbox Adult Social Relationship Scales

Cyranowski JM, Bode R, Butt Z, et al. Assessing social support, companionship, and distress: National
institute of health (NIH) toolbox adult social relationship scales. Health psychology. 2013;32(3): 293-
301.

6) C-SSRS "Since Last Contact"

Posner K, Brent D, Lucas C. Columbia-suicide severity rating scale (C-SSRS). New York, NY: Columbia
University Medical Center;2008.

7) Intervention Satisfaction Questionnaire

- Will be developed and added as an amendment to protocol by the research team.

8) Telephone screening Questions (developed by PI; attached to protocol submission)

Section 9.9 Data Safety Monitoring Board or Plan

9.9) Provide a Data Safety Monitoring Plan (DSMP) or the details of a Data Safety Monitoring Board; if a written plan is available, attach a copy of the plan to the submission form.

Monitoring of Suicidal Ideation: This is a challenging aspect the study and so we have developed our procedures to be consistent with the recommendations of organizations such as NIH in clinical research in people with elevated suicide risk (e.g., Issues to Consider in Intervention Research with Persons at High Risk for Suicidality). We will further refine our procedures by use of deployment focused discussions with stakeholders in the study start up phase and in collaboration with the Data Safety Monitoring board. The referral sources for this study are VASDHS' Veterans with inactive and active high-risk suicide flags. Veterans with active high-risk suicide flags are closely monitored and regularly assessed for suicide risk by the VASDHS' Suicide Prevention Coordinator (SPCs). At baseline, participants are administered the C-SSRS55. Veterans are informed during consenting that all suicidal behavior is documented in Suicide Behavior Reports in CPRS if not already entered. If ideation exceeds a score of 2, the PI will be contacted and will perform a telephone evaluation and refer the screened potential participant to the SPCs or emergency services as necessary. Our safety monitoring guide details these procedures, how they are recorded, and what the staff, facility, and investigator responsibilities are. All Veterans are provided the contact information for the Veterans' Crisis Line. Any new suicidal behavior will be documented in the Suicide Behavior and Overdose Report in CPRS by research staff. Participants who elect to withdraw from the study will continue to receive suicide prevention services per VA San Diego's protocol. We will monitor these protocols during the course of the study and will make adjustments to inclusion/exclusion criteria or safety protocol in case of adverse events.

All research personnel will complete VA TMS trainings pertinent to suicide prevention.

Confidentiality: In order to protect confidentiality, all participant data will be de-identified by

assigning each participant a unique ID in computer files, and all physical files from the study will be kept in a locked cabinet in study offices at the Veterans Medical Research Foundation building in San Diego. All electronic data and files will be stored on a secure server. Only study investigators and personnel will have access to these data. All documentation will identify participants only by their Unique ID number and not other personally identifying information.

Section 9.11 Pictures and Audio/Video Recordings of Patients

9.11) Describe the purpose of photographs (facial), or audio, or video recordings of patients. Describe whether the recordings will contain, or potentially contain, identifiers. ***Note: use of photographs or recordings must be covered in the informed consent process and documented consent documents (e.g., consent form, information sheets, telephone screen scripts).***

To ensure fidelity of the Caring Cards groups, the PI will review audiotapes of the group leader's treatment delivery using a fidelity rating scale; feedback will be shared with the group leader in weekly supervision. Audio recordings of the Caring Cards groups will contain Veterans speaking; Veterans in the group may say the names of one another; however, other identifying information (e.g., SSN) will likely not be shared out loud by group members.

The delivery of the assessments (baseline and follow-up) will also be audio recorded for quality assurance and fidelity.

In our original protocol we were approved to use VA-approved audio recording devices to record the groups to ensure fidelity. Given that some groups are likely to take place via telehealth, we would like to amend our protocol to include recording groups via WebEx. VA WebEx has a recording features and for all telehealth groups, we propose to use this feature to record the sessions. The recordings of these WebEx groups will be stored via within the VA WebEx account used to facilitate the group. These recordings will be stored via password protection behind VA firewall and encrypted VA-specific WebEx account (i.e., veteransaffairs.webex.com). Only study personnel will have access to these recordings.

Section 9.12 Off Station Activities

9.12) Describe each off-station activity including where it occurs, subject involvement, and any additional required protections. ***Note: if the off-station activity is being conducted under the approval authority of another institution, this is not VA offsite research and should be described as collaborative research effort. Please contact the HRPP office if you have any questions***

Off-station activities will only apply if COVID-19 precautions are still in effective and participants cannot safely participate in the study in-person.

In this case, off-station activity (e.g., Veterans' homes) will refer to: 1) Caring Cards group participation via WebEx, 2) optional meet-up groups via WebEx), and 3) collection of assessments via phone, VVC, or WebEx.

Section 10 - Human Subjects

10) Describe the characteristics of the proposed subject population. Include age, gender, ethnicity, and health status as appropriate. ***Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still describe the characteristics related to the subjects whose charts you will review.***

- **Provide inclusion and exclusion criteria as appropriate. Provide a statement how non pregnancy is confirmed if pregnancy is an exclusion criteria.**
- **For multisite studies, provide the total number of subjects from all sites and include description of the local site's role as a coordinating center if applicable.**
- **Indicate the number of VA participants to be studied.**
- **Indicate the estimated number of consented subjects that will fail the screening process, if any.**

The subject population in this study will be a total of 80 male and female Veterans (30 with

inactive high-risk suicide flags and 50 current high-risk suicide flag). Potentially eligible participants will be screened by research staff. Our inclusion and exclusion criteria were selected in order to increase the generalizability of our sample and broad reach. Participants will be of either gender and any race/ethnicity, decisional capacity, and at least 18 years of age. Complete Inclusion/Exclusion Criteria are as follows:

Inclusion criteria for card makers: (1) VASDHS Veteran with an inactive HRF, (2) 18 years of age or older, (3) access to transportation to attend the group, and (4) decisional capacity.

Inclusion criteria for card recipients: (1) VASDHS Veteran with an active high-risk flag, (2) 18 years of age or older, and (3) decisional capacity.

Exclusion criteria for all participants : (1) the absence of a mailing address or working phone number, (2) inability to read and write in English, (3) previous or current experience as either a card maker or recipient (in original pilot project), and (4) currently employed by the VA San Diego.

If COVID-19 precautions are in effect, Veterans will also be screened for access to reliable compter, tablet, or smartphone with camera and internet access, as well as the willingness to participate in this study remotely. Participants' decisional capacity for informed consent in order to meet eligibility for this study will be assessed during consent (separate from screening call) via the University of California San Diego Brief Assessment of Capacity to Consent (UBACC) will be collected by the study coordinator.

Section 10.2 Pregnant Women

10.2a) Are pregnant women the focus of the research?

○ Yes ◉ No

10.2b) Provide the justification for including pregnant women and address any special risks, protections, and safeguards.

Being pregnant is not an exclusion criterion for this study; they are not an explicit focus of this research. There are no risks associated with this study that would apply specifically to pregnant women.

Section 11 - Recruitment

11) Describe, step-by-step, the plans for recruitment of subjects (or selection of subjects as in record review). This description must include how, when, and where potential subjects are approached as well as procedures for identifying potential participants (through medical records, physician referral, third-party sources, etc.). Include how selection is equitable. Indicate if vulnerability to coercion may be present and if so plans to ensure voluntary participation.

Recruitment: The VASDHS keeps record of all Veterans with inactive and active HRFs. A waiver of HIPAA authorization will be obtained in order to extract CPRS contact information (i.e., mailing address and telephone number) of Veterans with inactive and active HRFs. A letter to prospective participants introducing the study (see letter attached to protocol submission) will be sent. Letters to Veterans with inactive HRFs will be sent by the Chief of Psychology, Eric Granholm, who is a co-I of this project. Letters sent to Veterans with active HRFs will be sent by their Suicide Prevention Coordinators who are in regular contact with HRF Veterans (via phone and mail). Per standard protocol, two weeks after the letter is sent, the study coordinator will contact the prospective participants by phone.

For inpatient prospects, the study coordinator will consult with the PI and/or the Veteran's treating inpatient teams to determine the appropriate timing of approaching Veteran on the unit. If appropriate, the study coordinator will conduct screening on the unit, and if agreeable to participate, consent and baseline assessments may be completed prior to or following discharge.

In our original protocol, we were approved to recruit participants by mailing them an introductory letter followed by a telephone call two weeks after the letter.

We would like to amend our approach by including recruiting participants via their providers. Specifically, we would like to approach VA healthcare providers/clinics (e.g., Primary Care Mental Health Integration, Center of Recovery Education, Mood Clinic, PTSD Clinic), with information about the study, asking them to share this information with their Veterans.

Providers will share study information verbally and/or via study flyer (see below) with Veterans during their standard clinical interactions. If a Veteran is interested in learning more about the study, providers will ask their permission to have our study personnel reach out to them to discuss screening/enrollment. Providers will alert study personnel to interested Veterans via encrypted VA email or adding them as additional signers to Veterans' CPRS progress notes.

Last, providers will inform Veterans that they can directly reach out to our study personnel if they are interested in participating. Contact information for personnel will be provided on our study flyer described below.

To facilitate recruitment via providers, we would like to share a study flyer with providers/clinics so they can distribute to their Veterans. Please see attached for a draft of our flyers – one for card makers and one for card recipients. Moreover, we have an information flyer for providers, which we have included as well.

Section 11.1 Recruitment Materials

11.1) Identify all recruitment materials (flyers, advertisements, letters, etc.) that will be used; include the web address for any web-based advertisements. The text of all communications with prospective participants must be reviewed and approved by the IRB before it can be used. You will be reminded to attach copies of recruitment materials to the initial submission packet. ***Note: Posting of flyers with pull tabs is not permitted within VASDHS (including the VMRF building). However, you may request to advertise on the e-boards (located at the elevators and throughout the facility) or on the VASDHS Research Opportunities web-page.***

Below are the two introductory letters that will be mailed to each set of prospective participants (i.e., Veterans with inactive HRFs and active HRFs).

Introductory Letter for Caring Cards Study
Card Makers (Inactive HRF)
XX/XX/20XX

Dear [INSERT VETERAN'S NAME],

My name is Dr. Eric Granholm. I am the Chief of Psychology at the San Diego VA. The reason for my letter is to inform you about a new research study taking place at the San Diego VA. Based on our records, you were identified as someone who may be eligible to participate.

The study is called "Caring Cards." This project focuses on creating opportunities for Veterans to help other Veterans who share similar mental health experiences.

What is Caring Cards?
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.

We would like to invite you join a weekly group where you and other Veterans will make caring cards for your fellow Veterans. These cards will then be sent to anonymous Veterans at the San Diego VA; they will not know your identity.

Caring Cards Group
Caring Cards group will meet once per week for 2 hours for 6 months. Groups will be held at either the main San Diego VA hospital in La Jolla or at one of our Mission Valley clinics. You may choose which location is most convenient for you. If we are unable to safely meet in person due to COVID-19, the groups may meet remotely (i.e., WebEx or VA Video Connect).

These groups are considered to be a standard clinical service, so you may be eligible to receive travel reimbursement for your attendance.

What would I need to do if I participated?

If you are eligible and choose to be in the study, you will be asked to participate for approximately 7 months. During this time, you will be asked to attend weekly Caring Cards groups. Each group will last 2 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 from when 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.

You will also be invited to attend one or more monthly, 2-hour meet-up groups at the San Diego VA (La Jolla). These groups are completely optional, and you do not have to attend them as part of your participation in this study. 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.

As a thank you for your participation and taking the time to answer the two sets of questionnaires, you can earn up to $120 ($60 for each set of questionnaires completed).

Will my information be kept secure?
We will keep your answers confidential and will not share your personal information with anyone outside of our research team. Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your survey responses will be identified by a randomly generated number that will not be associated with any of your identifying information. Any research records that identify you will be kept only as paper records in a secure San Diego VA location or as electronic files behind the secure San Diego VA computer firewall.

What happens after this letter?
In approximately two weeks, a member of our research team will reach out to you by phone to determine if you're interested in participating in this study. Participating in this study is optional. If you do not want us to call you, please feel free to let me know by calling me at the telephone number below, or you may decline via phone when the research team member reaches out.

Questions?
If you have questions, suggestions, or concerns regarding this study, or if you do not want us to contact you by phone to determine your interest and eligibility to participate in this study, please let me know.
You may reach my research associate, Dr. Blaire Ehret, who is facilitating this study, at 619-228-8080.

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 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

Best,
Eric

Eric Granholm, Ph.D.
Chief of Psychology, VA San Diego Healthcare System

Introductory Letter for Caring Cards Study
Card Recipients (Active HRF)
XX/XX/20XX

Dear [INSERT VETERAN'S NAME],

My name is [INSERT SPC'S NAME]. I am your suicide prevention coordinator at the San Diego VA. The reason for my letter is to inform you about a new research study taking place at the San Diego VA. Based on our records, you were identified as someone who may be eligible to participate.

The study is called "Caring Cards." This project focuses on creating opportunities for Veterans to help other Veterans who share similar mental health experiences.

What is Caring Cards?
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.

We would like to send you a series of these caring cards (one card every month for 6 months). These cards will be made by anonymous Veterans at the San Diego VA; they will not know your identity.

What would I need to do if I participated?
If you are eligible and choose to be in the study, you will be asked to participate for approximately 7 months. During this time, you will be asked to complete two sets of questionnaires to help us determine your satisfaction with receiving these cards and how the cards may make 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 from when 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.

You will also be invited to attend one or more monthly, 2-hour meet-up groups at the San Diego VA (La Jolla). These groups are completely optional, and you do not have to attend them as part of your participation in this study. These groups are meant to give Veterans who receive cards and opportunity to meet the Veterans who made 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.

As a thank you for your participation and taking the time to answer the two sets of questionnaires, you can earn up to $120 ($60 for each set of questionnaires completed).

Will my information be kept secure?
We will keep your answers confidential and will not share your personal information with anyone outside of our research team. Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your survey responses will be identified by a randomly generated number that will not be associated with any of your identifying information. Any research records that identify you will be kept only as paper records in a secure San Diego VA location or as electronic files behind the secure San Diego VA computer firewall.

What happens after this letter?
In approximately two weeks, a member of our research team will reach out to you by phone to determine if you're interested in participating in this study.

Participating in this study is optional. If you do not want us to call you, please feel free to let me know by calling me at the telephone number below, or you may decline via phone when the research team member reaches out.

Questions?
If you have questions, suggestions, or concerns regarding this study, or if you do not want us to contact you by phone to determine your interest and eligibility to participate in this study, please let me know.
You may reach my research associate, Dr. Blaire Ehret, who is facilitating this study, at 619-228-8080.

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 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

Best,
[INSERT SPC'S NAME]

[INSERT SPC'S NAME]
Suicide Prevention Coordinator, VA San Diego Healthcare System

Flyers:

Card Makers

Caring Cards to and from Veterans
A Peer Approach to Suicide Prevention

Researchers at the VA San Diego are studying a group therapy that focuses on Veterans helping other Veterans by making cards with messages of hope and support.

Research is always voluntary!

Would this study be a good fit for me?
The study may be a good fit if you:
• Have an interest in helping other Veterans.
• Like connecting with other Veterans for a common purpose.
• Enjoy drawing, writing, and being creative.

What would happen if I participated?
You would:
• Attend weekly sessions of a card making group, delivered via WebEx or in person for six months.
• Complete a set of assessments at the beginning and end of your participation.
• Allow study staff to audio record your group sessions.
• Be compensated $60 for each set of assessments you attend (up to $120 total).

For more information or to sign up for this study,
contact Dr. Blaire Ehret at (619) 800-6707 or (619) 228-8080.
You can also talk to the provider who gave you this flyer.

Card Recipients

Caring Cards to and from Veterans
A Peer Approach to Suicide Prevention

Researchers at the VA San Diego are studying if anonymous cards made by Veterans help other Veterans.

Research is always voluntary!

Would this study be a good fit for me?
The study may be a good fit if you:
• Would enjoy receiving anonymous cards from other Veterans.
• Would like to connect with other Veterans.

What would happen if I participated?
You would:
• Receive six cards via mail for six months (one card per month).
• Complete a set of assessments at the beginning and end of your participation.
• Be compensated $60 for each set of assessments you attend (up to $120 total).

For more information or to sign up for this study,
contact Dr. Blaire Ehret at (619) 800-6707 or (619) 228-8080.
You can also talk to the provider who gave you this flyer.

Providers

Caring Cards to and from Veterans:
A Peer Approach to Suicide Prevention and Recovery

Researchers at the VA San Diego are studying if anonymous cards made by Veterans with a history of elevated suicide risk help Veterans with current elevated suicide risk. We are seeking referrals for card makers and recipients!

Card Makers
Inclusion criteria:
• VA San Diego Veteran with an inactive high-risk flag for suicide
• 18 years of age or older
• Access to transportation to attend groups (if held in person; groups may be held via telehealth

due to COVID-19)
• Decisional capacity

Exclusion criteria:
• Absence of a mailing address or working phone number
• Inability to read and write in English
• Previous experience as either a card maker or recipient
• Currently employed by the VA San Diego
• If groups are held via telehealth, the absence of access to reliable computer, tablet, or smartphone with camera and internet access

What would being a card maker entail?
Veterans would meet weekly for 120-minutes for six months. In the group meetings they would connect with other Veterans and anonymously create caring cards for the card recipients described below.

Card Recipients
Inclusion criteria:
• VA San Diego Veteran with an active high-risk flag for suicide
• 18 years of age or older
• Decisional capacity

Exclusion criteria:
• Absence of a mailing address or working phone number
• Inability to read and write in English
• Previous experience as a card recipient
• Currently employed by the VA San Diego

What would being a card recipient entail?
Veterans would receive six cards via mail for six months (one card per month).

All participants will:
• Complete a set of brief baseline and follow-up assessments.
• Be compensated $60 for each assessment (up to $120 total).

For more information, please contact Blaire Ehret, Ph.D.
Phone: (619) 800-6707 or (619) 228-8080
Email: Blaire.Ehret@va.gov

Section 12 - Informed Consent

12) Indicate whether or not each category of consent is involved in this study:

12a) Will the study team obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without (or prior to) obtaining informed consent of the prospective subject or the prospective subject's LAR?

(•) Yes ( ) No

Check one or both of the below boxes if they apply to this study:

Information will be obtained through oral or written communication with the prospective subject or the subject's Legally Authorized Representative (LAR) and this is not a FDA regulated study.

(•) Yes ( ) No

Identifiable information or biospecimens will be obtained by accessing records or stored identifiable biospecimens and this is not an FDA regulated study.

(•) Yes ( ) No

If either or both of the above boxes is checked "yes", an informed consent waiver does not have to be requested for this activity if the protocol is initially approved after 01/01/2019 or if it has been converted to the 2018 Common Rule requirements. However, a request for a HIPAA waiver will still need to be requested and informed consent obtained for any research interventions after eligibility is established. Otherwise, waivers of consent and authorization must be requested for this activity. Waivers of consent and authorization are required for screening purposes for FDA regulated research.

12b) **Signed** informed consent

(•) Yes ( ) No

12c) Waiver of documented consent (e.g., **oral** consent) for all or part of the study.

( ) Yes (•) No

12d) Request for a **waiver** of consent for all or some study activities.

( ) Yes (•) No

12e) Alteration of **other required elements** of consent.

( ) Yes (•) No

12f) **Child** assent to participate (Director approval will be required)

( ) Yes (•) No

12g) Will any language **other than English** be used by those obtaining consent and understood by the prospective participant or the legally authorized representative?

( ) Yes (•) No

12h) **Decisional Capacity Assessment** to determine if participants have the capacity to consent for themselves.

(•) Yes ( ) No

12i) **Surrogate** consent (legally authorized representative)

(•) Yes ( ) No

Section 12.1 Informed Consent Process

12.1a) Will consent be obtained before any study procedures are performed (including screening procedures except screening procedures with Consent and/or HIPAA waiver when required)?

(•) Yes ( ) No

12.1b) Will the information being communicated to the participant or legally authorized representative during the consent process include exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights or release or appear to release the Researcher, Sponsor, the VA or its agents from liability for negligence.

( ) Yes (•) No

12.1c) A master list of all VA subjects consented (written or not) under this protocol will be maintained.

(•) Agree ( ) Disagree

12.1d) Identify the circumstances under which consent will be obtained including where the process will take place; any waiting period between describing the research and obtaining consent including sufficient time for the prospective participant to consider participation, and any steps taken to minimize the possibility of coercion or undue influence.

An introductory letter will be sent to all prospective participants, describing the research (see 11.1 Ads & Flyers for details). Letters to Veterans with inactive HRFs will be sent by the Chief of Psychology, Eric Granholm, who is a co-I of this project. Letters sent to Veterans with active HRFs will be sent by their Suicide Prevention Coordinators who are in regular contact with HRF Veterans (via phone and mail).

Prospective participants will have approximately two weeks to consider participation. Following two weeks from the date the letter was sent, a member of the research team will reach out to the Veteran via phone to determine if they are interested in being screened for the study. To minimize the possibility of coercion or undue influence, the letters do not guarantee Veterans any direct benefits and clearly state participation in the study is options. There is also information in the letter for Veterans to opt out of being called by a member of the research team, as well as contact information the local Research Compliance Officer, VA Research Service, VA Regional Counsel and the VASDHS Institutional Review Board should they have any questions or concerns about this study or their prospective participation.

For all study prospective participants, after they have been screened, determined to be eligible to participate, and agree to participate, a member of the research team (e.g., study coordinator) will obtain Veterans' consent to participate in the study and assess decisional capacity for informed consent at this time. Consent may be obtained in person (at VA San Diego La Jolla or Rio clinic locations), via phone, WebEx, or VA Video Connect. As previously mentioned, if consent if obtained remotely, we will adhere to current approved guidelines (i.e., use My Health-e-Vet, using MS Azure, have Veteran send signed consent form via email, have Veterans fax, or have the study coordinator take a screen shot of the signed consent during their VVC or WebEx session).

For inpatient prospects, the study coordinator will consult with the PI and/or the Veteran's treating inpatient teams to determine the appropriate timing of approaching Veteran on the unit. If appropriate, the study coordinator will conduct screening on the unit, and if agreeable to participate, consent and baseline assessments may be completed prior to or following discharge.

If a Veteran is conserved, the study coordinator will obtain their conservator's consent for study enrollment, as well as the assent of the conserved Veteran.

Due to the persistence of the COVID-19 pandemic, we plan to enroll participants via telehealth. In our original protocol, we received approval to obtain consents via telehealth. Per our original protocol, "If consent is obtained via phone or VVC, or WebEx, we will adhere to current approved guidelines (i.e., use My Health-e-Vet, using MS Azure, have Veteran send signed consent form via email, have Veterans fax, or have the study coordinator take a screen shot of the signed consent during their VVC or WebEx session)." We would like to amend this approach to include obtaining consent via the WebEx File Transfer feature. Below are the procedures that will be taken to obtain consent via this method.

Webex Consent Appointment (for participant on laptop/computer)
1. Go to your Personal Room by visiting its URL on your computer's browser outside of your remote connection/CAG and click Join Meeting.
a. https://veteransaffairs.webex.com/meet/first.lastname
2. Go to your Personal Room by visiting its URL on the browser inside your remote connection (CAG).
3. Allow your outside connection entrance into the meeting
4. In the WebEx app inside your CAG connection,
a. click the red X, select Leave Meeting,
b. Select a New Host —> select your outside account
This will transfer hosting privileges to your non-CAG connection and allow you to run the meeting outside of a VA connection.
5. Invite your participant
a. Hit button with 3 dots "More options"
b. Click "Invite and remind"
c. Type in participants email address and hit send
6. Call participant phone-to-phone and help them with downloading process, can let them know they do not need to enable audio or video
7. Obtain location, phone information and emergency contact at start of call
8. Documents to have open inside your citrix desktop
(Fill out participant's name and the date prior to appt.)
a. HIPPA
i. Need signatures on PAGES 4 & 5
b. Informed Consent
i. Need signatures on PAGES 5 & 6
c. Bill of Rights
d. Vendor Form (if participant is not vendorized)
e. UBACC
Instructions for sharing inside Citrix
9. After participant joins webex—> RA shares screen from outside of Citrix by clicking "Share Window" and chooses "Citrix Workspace" desktop
a. Informed consent & HIPPA inside your Citrix desktop should appear on screen

10. Read through informed consent with participant
11. Conduct UBACC to confirm decisional capacity
12. Once decisional capacity is determined and Veteran agrees to be enrolled, set up the document to allow participant to sign the consent
a. Participant will sign and date the consent form by clicking "Sign" on adobe
i. This is done by clicking "Add Signature +"
ii. Clicking the "Draw" tab
iii. Inform them of the slight delay
13. Have participant gain control of the RA's screen
Option 1:
a. Once sharing your citrix screen, go to orange box on top of the screen and click assign
b. Choose "Pass keyboard and mouse control"
c. Choose participant's name
Option 2:
a. Have participant gain control by clicking "Ask to Control" button in the left-hand side of their screen (2nd button from the top)
14. RA grants control either way
a. Participant uses their mouse to draw their signature
b. Participant places their drawn signature on the line on page "Subject's Signature"
15. RA takes back control by going back to the assign button in the orange box and unclicking the participants name/ or having the participant push ESC / or by stopping the screen share
16. RA saves the document into participant folder
17. Read through HIPAA with participant
a. Either repeat steps 11-14, or ask permission from participant to use their signature that was saved from their last signature
b. Save the form into the participant folder
18. Read through Participant's bill of rights
19. Fill out vendor form with participant *if not vendorized
20. Fill out Screen packet with participant
Inform them of their options to 1) have control shifted to them again so they can fill out the packet on their own, or 2) indicate to the RA which answers to put
21. End screen share
22. Conduct
a. Instructions and fillable form open
23. Re-join Webex from inside your citrix connection
a. Hit file —> transfer
i. Select Informed Consent, HIPAA, and Bill of Rights over to participant
ii. Have them click on each file and hit "Download"
24. End Appointment

If participant is using phone or tablet:
Follow steps 1-12 above, then
13. Have participant click the "annotate" option. (it is a squiggly line button for them)
14. Have participant adjust width and color of the pen tool and then draw their signature and place it onto appropriate areas
15. Ensure a blank word document is open and that the page you are screenshotting is zoomed to view entire page
PC: Take a screenshot by hitting "Print Screen" and have screenshot appear in the word document, can save as pdf, crop the sides, and combine into original consent or HIPAA materials
MAC:
a. From inside citrix, ensure that your WebEx screen shows the adobe document
i. Go into that word document
ii. Hit insert —> Screenshot —> screen clipping
iii. Take screen clipping of desired page
iv. Ensure screen clipping inserts into the open word document
v. Can save as pdf, crop the sides, and combine into original consent or HIPAA materials
16. Complete these steps for necessary pages in both HIPAA and Consent Packet, ensuring to review with participant. Resume @ step 17
17. Print out and mail informed consent documents

—
The study investigators are requesting to use DocuSign (eSig) to consent participants. We received approval to use DocuSign (eSig) by ORD on 2/3/2021.

ORD is providing us with 150 envelopes for this study. We've been instructed to work with our local IRB/research office to integrate the SOPs, which have been sent to the IRB team, into the local processes. I have corresponded with Debra Van Etten about next steps for setting up this process.

Below are the steps the research team will take to use DocuSign (eSig) to consent participants:

1) Potential subjects will be mailed our IRB approved introductory letter explaining the study and providing a study staff contact phone number. (These letters have already been IRB approved for both card makers and recipients).

2) During the screening phone call with the potential subject (scripts have already been IRB approved), if the potential subject screens eligible and is interested in learning more about the study, the study team member will schedule a time to go over study documents (Informed Consent Form and HIPAA Authorization [or combined ICF/HIPAA]) using DocuSign.

3) At the time of remote consenting, the study team member/consenter will send a DocuSign envelope (email containing links to the study documents) to the potential subject. The email will contain a reminder for the recipient to not sign the documents prior to the scheduled contact time. (See "Email Script" and "Stand Alone eSig service SOP," section 3 [attached and highlighted for reference]).

4) At the scheduled time, the study team member (referred to as "consenter") will contact the potential subject via phone, VA Video Connect (VVC), or other approved secure communication method (i.e., WebEx). The consenter will guide the potential subject to open the DocuSign envelope (email) and the linked study documents therein. The consenter will open a copy of the study documents on their own computer as a reference. The consenter will review the study documents with the potential subject, ask questions to gauge comprehension, and answer any questions and concerns. If the potential subject agrees to participate in the study, the consenter will guide them to fill in the fields in the study documents (e.g., "Last, First, Middle Initial" name field, Last 4 SSN field, etc.) and to sign the documents. When the subject has signed the documents, they will click "FINISH" to finalize the documents.

5) While still on the phone/VVC (or other approved secure communication method, i.e., WebEx) with the subject, the consenter will receive an email notification to log into DocuSign. The consenter will verify that all fields are completed accurately and, if necessary, subsequently sign the document(s) (e.g., ICF). The consenter will guide the subject on how to download a copy (ies) of the signed document(s) to the subject's personal computer for their record. The consenter will thank the subject and end the call.

6) The consenter will download a copy(ies) of the signed document(s) (see "Stand Alone eSig service SOP," section 3) to a study folder in VA network drive (i.e., R:\Ehret) as study record. If necessary, the consenter can sign the ICF and save it back to this folder. The consenter will also place another copy(ies) of the signed document(s) in another study-specific folder (e.g. W:\) for HIMS to upload the documents into Electronic Health Record (EHR; i.e., VistA/CPRS or Cerner) (or other ways as agreed upon by local HIMS). The consenter should notify HIMS that the documents need to be placed in the EHR (per local agreement). The consenter will then check the EHR one week later to ensure the documents have been uploaded. If the documents have been uploaded, the consenter will remove the documents from the W:\ drive. If the documents have not been uploaded within one week, the consenter will re-notify HIMS to upload the documents into the EHR.

7) The consenter will document the consenting process as a "Research/Informed Consent" note in the subject's medical record (in CPRS). The note will specify that consent was obtained over phone/VVC/WebEx and DocuSign on the specific date. HIMS will attach the signed documents to this note.

Section 12.6 Decisional Capacity Assessment

12.6a) Describe the method(s) for determination of decisional capacity: (see ? for guidance) ***Please note that documentation of the assessement is required.***

Participants must have decisional capacity for informed consent in order to meet eligibility for this study. To ensure this, the University of California San Diego Brief Assessment of Capacity to Consent (UBACC) will be used. The UBACC is a 10-item questionnaire tailored to specific study procedures. It queries participants about the basic procedures, risks, benefits, and purpose of the study, along with participant rights. Each item on the UBACC is scored on a 0 (incapable) to 2 (capable) scale. This will be administered at the time of obtaining informed consent.

The following are the questions and answers to this study's UBACC for card makers and recipients:

Card Makers:

1. What is the purpose of the study that was just described to you?
a. Response (2 = Study about Veterans making and receiving cards for suicide prevention and/or social connection)
2. What makes you want to consider participating in this study?
a. Response (2 = Increased social connection, help others, decreased suicide risk/behaviors)
3. Do you believe this is primarily research or primarily treatment?
a. Response (2 = Research)
4. Do you have to be in this study if you do not want to participate?
a. Response (2 = No)
5. If you withdraw from this study, will you still be able to receive regular treatment?
a. Response (2 = Yes)
6. If you participate in this study, what are some of the things that you will be asked to do?
a. Response (2 = Answer questions and attend a weekly card making group)
7. Please describe some of the risks or discomforts that people may experience if they participate in this study.
a. Response (2 = Feeling bored or fatigued, feeling anxious or discomfort while talking about myself and/or symptoms, feeling uncomfortable drawing upon my lived mental health experience to create caring cards for other Veterans in need.)
8. Please describe some of the possible benefits of this study.
a. Response (2 = Increased social connectedness and sense of purpose, help others, decreased suicide risk and related behaviors).
9. Is it possible that being in this study will not have any benefit to you?
a. Response (2 = Yes)
10. Who will pay for your medical care if you are injured as a direct result of participating in this study?
a. Response (2 = VA San Diego)

Card Recipients:

1. What is the purpose of the study that was just described to you?
a. Response (2 = Study about Veterans making and receiving cards for suicide prevention and/or social connection)
2. What makes you want to consider participating in this study?
a. Response (2 = Increased social connection, decreased suicide risk/behaviors)
3. Do you believe this is primarily research or primarily treatment?
a. Response (2 = Research)
4. Do you have to be in this study if you do not want to participate?
a. Response (2 = No)
5. If you withdraw from this study, will you still be able to receive regular treatment?
a. Response (2 = Yes)
6. If you participate in this study, what are some of the things that you will be asked to do?
a. Response (2 = Answer questions and receive cards)
7. Please describe some of the risks or discomforts that people may experience if they participate in this study.
a. Response (2 = Feeling bored or fatigued, feeling anxious or discomfort while talking about myself and/or symptoms, feeling uncomfortable receiving cards that might remind me of my symptoms)
8. Please describe some of the possible benefits of this study.
a. Response (2 = Increased social connectedness, decreased suicide risk and related behaviors).
9. Is it possible that being in this study will not have any benefit to you?
a. Response (2 = Yes)
10. Who will pay for your medical care if you are injured as a direct result of participating in this study?
a. Response (2 = VA San Diego)

12.6b) If subjects with limited decisional capacity will be enrolled, describe methods for obtaining subject assent or why they are not indicated:

Participants with limited decisional capacity will not be enrolled.

12.6c) If subjects with limited decisional capacity will be enrolled, describe procedures for respecting subject dissent and any additional safeguards or why these features are not needed:

Participants with limited decisional capacity will not be enrolled.

12.6d) If subjects with limited decisional capacity will be enrolled, describe the risk and, if greater than minimal, the relation to potential benefits:

Participants with limited decisional capacity will not be enrolled.

12.6e) If subjects with limited decisional capacity will be enrolled, describe the justification for the inclusion of any incompetent persons or persons with impaired decision-making capacity:

Participants with limited decisional capacity will not be enrolled.

Section 12.7 Consent by Legally Authorized Representative (Surrogate Consent)

12.7a) Where endorsed by the IRB, the following persons may be authorized to consent on behalf of persons who lack decision-making capacity in the indicated order of priority: (a) Health care agent (i.e., an individual named by the individual in a Durable Power of Attorney for Health Care (38 CFR.17.32(a)(iii)); (b) Legal guardian or special guardian; (c) Next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; (d) A close friend [however, California Health and Safety Code §24178 does NOT include the close friend category]

(•) Agree ( ) Disagree

12.7b) Legally Authorized Representatives (LARs) will be told that their obligation is to try to determine what the subjects would do if able to make an informed decision. If the potential subject's wishes cannot be determined, the LARs must be told they are responsible for determining what is in the subjects' best interests. LARs generally assume the same rights and responsibilities as the individuals who lack decision-making capacity in the informed consent process.

(•) Agree ( ) Disagree

12.7c) If feasible, the investigator will explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research (i.e., if they dissent) protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.

(•) Agree ( ) Disagree

12.7d) For subjects with fluctuating decision-making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent will be employed when needed

(•) Agree ( ) Disagree

Section 12.9 HIPAA Authorization

For each category below, indicate whether or not this study involves the indicated process:

12.9a) **Signed** HIPAA Authorization. ***New Template is available in the ? Help section***

(•) Yes ( ) No

12.9b) HIPAA waiver to cover the entire study

( ) Yes (•) No

12.9c) HIPAA waiver for recruitment, screening, and/or for a portion of the study.

(•) Yes ( ) No

12.9d) HIPAA Authorization or waiver is **not required** for some or all of the study subjects (e.g. no health data).

( ) Yes (•) No

Section 12.10 HIPAA Waivers and Alterations

12.10a) Describe the purpose/nature of the HIPAA waiver or alteration and list specifically, what identifiers and health information are being requested under the waiver/alteration and identify whether the waiver is for access, use, and/or collection of this information.

The purpose/nature of the HIPAA waiver is for screening activities; the study coordinator will need access to CPRS to collect and use potential subjects' names, telephone numbers, mailing address, SSNs, as well as CPRS medical records (notes) as they apply to the inclusion/exclusion criteria and the use of VASI. The following will be collected from the Veteran during the initial telephone screen.

Inclusion criteria for card-makers: (1) VASDHS Veteran with an inactive high-risk flag, (2) 18 years of age or older, (3) access to transportation to attend the group, and (4) decisional capacity. Inclusion criteria card recipients: (1) VASDHS Veteran with an active high-risk flag, (2) 18 years of age or older, and (3) decisional capacity. Exclusion criteria for card makers and recipients: (1) the absence of a mailing address, working phone number, and email address, (2) inability to read and write in English, (3) previous or current experience as either card maker or recipient, and (4) currently employed by the VA San Diego. If COVID-19 precautions are in effect, Veterans will also be screened for access to reliable computer, tablet, or smartphone with camera and internet access, as well as the willingness to participate in this study remotely. Participants' decisional capacity for informed consent in order to meet eligibility for this study will be assessed during consent (separate from screening call) via the University of California San Diego Brief Assessment of Capacity to Consent (UBACC) will be collected by the study coordinator.

12.10b) The proposed access, use, and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals.

(•) Agree ( ) Disagree

12.10c) The plan to protect the identifiers from improper use and disclosure is adequate.

(•) Agree ( ) Disagree

Describe the plan

To prevent improper use and disclosure of identifies, only the PI and study coordinator will have access to the database of these identifiers, as stored it on a secure VA computer within a password protected file.

12.10d) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

(•) Agree ( ) Disagree

12.10d2) Describe the plan:

The secure database with identifiers will be destroyed at the earlier opportunity, consistent with RCS-10 guidelines.

12.10e) By signing this protocol for submission, the PI is providing written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the

research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule. 38 U.S.C. 7332 Information: If the waiver of HIPAA authorization is for the use of 38 USC 7332 information (applicable to drug abuse, alcohol abuse, HIV infection, and sickle cell anemia records), by signing this protocol for submission the PI is providing written assurance that the purpose of the data is to conduct scientific research and that no personnel involved may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. (Ref: 38 U.S.C. 7332(b)(2)(B))

(•) Agree ( ) Disagree

12.10f) The research could not practicably be conducted without the waiver or alteration.

(•) Agree ( ) Disagree

12.10f2) Describe how the waiver/alteration enables the research to be conducted

The waiver is essential is for screening subjects and having access to CPRS to collect and use the names, telephone numbers, mailing address, as well as CPRS medical records (notes) as they apply to the inclusion/exclusion criteria (see 12.10a for details on what information will be collected during the telephone screens).

12.10g) The research could not practicably be conducted without access to and use of the PHI.

(•) Agree ( ) Disagree

12.10g2) Describe why it would be impracticable to conduct this research without the PHI described 12.10a. (v3 /8/18)

Access to and use of the PHI is critical to identifying eligible participants, sending them an introductory letter to the study, and conducting a telephone screen thereafter. The present study depends entirely on access to this PHI and could not be completed without it.

Section 13 - Alternatives to Participation

13) Describe the alternatives to participation in this research study (see ? for guidance)

The alternative to participation is to not participate. Veterans with inactive HRFs may participate in other VASDHS mental health groups; Veterans with active HRFs may continue receiving regular outreach by VASDHS' Suicide Prevention Coordinators (e.g., phone calls).

Section 14 - Potential Risks

14) Describe any potential or known risks or discomforts and assess their likelihood and seriousness (see ? for guidance)

There are minimal risks to participating in the Caring Cards group, meet-up groups (optional), or receiving cards.

Disclosure or Identification of Suicidal Ideation or Intent to Harm Self: Participants to be enrolled are at elevated risk of suicide and reporting active suicidal ideation. During structured interviews concerning suicide (via the C-SSRS and BSS) or extemporaneous discussion with rater or other staff, participants may disclose a level of risk of harming themselves that would require a higher level of care. Further, during the intervention, participants may experience an increase in suicidal ideation beyond that which they reported at baseline.

Assessments: The questionnaires are non-invasive clinical assessments associated with minimal risk. All measures are physically non-invasive, have been used in prior studies with seriously mentally ill participants, and have been found to elicit minimal distress and discomfort. Nevertheless, participation in the psychosocial evaluation and responding to questions will require time and attention. Some participants may become bored or fatigued completing the evaluation. Some participants may also become distressed during the psychiatric evaluation, which requires them to discuss their current symptoms.

Intervention Period: Risks involved in participating in this intervention are minimal. During the Baseline assessment and follow-up assessments, participants may experience feelings of anxiety or discomfort while talking about themselves and/or symptoms. Participants may also become fatigued by filling out questionnaires or answering questions in person.

In addition, card makers may experience some discomfort drawing upon their lived mental health experience to create caring cards for other Veterans in need. Card recipients may experience discomfort receiving cards, as it may remind them of their mental health concerns.

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.

COVID-19 Exposure: During the COVID-19 pandemic, all face-to-face visits (i.e., group participation and assessments) present risk for virus exposure.

Section 15 - Risk Management

15) Describe the procedures for protecting against or minimizing any potential risks/discomforts, and the adequacy of resources for conducting the study and resources participants may need as a consequence of the research. When applicable, include detail of the following safety measures: (a) The type of safety information to be collected, including AEs; (b) Frequency of safety data collection; (c) Frequency or periodicity of review of cumulative safety data; (d) Statistical tests for analyzing the safety data to determine if harm is occurring; and (e) Conditions that trigger an immediate suspension of the research. See ? for further requirements.

During the telephone screening portion of our study, risk will be mitigated by using a set of screening questions that will elicit the least amount of sensitive or personal information necessary to assess eligibility. Only qualified interviewers with significant prior experience in treatment or assessment of relevant populations/conditions will conduct these assessments. All study personnel will be trained, observed, and certified by the study's PI, who is a licensed clinical psychologist. The first three months of this study will be included focused training on assessment administration. For example, the C-SSRS has a standard series of training videos that study personnel will undergo to ensure proper administration of this instrument. Standardize trainings will take place for any instruments where this type of formal training is available.

In addition, to further mitigate risk participants will be informed that they do not have to answer any question they do not want to, and can decide, at any time, if they want to withdrawal from the study. The study PI will be available to discuss any concerns participants may have with the study.

If during the course of the study participants experience an adverse reaction during screening, assessment administration, or group participation (i.e., for card makers), imminent risk for suicide is determined, or a suicide attempt (that has not been previously recorded) is disclosed, the research team will adhere to the following to ensure Veterans' safety.

Monitoring of Suicidal Ideation: This is a challenging aspect the study and so we have developed our procedures to be consistent with the recommendations of organizations such as NIH in clinical research in people with elevated suicide risk (e.g., Issues to Consider in Intervention Research with Persons at High Risk for Suicidality). We will further refine our procedures by use of deployment focused discussions with stakeholders in the study start up phase and in collaboration with the Data Safety Monitoring board. The referral sources for this study are VASDHS' Veterans with inactive and active high-risk suicide flags. Veterans with active high-risk suicide flags are closely monitored and regularly assessed for suicide risk by the VASDHS' Suicide Prevention Coordinator (SPCs). At baseline and follow-up, participants are administered the C-SSRS and BSS. Veterans are informed during consenting that all suicidal behavior is documented in Suicide Behavior Reports in CPRS if not already entered.

As such, if any of the following items are endorsed (respective item scores are noted below) on the Beck Scale for Suicidal Ideation (BSS) a LIP will be notified immediately:

- Item 4 (2)
- Item 9 (1 or higher)
- Item 13 (2)
- Item 14 (2)

• Item 15 (2)
• Item 16 (1 or higher)
• Item 17 (1 or higher)
• Item 18 (2)
• Item 20 (1 or higher)

If any of the following items are endorsed on the C-SSRS (initial screener):

• Item 4 (Active Suicidal Ideation with Some Intent to Act, without Specific Plan)
• If a Veteran answers "Yes" to the question about preparatory acts or behaviors within the past month - i.e., "Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?"

If any of the following items are endorsed on the C-SSRS (since last contact):

• Item 4, "Have you had any intention of acting on these thoughts of killing yourself? (As opposed to you have the thoughts, but you definitely would not act on them?)"
• Item 5, "Have you started to work out, or actually worked out, the specific details of how to kill yourself and did you intend to carry out your plan?"
• Item 6 "Have you done anything, started to do anything, or prepared to do anything to end your life?"

Our safety monitoring guide details these procedures, how they are recorded, and what the staff, facility, and investigator responsibilities are. All Veterans are provided the contact information for the Veterans' Crisis Line. Any new suicidal behavior will be documented in the Suicide Behavior and Overdose Report in CPRS by research staff. Participants who elect to withdraw from the study will continue to receive suicide prevention services per VA San Diego's protocol. We will monitor these protocols during the course of the study and will make adjustments to inclusion /exclusion criteria or safety protocol in case of adverse events.

Adverse events in this research project are expected to be extremely rare. However, we have established plans for resolving any adverse event should one occur. First, during screening for the project, trained research personnel will assess (using standardized screening tools) for any serious medical or psychological conditions that may require immediate medical attention or psychiatric treatment. The rationale for this is because the presence of serious medical or psychiatric conditions would make these individuals inappropriate for the proposed research study. Should attention be required, staff will provide these individuals with information about suitable referrals, including local hospitals, clinics, and/or relevant healthcare and mental health professionals, and they will strongly encourage the individuals to follow up with these referrals.

All research personnel will complete VA TMS trainings pertinent to suicide prevention.

Confidentiality: In order to protect confidentiality, all participant data will be de-identified by assigning each participant a unique ID in computer files, and all physical files from the study will be kept in a locked cabinet in study offices at the Veterans Medical Research Foundation building in San Diego. All electronic data and files will be stored on a secure server. Only study investigators and personnel will have access to these data. All documentation will identify participants only by their Unique ID number and not other personally identifying information.

COVID-19 exposure: To mitigate participants' exposure to COVID-19, web (i.e., VVC, WebEx) or telephone-based visits may be used instead of face-to-face visits.

WebEx and DocuSign Consenting:
Veterans may feel uncomfortable using WebEx and DocuSign to sign consent forms. To mitigate this, we will offer alternative routes to obtaining signed informed consent, including the approaches in our original approved protocol (i.e., use My Health-e-Vet, using MS Azure, have Veteran send signed consent form via email, have Veterans fax, or have the study coordinator take a screen shot of the signed consent during their VVC or WebEx session).

Inclusion/exclusion criteria card makers:
With our additional exclusion criteria for card makers, we may exclude Veterans without access to reliable forms of technology. To mitigate this, we will either (1) invite Veterans to consider participating in an in-person group (if offered during study's duration), or (2) remind Veterans of alternatives to participation (i.e., other VASDHS mental health groups).

Section 17 - Potential Benefits

17) Discuss benefits that may be gained by the subject as well as potential benefits to society in general (see ? for guidance)

There is no guaranteed direct benefit to Veterans who participate in this study. This study has the potential to enhance our understanding the feasibility and acceptability of Caring Cards as a potential suicide prevention intervention, and may improve Veterans' satisfaction with VASDHS services.

Participation in CC may not directly benefit to participants. However, benefits to the individual participants may include increased social connectedness and sense of purpose. Participants' suicide risk and related behaviors may decrease. They may be more engaged in subsequent mental health appointments as well.

Section 18 - Risk/Benefit Analysis

18) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

There are minimal risks to participants (e.g., Veterans may feel discomfort answering questions and/or making/receiving cards), and although there are no guaranteed direct benefits, there are potential benefits that could improve Caring Cards, as a suicide prevention intervention, as well as Veterans' satisfaction with VASDHS' services. In addition, participation may enjoy connecting with one another, receiving support from another Veteran, and doing something kind for another Veteran in need. COVID-19 exposure during face-to-face visits is another potential risk for participants. As such, web (i.e., VVC, WebEx) or telephone-based visits may be used instead of face-to-face visits.

Section 20 - Compensation for Participation

20) Provide all details and justifications of the compensation plan. See ? for detailed requirements.

Participants will be paid a total of $120 to complete baseline and follow-up assessments ($60 each). We elected to provide compensation for participation due to the time commitment these assessments will require.

We would like to include two options to pay participants:

Option #1 - pay $120 at baseline
Option #2 - pay participants at two assessment timepoints ($60 baseline and $60 follow-up)

Section 21 - Responsibilities and Qualifications

Here are the identified study staff members

Emily B. Treichler, PhD

Blaire C. Ehret, PhD, Colin A. Depp, PhD, Eric L. Granholm, PhD, Neal M. Doran, PhD, Camila Martinez Ceren, Cara T. Pozun, MA, LMFT, Christen Lee Shriver, Phillip J. Ehret, PhD, Brandon Ferragut, Cindy Chang, PhD, Emma M. Parrish, Samantha A. Chalker, PhD

21) For each staff member listed above, describe their role and qualifications. Also indicate which of the study staff are authorized to obtain consent, when applicable to the study.

Emily B. Treichler, Ph.D.- P.I and clinical psychologist; will oversee management of staff, administrative tasks, database collection, publication(s), and budgetary requirements.

Blaire C. Ehret, Ph.D.- Non-VASDHS Collaborator and former PI; will serve as consultant to study personnel, assist with database preparation, and assist with publications.

Colin A. Depp, Ph.D.- co-I and clinical psychologist; serves as project co-investigator.

Eric Granholm, Ph.D. - co-I and clinical psychologist; serves as co-investigator.

Neal Doran, Ph.D. - co-I and clinical psychologist; serves as co-investigator.

Christen Lee Shriver- Will assist until permanent study coordinator is hired and added to IRB via amendment; will oversee administrative duties of the project (e.g., coordinating to secure provision of funds)

Phillip Ehret, Ph.D.- Health Science Research Specialist; will assist with database cleaning and preparation.

Samantha Chalker, Ph.D.- facilitate Caring Cards groups; provide administrative and data collection support.

Camila Martinez Ceren - research assistant; provide administrative support and may administer assessments under PI's supervision; will co-facilitate Caring Cards group

Cara Pozun, LMFT - Will serve as study coordinator; will oversee administrative duties of the project (e.g., coordinating to secure provision of funds) and facilitate Caring Cards groups

Cindy Chang, Ph.D. - provide administrative and data collection support; will assist with database cleaning and preparation; will collaborate with team for authoring publications

Emma Parrish, M.S. - Provide administrative and data collection support.

Section 22 - Bibliography

22) List relevant articles that the IRB can use to provide necessary background for the protocol. Do not include an extensive NIH-grant-style bibliography. (Up to 5 recommended, but use more if needed to support the protocol or citations above.)

Motto, J. A., & Bostrom, A. G. (2001). A randomized controlled trial of postcrisis suicide prevention. Psychiatric services, 52(6), 828-833.

Denchev, P., Pearson, J. L., Allen, M. H., Claassen, C. A., Currier, G. W., Zatzick, D. F., & Schoenbaum, M. (2017). Modeling the cost-effectiveness of interventions to reduce suicide risk among hospital emergency department patients. Psychiatric services, 69(1), 23-31.

Luxton, D. D., Thomas, E. K., Chipps, J., Relova, R. M., Brown, D., McLay, R., ... & Smolenski, D. J. (2014). Caring letters for suicide prevention: Implementation of a multi-site randomized clinical trial in the US military and veteran affairs healthcare systems. Contemporary Clinical Trials, 37(2), 252-260.

Carter, G. L., Clover, K., Whyte, I. M., Dawson, A. H., & D'este, C. (2013). Postcards from the EDge: 5-year outcomes of a randomised controlled trial for hospital-treated self-poisoning. The British Journal of Psychiatry, 202(5), 372-380.

Reger, M. A., Gebhardt, H. M., Lee, J. M., Ammerman, B. A., Tucker, R. P., Matarazzo, B. B., ... & Ruskin, D. A. (2018). Veteran preferences for the caring contacts suicide prevention intervention. Suicide and Life#Threatening Behavior.

Section 23 - Sponsors and Collaborators

23) Clarify any industry financial or other support (e.g., NIH funds the study or Company X provides the assay kits). Identify non-VA Research collaborators and their role in this protocol, including whether or not they have access to subjects or identified data.

VA RR&D SPiRE

In the submission form, upload a copy of the grant, subaward, CRADA, etc. as appliable to the study.

Section 25 - Impact on Clinical Services

25a) Which VA Clinical Services participate in the performance of the project? (NOTE: All clinical trials and any use of clinical services will require project review and approval by the Office of Research Agreements Management (ORAM) to assure availability of those clinical resources. Prior discussion with the appropriate clinical service chief is strongly encouraged)

Check all that apply

- [ ] Pharmacy
- [ ] Laboratory
- [ ] Cardiology
- [ ] Radiology
- [ ] Nursing
- [ ] Pathology
- [ ] Nuclear Medicine
- [ ] MAS (Charts)
- [x] Other (list below)

List others here

Mental Health

25b) Describe the specific impact or service that will be provided for this protocol.

Caring Cards group will be offered as part of the VASDHS' Mental Health Care Line as therapy groups.

Section 27 - Privacy, Confidentiality, and Information Security

27a) Provide a brief description of how participant privacy and confidentiality will be protected in this study. Describe the circumstance under which it may be possible for a research team member to identify subjects and any related protections or assurances to prohibit or avoid identification. Describe how the number of people with access to identifiers for research purposes is limited in order to protect a participant's privacy.

Veterans' information is stored in a password protected Excel file stored on a secure VA computer. Only the PI and study coordinator will have access to this database. Once data collection has ended, the Research Scientist will be granted access so he can clean and prepare the database. The number of people who have access to this document are limited in order to protect Veterans' privacy.

27.b) Entry of a CPRS Research Informed Consent Note is required when subjects will be admitted as inpatients or treated as an outpatients for research *and* the study involves research medical care or may affect medical care.

- ***If a Research consent Note is required, then a Research Progress Note should also be entered for each procedure or intervention.***
- ***Scanning the Consent and HIPAA Authorization into CPRS is not required. Linking the Consent to the Research Informed Consent Note may be permitted and can be useful for trials involving the Research Pharmacy or when research will be performed in conjunction with clinical procedures.***
- ***For Non-Veterans, if Research Informed Consent Notes are entered, then the NOPP Acknowledgment must be scanned into the record. Otherwise a copy of the signed NOPP must be retained with the Investigator's research records and a copy sent to the Privacy Officer; see the ? Help for more information.***

27.b1) Is entry of CPRS notes required based on the above criteria?

- (•) CPRS notes are needed for ALL subjects
- ( ) CPRS notes are needed for SOME subjects
- ( ) CPRS notes are NOT needed for any subjects

27c) Select the VA Sensitive Information (VASI) use category

- ( ) This study does not collect or use any VASI
- ( ) This study uses but does not save, collect, copy, or record VASI
- (•) This study does collect or record VASI

Section 27.1 VA Sensitive Information (VASI)

27.1a) For each type of VASI, indicate all that apply:

Indicate which of the following will be collected/recorded:

- [x] Protected Health Information (PHI)
- [x] Names
- [ ] Device identifiers and serial numbers
- [x] E-mail addresses
- [ ] Medical record numbers
- [ ] URLs (Universal Resource Locator)
- [ ] All elements of dates (except year) or any age over 89
- [ ] Health plan beneficiary numbers
- [ ] IP Addresses (Internet Protocol)
- [x] Telephone numbers
- [ ] Account numbers
- [ ] Biometric Identifiers including finger and voice print
- [ ] Fax numbers
- [ ] Certificate or license numbers
- [ ] Full face photographic images and comparable images
- [ ] All geographic subdivisions smaller than a state
- [ ] Vehicle ID and serial numbers including license plate numbers
- [x] Social security numbers or scrambled SSNs (describe below)
- [x] Other unique identifying number, characteristic, or code (describe below)

27.1a1) Describe why SSN are needed for this study

So Veterans' charts can be reviewed for project-relevant information (e.g., confirm address, telephone number) in order to send them an introductory study letter and follow-up with them concerning study participation.

27.1a2) Identify the specific other identifier/s that will be used or recorded

Mailing address, high-risk flag status

27.1b) Consent Forms and/or HIPAA Authorization

(•) Yes ( ) No

27.1c) Images with personal identifiers are used for this study (x-rays, MRI images with patient names, record numbers, dates, etc.)?

○ Yes ◉ No

27.1d) Photos with faces or audio video recordings are used for this study.

◉ Yes ○ No

27.1d1) Identify the device or devices that will be used to take/make the photographs or recordings.

Philips Pocket Memo Voice Recorder DPM8000. Secure VA WebEx account for WebEx groups.

27.1d2) Identify where images will be stored (e.g., in the medical record, with study hardcopy records, with study electronic VASI records

Audiotapes will be stored in a locked box within a locked filing cabinet. Only the PI and study coordinator will have access to these. These will be located in VMRF (building 13) C2-228 (cubicle). Secure VA WebEx account for WebEx groups.

27.1e) Biological specimens with identifiers are used for this study.

○ Yes ◉ No

Section 27.2 Data Collection, Tools, and Resources

27.2a) Will any specially obtained software be used?

○ Yes ◉ No

27.2b) Will any mobile devices (laptop, tablet, portable hard-drive, etc.) be used in support of this study?

○ Yes ◉ No

27.2c) Does the study require use of an electronic data capture system?

○ Yes ◉ No

27.2d) Will any other web-based applications be used (e.g., for recruitment, completing online questionnaires, or processing data)?

◉ Yes ○ No

27.2d1) Provide the web address, details regarding their security features, the nature of the data involved, and the research purpose. Also include a description of how VA retains a copy of the data generated using these tools.

If COVID-19 precautions are in effect, and assessments cannot be collected safely in person, baseline assessments will be collected via phone, WebEx or VA Video Connect. Due to the specific C-SSRS version collected at baseline, this questionnaire cannot be completed online (i.e., without assessor). However, the C-SSRS "Since Last Visit" is able to be completed online (without assessor administration). As such, follow-up assessments may be completed via phone, WebEx, or VA Video Connect.

27.2e) Will coded data that excludes personal identifiers be used? Coded data excludes *all* HIPAA identifiers (per VHA Handbook 1605.1 Appendix B), including dates

(•) Yes ( ) No

27.2e1) Identify where the code key is stored and in what format (electronic, paper).

On the research drive behind the VA firewall and is in password protected electronic format. \\R01SDCHSM02.R01.MED.VA.GOV\Research

Section 27.3 Data Sharing and Transportation

27.3a) Does this study involve collecting, sharing or transporting any type of data outside of the local VA?

(•) Yes ( ) No

27.3b) This study collects VASI outside of VA (i.e., at a non-VA location).

( ) Yes (•) No

27.3c) VASI is transported outside of VA for any purpose other than sharing.

( ) Yes (•) No

27.3d) PHI may be disclosed to monitoring/auditing agencies by HIPAA Authorization. *Note: The Research Office must be notified when monitors come to audit*

(•) Yes ( ) No

27.3e) Data may be shared with collaborators or others in the conduct of this protocol.

(•) Yes ( ) No

27.3e1) Describe the data to be shared or disclosed, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data. For PHI and VASI, indicate the authority/ies permitting the sharing or disclosure of data (HIPAA Authorization, Limited Data Set, Data Use Agreement, VA Form 10-5345-Request for and Authorization to Release Health Information., etc.).

Final data sets underlying publications resulting from this research will be shared upon written request. Requests for access must be made in writing signed by a requestor from the United States and include an email address for delivery and an assurance that the recipient will not attempt to identify or re-identify any individual. The request should reference the publication underlying the request. Requests may be made to the Principal Investigator/lead point-of-contact for the publication. If the investigator leaves the VASDHS the requests may be sent to the Associate Chief of Staff for Research.

Section 27.4 Research Record Storage and Retention

For each type of record, indicate whether it is collected for this study

27.4a) Hardcopy records/data (includes paper, pictures, film, etc.)

(•) Yes ( ) No

27.4a1) Identify precisely where hardcopy data will be stored to include physical site, building, and room number, etc. For each location identify whether VASI or non-sensitive information is stored at that location. For VASI, identify how the data is secured.

In a locked filing cabinet inside of VMRF. Specific space to be assigned.

27.4a2) Are all of the above locations at VA?

(•) Yes ( ) No

27.4b) Electronic study records (includes computer files, removable disk files, digital files, etc.).

(•) Yes ( ) No

27.4b1) Identify precisely where ***non-sensitive*** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

Non-sensitive information, which is the standard letter that was includes with each card was stored on the PI's personal H Drive on her secure, VA desktop. See below for full map drive.

\\R01SDCHSM02.R01.MED.VA.GOV\Homedir$\VHASDCEHRETB\My Documents\Research\Caring Cards

27.4b2) Identify precisely where ***VASI*** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

If no VASI is collected or recorded for this study, simply indicate that the “Study does not collect or record VASI”.

A database of VASI is stored on the S drive, CORE folder, behind the VA firewall. See below for full map drive. The database is an Excel document that is password protected and only the PI has the password. The document includes the following information: Veteran name, last 4 of SSN, mailing address, telephone number, presence of high-risk flag, if eligible to receive card, date cards are mailed, date of assessments, all survey questions and the participants' answers, information about attendance to Caring Cards groups, and optional meet-up groups.

R:\Psychology\CORE\Research\Caring Cards

27.4b3) Are any of the locations described in 27.4b outside of the VA Secure Network? *Note: this includes storage on a computer local hard drive.*

○ Yes ◉ No

27.4c) Record Retention - VHA requires compliance with Records Control Schedule (RCS-10) for retention of electronic and hard copy records. Following study closure, these temporary records must be retained for six years and then destroyed. Longer retention may be permitted if requred by other Federal regulations or requirements. Will RCS-10 requirements be followed (i.e., 6-year retention)?

◉ I will adhere to VHA Records Control Schedule-10 requirements
○ I request an exception to RCS-10 requirements

Section 27.5 Additional Privacy or Information Security Details

Provide any other privacy or information security details here.

Section 27.6 Attestations

In the event of real or suspected breach of security, the Information Security Officer, Privacy Officer, VA Police (if appropriate), and the individual’s supervisor will be notified within one hour of learning of the event.

◉ Agree ○ Disagree

Study staff will be up to date on any required VHA Privacy Policy and Information Security training or they will not be allowed access to VA Sensitive Information.

◉ Agree ○ Disagree

Access to research sensitive information, if any, will be removed when study personnel are no longer part of the research team.

◉ Agree ○ Disagree

At least one copy of all study records (whether sensitive or non-sensitive) will be retained under VA control and only destroyed in compliance with the approved Records Control Schedule

◉ Agree ○ Disagree

The VA retains ownership of the research data. Should the investigator leave the VA, custody of the research records will be assigned to another investigator and the Research Service notified in writing, or custody of the

research records will be transferred to the Research Service.

(●) Agree ( ) Disagree

Section 28 - Protocol Association to New or Existing Project

28) Is this a new R&D Project? Before you go on to complete the *Initial Review Submission Form* (which is used for attachments), please address the association of this Protocol to an R&D Committee Project. This Protocol may represent a new R&D Project, or it may be an additional Protocol under an existing R&D Project (such as when a single grant supports multiple Protocols). Will this Protocol be submitted to the R&D Committee as a new Project?

( ) Yes (●) No

Section 29 - Existing Project Association

29) The associated R&D Project should already exist in the database. Identify the R&D Project(s) that correspond to this protocol.

Project Status	Proposal Number	Project Title	Principal Investigator
No Projects are Linked to this Study			

The Protocol Application is now complete for a Protocol attached to an existing Project.

Next you will go on to the Initial Review Submission Form. This form is used to collect the Application and any other needed attachments for submission to the IRB for review.

Press *Save and Continue*