Official Title: “A Randomized Controlled Trial of Coaching into Care with VA-CRAFT to Promote Veteran Engagement in PTSD Care”

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| Title of Study: A Randomized Controlled Trial of Coaching Into Care with VA-CRAFT to Promote Veteran Engagement in PTSD Care | |
| Title of Consent (if different from Study Title): | |
| Principal Investigator: **Eric Kuhn, Ph.D.** | VAMC: VA Palo Alto HCS |

**Title of Study:** A Randomized Controlled Trial of Coaching Into Care with VA-CRAFT to Promote Veteran Engagement in PTSD Care

## Consent Form

### What is this research about?

The purpose of this study is to evaluate a program for family members of Veterans with untreated PTSD to help them understand how to improve their own well-being and help their Veteran get into mental health care. Participants in this study will be randomized to one of two conditions. If you are assigned to the first condition, you will receive four sessions of telephone coaching while completing a web-based program. If you are assigned to the second condition, you will receive Coaching Into Care, an existing VA telephone coaching program for family members of Veterans. The term "randomized" means that condition assignment is based only on chance, like a flip of the coin or the roll of dice, and not based on any characteristic or behavior of the participant. In this case, you will have a 50 percent chance of being assigned to either condition. Participants who are assigned to the telephone coaching with web-based program condition will be asked questions about their experiences being involved with it. We expect to enroll 230 participants in this study.

This study includes collaborating researchers at the Corporal Michael Crescenz VA Medical Center (Philadelphia) who are involved in research activities including delivering telephone coaching and assisting in analyzing study data and the VA Minneapolis who are responsible for conducting telephone interviews and assisting in analyzing study data.

### What is expected of me?

If you wish to participate in this study, you must select "Yes" at the end of this form. The alternative is not to participate in the study. Total study time is estimated at up to 4 hours to complete study assessments and 7 hours to complete the telephone coaching calls and web-based program over approximately 6 months. All of the assessments will be completed online. You may be asked to also take part in a 1-hour telephone interview to better understand your experiences with the coaching and web program. You will be asked to do the following:

1) Complete a baseline assessment of computerized questionnaires. This baseline assessment will ask you questions about your thoughts, feelings, and difficulties related to being in a relationship with a Veteran with untreated PTSD. You have the right to refuse to answer particular questions. We anticipate that it will take you roughly 45-60 minutes to complete the baseline assessment, depending on how quickly you can read, understand, and respond to the online survey.

2) Complete a call with the research coordinator to verify the information you provided in the baseline assessment and to gather information about your Veteran. This call will take 5-10 minutes.

3) If assigned to the telephone coaching with web program condition: You will be asked to complete the web-based program and four 45-minute calls with a telephone coach over 12 weeks. Your use of specific parts of the web-based program will be stored, time stamped, monitored, and saved. Beyond being asked to complete the web-based program, which is estimated to take about 3 hours, any other time you spend using the program is entirely up to you. If you have not started using the program after 3 days from when you were given access to it, the research assistant will call you to see if you are having difficulties and require assistance logging on and using it.

4) Complete a post-treatment assessment. You will be asked to complete a second survey 12 weeks after the baseline assessment. The survey is expected to take roughly 45-60 minutes to complete. You have the right to refuse to answer particular questions.

5) Participants in the telephone coaching plus web-based program condition at 12 weeks will be asked to take part in a 1-hour telephone interview about their experiences in this condition. If you agree to participate in the interview, you will be contacted by telephone to arrange a time to complete the interview with a researcher by phone. The interview will be audio recorded and later transcribed for analysis. All of your comments will be strictly confidential, and the investigators will not share any of your information with anyone unless you informed the investigators that you or someone else is in immediate danger. In that situation, the investigators would contact 911 and provide only as much information as necessary to protect your safety. By agreeing to be in this study, it means that you may be called to participate in a telephone interview. If called, you may choose to decline to participate in the interview at that time.

6) Complete a follow-up assessment 24 weeks after completing the baseline assessment. This survey is expected to take roughly 45-60 minutes to complete. You have the right to refuse to answer particular questions.

Do you understand the purpose of this research and what is expected of you as a participant?

- ❍ Yes
- ❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**What are my responsibilities as a participant in this study?**

As a participant in this study, your responsibilities include:

- Follow the instructions of the investigator and study staff.
- Complete your web surveys as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, you should not take part in any other research study without approval from the principal investigator.
- If you schedule an appointment to talk with research staff (e.g., for the telephone interview), please keep the appointment if at all possible because it can be very difficult to schedule and coordinate these calls.
- If it is necessary to miss an appointment, please contact research study staff to reschedule as soon as you know you will miss the appointment.

Do you understand this list of the participant's responsibilities?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**What are the possible risks or discomforts?**

The risks associated with this study are that answering questions on some of the questionnaires may provoke mild feelings of frustration, sadness, or anxiety. You have the right to refuse to answer any question that makes you feel uncomfortable on any of the questionnaires. In addition, you may feel uncomfortable revealing certain personal information, but your responses will remain strictly confidential and will only be reported when combined with data from other study participants. We do not intend to disclose this information.

Do you understand the possible risks, discomforts, and inconveniences, as we have described them?

❍ Yes
❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**Will I benefit from the study?**

We cannot and do not guarantee or promise that you will receive any benefits from this study. However, you may enjoy using the web program and talking to a telephone coach and find they are helpful in learning more about your Veteran's PTSD symptoms, ways to improve your own well-being and help get your Veteran into mental health treatment. We hope to benefit science through the results of this study.

Do you understand that there is no evidence yet that you will directly benefit from this study?

- ❍ Yes
- ❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**What are my alternatives to being in this study?**

The alternative to being in this study is to not participate in this study.

**Will I get paid?**

Participants will receive a $30 check for completing the baseline survey and a $40 check for completing for the posttreatment survey 12 weeks. If you are invited to take part in and complete the telephone interview at 12 weeks, you will receive another $50 check. Finally, participants will receive a $50 check for completing the follow-up survey at 24 weeks. In order to mail you these checks, we will ask you to provide your home address and you may need to provide your social security number to receive payment.

Do you understand what form the compensation will be in, when the compensation will be given to you, and the information we will need to collect in order to provide compensation?

- ❍ Yes
- ❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**Will I have to pay anything?**

You will not have to pay anything to be in this study. Participants of this study must have access to a computer with Internet connection and phone access in order to participate in the telephone coaching and web-based program, complete study assessments, and to be contacted by study staff.

**Do I have to be in this study?**

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you want to end your participation in the study, you should tell the investigator or study staff. You can do this by calling the principal investigator at (650) 614-9997, extension 23160.

Do you understand that refusing to participate will not have a negative impact on you?

- ❍ Yes
- ❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**Can I change my mind later and stop being in this study?**

Participants can withdraw from the study at any time without penalty or loss of benefits they may be entitled.

Do you understand that you may withdraw from the study any time without losing the benefits you are otherwise entitled to?

- ❍ Yes
- ❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

It is possible that, based on information gained from this study, the researchers may be required to report information about your health and/or safety (e.g., information relating to suicide, physical abuse or sexual abuse) to the appropriate authorities. In such a case, the

researchers may withdraw you from the study and/or contact you and provide a referral for your care. If the investigators had reason to believe that your life or that of another was in immediate danger, the investigators would, by law, be required to contact 911 and disclose enough information about you in order to ensure your safety. Furthermore, the investigator may withdraw you from the study for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff.
- The investigators decide that continuing your participation could be harmful to you.
- You need treatment not provided in this study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Do you understand the reasons why the investigators may withdraw you?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 614-9997, extension 23160.

**Will my information be protected from the public?**

We will keep your name and all the information you tell us in this study confidential. All of your responses to the study surveys will be stored in the online REDCap survey tool maintained by Stanford University. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. Your individual privacy will be maintained in all published and written data resulting from the study. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General, may have access to your information.

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement of the consent, we do not intend to disclose this information.

To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States National Institutes of Health Department of Health (NIH).

With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study. If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

You should understand that we will in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to yourself, children, or others (for example, in the case of child abuse or neglect).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by VA Heath Services Research and Development (HSR&D) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?**

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, Dr. Eric Kuhn (phone number: (650) 614-9997, extension 23160). You should also contact him at any time if you feel you have been hurt by being a part of this study.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

**Permission to Audio Record**

During the coaching calls for the telephone coaching and web-based program condition and the telephone-based interviews, audio recordings will be made of your voice. These recordings will be used for research purposes only. No further use will be made of them. The digital audio files will be stored on a secure, encrypted VA computer network and will be transcribed by VA research transcription service. The audio file will be deleted following transcription and statements from the transcript may be used in scientific presentations and publications ensuring that no identifying information is included.

I give consent to be audio recorded during this study:

- ❍ Yes
- ❍ No

By selecting "Yes" below, I acknowledge that I have read and understood this consent form, and that I wish participate in this study.

- ❍ Yes
- ❍ No

## HIPAA Confidentiality

HIPAA (Health Insurance Portability & Accountability Act) is a federal privacy law that protects the confidentiality of health information collected about you. The following explains how health information collected about you will be used by the investigators and with whom they may share your health information as part of this research.

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you electronically sign this form by typing your name in the box at the bottom of the page, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the consent information. Please read it carefully before electronically signing it.

### What is Purpose of this research study and how will my health information be utilized in the study?

As noted above, the goal of the current study is to assess the effectiveness of a telephone coaching and web-based program for family members of Veterans with untreated PTSD. Knowledge gained from this study may help family members of Veterans with PTSD as well as the Veterans themselves.

### What Personal Health Information Will Be Used or Shared?

The following health information, linked to you by your name, address, phone number and email address about you will be used for this research:

- Gender, race or ethnicity, and age
- Your Veteran's gender, race or ethnicity, and age
- Your Veteran's mental health service utilization
- Caregiver burden
- Quality of life
- Emotional well-being (i.e., symptoms of depression and anxiety)

- Relationship functioning
- Your perceptions of the support you are providing to your Veteran
- Your perceptions of your Veteran's PTSD symptoms
- Your perceptions of your Veteran's alcohol use
- Alcohol use
- Mental health service utilization

Those who have access to your information are listed below.

**Who May Use or Share Your Health Information?**

By typing your name in the box at the bottom of the page, you allow the following individuals and entities to obtain, use and share your health information for this research study:

- The VA Palo Alto Principal Investigator, Dr. Eric Kuhn, and the VA research team, including Dr. Jason Owen, Dr. Maggie Mackintosh, and Dr. Lindsey Zimmerman.
- Research team members at the study's collaborating sites: the Corporal Michael Crescenz VA Medical Center (Philadelphia) (Dr. Steven Sayers) and the VA Minneapolis (Drs. Christopher Erbes, Hildi Hagedorn, & Laura Meis)
- Departments within the VA Health Care System and Stanford University responsible for the oversight, administration, or conduct of research.
- Stanford University School of Medicine's secure REDCap web-based survey platform

The parties listed above may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services.

Your information may be re-disclosed if the recipients described above are not required by law to protect the privacy of the information.

## Expiration

Your authorization for the use and/or disclosure of your health information will continue until the study expires on 02/28/2050.

## Do I have to electronically sign this authorization form?

You may choose to electronically sign this authorization form by typing your name in the box at the bottom of the page. You do not have to electronically sign this authorization form. But if you do not, you will not be able to participate in this research study. Electronically signing the form is not a condition for receiving any medical care outside the study.

## If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Eric Kuhn, National Center for PTSD (MPD-334), 795 Willow Road, Menlo Park, CA, 94025.

By selecting "Yes" below, I acknowledge that I have read and understood this HIPAA Authorization, and that I wish to participate in this study.

- ❍ Yes
- ❍ No

Participant Name: _____

Participant Signature: _____

Note: Please print a copy of this form for your records.