Official Title:

Development of a Novel Couples-Based Suicide Intervention: Treatment for Relationships and Safety Together (TR&ST)

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Study Title: Development of a Novel Couples-Based Suicide Intervention: Treatment for Relationships and Safety Together (TR&ST)

Principal Investigator: [redacted], Staff Psychologist

VA Facility: VA San Diego Healthcare System

Participant Name:	Date:

STUDY SUMMARY

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

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

[redacted] is conducting a research study to find out more about the effectiveness of interventions that target suicidal thinking and behavior among Veteran couples. The study compares couple therapy meetings with a therapist in which suicidal thoughts and strategies for coping with them are discussed versus VA Standard Suicide Intervention. Please note that you will receive calls from a social worker if you have a "high risk" flag on your medical record and you will not receive these calls if you do not have this flag. It is funded and you can receive up to $190 each for completing all assessments.

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

If you decide to participate, you will be randomly assigned to either Treatment for Relationships & Safety Together (TR&ST) or VA Standard Suicide Intervention. If assigned to TR&ST, you will be asked to complete 11 weekly 60–75-minute therapy appointments as a couple. If assigned to VA Standard Suicide Intervention, you will proceed with care as usual in the VA, which may include a safety plan, a referral to outpatient mental health, and telephone contacts with a member of the Suicide Prevention Team as appropriate. Please note that Veterans with a high-risk flag will receive these telephone contacts, regardless of which intervention they are assigned to. You will also be asked to answer some questions about your mental health and your relationship before when you enroll in the study and about 7 weeks, 13 weeks, and 25 weeks after completing the first assessment. Your participation in this research will last about 25 weeks (or six months) total.

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

TR&ST is designed to help reduce suicidal thoughts and behaviors while also aiding couples in improving their relationship satisfaction. If you participate in this study, you might experience a reduction in suicidal thoughts and behaviors. Additionally, as a couple, you might experience more relationship satisfaction, develop better communication skills, and/or resolve issues in your relationship.

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

You may be become bored or upset discussing your history of mental health concerns or treatment. During the study, you may experience an increase in suicidal thinking or engage in suicidal behavior and report this during a research assessment. We may feel anxious or distressed when addressing some of the problems in your relationship. Finally, although we take many steps to keep your information safe, your confidentiality could be

compromised if someone were to learn information you provided during this study (e.g., due to a mandated report).

Because this is an investigational study, there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you. A complete description of risks is included in the Research Details Study Risks section.

Participation is voluntary. If you choose not to participate, you can instead complete alternative couple therapy, individual therapy, or other self-help programs either through the VA or in the community. A complete description of alternate treatment/procedures is provided in the Research Details Alternatives section.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] of the VA San Diego Healthcare System. If you have questions or concerns regarding this study or you want to withdraw from the study, her phone number is [redacted]

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

The Principal Investigator (PI) of this study is [redacted], of the San Diego VA and the co-investigators (Co-I) are [redacted], and [redacted], of the San Diego VA. Together, the PI and Co-Is are asking for your consent to this research. This research is sponsored by VA Rehabilitation Research and Development.

The purpose of the research is to compare the TR&ST intervention and the VA Standard Suicide Intervention in reducing suicidal thoughts and behaviors and improving intimate relationships.

You are being asked to participate because you have expressed interest in completing treatment for suicidal thoughts and behaviors. Approximately 140 people (70 Veterans and their partners) will take part in this research at this facility.

FOR HOW LONG WILL I BE IN THE STUDY?

Your participation will take approximately six months total. During that time, you will complete one baseline assessment, either 11 weeks of TR&ST or VA Standard Suicide Intervention, and three follow-up self-report questionnaires at 7 weeks, 13 weeks, and 25 weeks after the baseline assessment.

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

Screening and Assessment: If you decide to participate in this study, you and your partner will first answer some questions about mental health and your relationship either in-person on paper questionnaires, through video on PDF questionnaires, or through Qualtrics. Some of these questions will be used to determine your eligibility for the study, and some will be used to provide information for the research study. You and your partner will each answer some of the same questions again at 7 weeks, 13 weeks, and 25 weeks after the baseline assessment. Finally, you will be asked to give your feedback (e.g., what you think of the program) at the end of the program and 3 months after you complete treatment. During all these assessments, you can skip any questions that make you uncomfortable, and you can stop at any time.

Intervention: You will be randomly assigned with a 50-50 chance to either a) meetings with your partner and a therapist to complete a program called Treatment for Relationships and Safety Together (TR&ST) for approximately 11 weekly 60-75-minute meetings. You will have the option of completing these sessions in person at the VA San Diego or over clinical video teleconferencing. OR b) VA Standard Suicide Intervention, which may include suicide risk assessment, safety planning, referral to outpatient treatment, and telephone contacts with a member of the Suicide Prevention Team, a VA service that provides outreach to Veterans who have recently endorsed suicidal thoughts or behavior, as appropriate. Please note that Veterans in both groups will receive calls from a social worker if you have a "high risk" flag on your medical record and you will not receive these calls if you do not have this flag.

Participant Expectations: If you decide to participate, we will ask you to do the following:

- ***Participate as a couple.*** Although some intervention activities will be completed individually, both members of a couple must participate in the study and complete the assessments to be eligible. TR&ST sessions will be completed with both couple members and Suicide Prevention Team calls, if applicable, will be completed with the Veteran. Veterans and partners in both groups will complete the assessments.
- ***Attend your appointments as scheduled.*** Just like with any other medical or mental health appointment, please contact us if you need to reschedule. We ask that appointments are not rescheduled more than twice during study participation.
- ***Contact us with any questions or technical difficulties.*** The study investigator, [redacted], can be reached with any questions or concerns at the following phone number: [redacted]. For help with troubleshooting technical problems, you can contact the National Help Desk at (866) 651-3180.

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

The assessments and TR&ST program are part of the research. All the assessment measures have been tested in other research studies, but they are not part of standard clinical care. TR&ST is not part of standard clinical care. The Suicide Prevention Team phone calls and the VA Video Connect telehealth system are part of VA standard clinical care. Any other outpatient mental health programs that Veterans in the VA Standard Suicide Intervention condition choose to engage in will be tracked and are considered part of standard clinical care.

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

Any intervention has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed next. Rare, unknown, or unexpected risks also may occur. You will be informed if the researchers learn of any change in the amount of risk to you.

A. Common risks:

- **Emotional discomfort:** You may feel uncomfortable when answering questions about emotional topics, symptoms, or your relationship, and you may feel upset temporarily when you talk about your problems. Any such discomfort normally goes away as people learn new skills. However, you are free to refuse to answer any of the questions in the assessments.
    - If your suicidal thoughts or behaviors become worse or you have other adverse reactions, please let us know. You can call [redacted] at any time at [redacted]. You can contact the VA at (858) 552-8585 and ask for the "psychiatrist-on-call" or call the Access and Crisis Line (Crisis and Suicide Intervention, Mental Health Information and Referral) at (888) 724-7240. You can also call or text the National Suicide Lifeline at 988 (press 1 for the Veterans Crisis Line). In case of a life-threatening emergency, call 911.
- **Relationship distress:** You and your partner may disagree or argue. Because couples typically argue about the biggest issues in their relationship, we do not expect that this risk will be worse than what you are likely to experience without this study. If you do experience relationship distress as a result of this study, you can contact [redacted], who is an experienced couple therapist.
- **Discomfort with audio recording:** Some people feel uncomfortable about being audio recorded. This is a normal response and discomfort usually goes away over time. By signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by your assessors and your study therapist while you are participating in this study for the purposes of assessment fidelity, intervention standardization, and clinical supervision. You will not receive any royalty, fee, or other compensation for such use. The recordings will not be shared with anyone outside the study. We will keep recordings separate from other materials (e.g., your questionnaires) to help ensure your confidentiality. Recordings will be kept in a locked cabinet in a locked office or on protected folders in the secure VA research server. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used.

B. Less common risks:

- **Loss of confidentiality.** Research records will be kept confidential to the extent allowed by law. The most common reasons for confidentiality to be broken occur in situations where you would be in danger of hurting or killing yourself or others (e.g., suicidality, homicidality) or if you disclose knowledge of abuse or neglect of someone who is currently a minor, considered a dependent adult, or over the age of 65. However, there are some other legal situations in which confidentially may be broken to ensure the safety of the participant or the public. No information that could identify you will be used in papers or presentations about this study without your written consent. This information will not be shared with anyone outside the study. Your questionnaires and interview materials will not have your name on them,

only a code number. Completed questionnaires will be stored on secure local VA research servers accessible only by authorized users on password-protected computers. This consent form will be stored separate from your questionnaires on the VA server.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include reduction in suicidal thoughts and behaviors and relationship conflict as well as improvements in relationship satisfaction, communication, and resolution of relationship problems. In addition, the information we get from your participation in this study may help other Veteran couples access effective couples' interventions for suicidal thoughts and behaviors.

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

Participation is voluntary, and you do not have to participate in this study. If you or your partner do not want to join this research study, you can obtain help for suicidal thoughts and behaviors from a variety of other sources. In-person and virtual therapy (both for suicide and couples) is available from the VA and community providers. In addition, individual therapy to address individual concerns can be helpful for relationships; individual therapy is also available from the VA and from community providers. Finally, you can choose to engage in self-help interventions, such as reading books on suicide or relationships.

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

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

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled. If you are a VA employee, refusal to take part in this study will in no way influence your employment, job performance or reviews, subsequent recommendations, or any other employment decision.

HOW DO I END PARTICIPATION IF I NO LONGER WISH TO BE IN THIS STUDY?

If you decide that you no longer wish to participate in this study, please call [redacted] at [redacted]. We will encourage you to contact us for a final visit if you decide to stop your participation in this study so we can check in with you about your health and well-being. If you begin but do not finish an intervention, you may experience continuation or exacerbation of your relationship concerns. Data collected prior to withdrawal may continue to be used for research purposes, but no new data will be collected.

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RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest. For example, if you do not follow the study instructions, such as attending you research appointments, we will call you to see if you desire alternative care. If circumstances occur that make you ineligible for this research study (e.g., intimate partner violence, uncontrolled psychiatric symptoms, substance dependence, or other safety concerns), we may stop your participation in this study and connect you to other appropriate care.

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

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

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

Participants will receive up to $190 for study participation. Each participant (i.e., Veteran and partner) in the study may receive the following compensation: Baseline, 7-week, and 13-week: $30, 25-week: $40, and post-treatment interviews: $30 each.

Participants will receive the stipend through direct deposit to their bank accounts. This payment will be made directly to your bank account using electronic funds transfer. To receive payment, participants who are not already registered to receive VA reimbursement will register on ID.me and VA's Customer Engagement Portal (CEP) at the time of study enrollment. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation. Under 24 USC 30, payment to Federal Employees and Active-Duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50. If you are a Federal Employee, you understand that you may not receive any other payment or nonmonetary compensation for participation in this research study unless you are off duty or on leave during the time you are participating in the research study.

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

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

RE-CONTACT

You may be eligible for other research studies in the future. Are you willing to be contacted by this research team by phone to discuss other studies?

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

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

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Any information obtained from the research study that can be linked to you will be disclosed only as outlined in the attached Authorization for Release of Protected Health Information for Research Purposes form unless otherwise required by law (e.g., if you tell the researchers that you are a danger to yourself or others).

- If you are a Veteran, a record of your participation (including the name of this study) and your treatment progress will be entered in your computerized patient record, which is standard practice.
- If you are not a Veteran, we will collect all information needed to open a VA medical record for you at the time you enroll in the study (including your social security number). However, we will not create a medical record for you or enter treatment records unless it becomes necessary, such as documenting a safety concern.

We will protect your VA sensitive information by labeling your research records with a code number. The list that matches your name with the code number will be kept in a locked file on the VA server. Any research records that identify you will be kept only as paper records in a secure VASDHS location (in a locked cabinet in a locked office) or as files behind the secure VASDHS computer firewall.

We will keep confidential all research and medical records that identify you, to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, and federal compliance officers may look at or copy portions of records that identify you. Any information about you leaving VASDHS will be coded and will not include your name, initials, address, or any other direct identifiers. It will be assigned a code number that only the site can connect back to you. The research team may also need to disclose information to others as part of the study process. Others who may be allowed to receive this information are federal compliance officers. Research records will be stored in a confidential manner so as to protect the confidentiality of participant information. Any presentations or publications from this information will not identify you.

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For Veterans, we will include information about your study participation in your medical record. While this study is being conducted, you will have access to your research related health records via your medical record.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

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

_____has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it as well as a copy of the Health Insurance Portability and Accountability Act (HIPPA) Authorization that I sign. I will also retain a copy of the California Experimental Subject's Bill or Rights.

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

_____ _____
Participant's Signature Date

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

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

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Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history and mental health diagnosis and treatment. The research team may also need to share your health information and the information it collects to other entities as part of the study progress, including the Institutional Review Board (IRB), Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

Your health information disclosed outside the VA as described in this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address:

[redacted]
VA San Diego Healthcare System
3350 La Jolla Village Drive [redacted]
San Diego, CA 92161

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

While this study is being conducted, you will not have access to your research-related health records.

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

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study; any study information that has been placed into a repository to be used for future research will not expire.

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AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

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

Participant's Signature	Last 4 of SSN	Date

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

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

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

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

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5

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