RESEARCH CONSENT FORM

Providence VA Medical Center

IRB # 00001402

Subject Name: **Date:**

Title of Study: Veterans Coping Long-term with Active Suicide - Veteran

Principal Investigator: Jennifer Primack, Ph.D.

Study Sponsor (if applicable):

1. Purpose of study and how long it will last:

This is a research study supported by the Department of Veterans Affairs, Veterans Health Administration. The purpose of the study is to test the use of a program to reduce suicide in Veterans. You have been invited to participate because you are a Veteran and you have been in the hospital for suicide thoughts or behaviors. If you agree to participate, you will be part of the study for 12 months. A total of 200 Veterans will be part of this study.

2. Description of the study including procedures to be used:

This study is to look at the how well a program is able to reduce suicide thoughts and behaviors in Veterans. Half the Veterans who participate will take part in the program. The other half will get enhanced monitoring of suicide thoughts and risk in addition to their regular V.A. treatment. A computer program will decide which program you will receive. If you agree to be in this study you will complete a screening to see if the study is a good fit for you. Full study participation will include a screening, an initial assessment, and 4 other assessments.

During the screening you will be asked to answer questions about your thoughts of death or suicide. If you are eligible for the study, we will ask you some questions about your mood and thoughts of death. You may also be asked to fill out some forms about different things related to depression and how well you function. The first assessment will take 1-2 hours. After the first assessment, if you are a good match for the study, a computer will pick whether you will get the program or the monitoring. If you are not eligible for the study, you will just complete the interview portion.

The other 4 assessments will take place 3, 6, 9, and 12 months after our first meeting. During those assessments you will answer questions about your mood and thoughts of death. You will also fill out the same forms you filled out at the beginning of the program.

If you are chosen for the program you will be asked to name a family member, partner, or close friend to participate with you. The program is called “Coping Long Term with Active Suicide Program (CLASP).”CLASP is a program that includes 4 meetings and 11 phone calls. If you are chosen for the program you will get 3 one-on-one meetings, 1 family meeting, and 11 phone calls spaced out over 6 months. Your family member will come to the family meeting and will also get 11 phone calls. All meetings and phone calls are to help you feel better, check your progress from week to week, help you solve problems, and keep you safe. Meetings will last 1-2 hours each. We will try to plan the meetings for when you are in the hospital. Phone calls will be 15-30 minutes. They will start once you leave the hospital. We will call you 11 times over 6 months.

If you are not chosen for CLASP, you will still be asked to do all the assessments. We will share the assessment results with your doctor. This will let you provide your doctor with regular information about your mood and safety. We will prepare a report based on your assessments to give to your doctor who will work with you to help you stay safe and feel better. The report will include things like any risk factors, your mood, and any improvement or decline in your functioning.

Interviews and phone calls will be audio taped. Recordings will be carefully reviewed by supervising therapists and researchers to make sure that you are receiving the best service possible. Recordings of your interviews or calls may be reviewed by our team. Recordings will be kept confidential and only our research team will be able to hear them.

During all assessments, including the screening session, you may refuse to answer any question that you do not feel comfortable answering. You may stop your participation at any time. You will not have to tell the study staff your reasons for ending your participation. If your partner decides to exit the study, you may still continue to participate.

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3. Description of any procedures that may result in discomfort or inconvenience:

You may feel sadness or other negative feelings when answering questions about your mood, behavior, or suicidal thoughts. You may also become aware of problems in your life during your participation. We will do our best to reduce any discomfort that you may feel. A goal of the program is to help you solve some of your life problems. If you are selected for CLASP, you will be asked to find a person to participate with you. You may find it hard to discuss personal problems with your support person.

4. Expected risks of study:

Some of the assessments concern sensitive information about you. Most people do not experience any discomfort during these assessments and find them to be helpful. However, it is possible that you may find some questions upsetting or uncomfortable. We will make every effort to minimize discomfort you may feel during the process.

Another possible risk is loss of privacy. We will minimize this risk by keeping all your information strictly confidential and available only to our research staff. All the forms you fill out, questions you answer, and recordings will be kept locked and identified only by a number. There is a risk that your bank account information or social security number can be stolen and misused. If you are chosen for CLASP, you will be asked to name a support person to participate with you. You will be asked to share information with your support person. If you are feeling worse, we may ask your support person to give you extra help. We will always ask you before we share any information with your support person. If you are chosen for the monitoring, we will give your doctor a summary of your assessments. Information shared with your doctor is done to help you stay safe and get the best treatment possible.

A risk of participating is that the program may not improve your symptoms. If we notice that you are feeling worse during the program, Dr. Primack will talk to you about your choices (e.g., different types of treatment available, etc.). We will only disclose information that is related to your mood or mental health.

In addition to the risks listed above, you may experience a previously unknown risk.

5. Expected benefits of study:

We think our program will help you feel better and reduce your thoughts of death and suicide. Early testing of the program indicates that people feel better after doing the program. If assigned to CLASP, you will have regular contact with an advisor. The advisor will work with you to help you feel better. The advisor will also help you to have better contact with your doctors. It is possible you may experience fewer thoughts of death. If you are chosen for the monitoring, your doctor will be given reports. These reports will help you and your doctor work together to get the most out of your treatment. We think that all participants will feel better and less suicidal in either program.

6. Other treatment(s) available:

This program is not intended to replace any of your regular care. We ask you to continue your treatment with your mental health providers. If you don't see any improvement in mood, or if you start to feel worse, you will be given information for other treatments. You may also withdraw from the study at any time. Your involvement in other mental health treatment is encouraged and we are happy to discuss additional treatment options.

7. Costs to participants and compensation:

Costs to Participants: A Veteran participant will not be required to pay for care and services (treatment) received as a participant in this VA research project. However, some veterans are required to pay co-payments for medical care and

services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

Compensation Offered for Participation: You will receive compensation for doing each in-person follow up assessment at 3, 6, 9, and 12 months. You will be compensated $50 using electronic funds transfer (EFT) cash, prepaid debit cards, or gift cards for each assessment. To receive funds by EFT, you will have to provide your bank account number, bank routing number, and social security number on the form provided, so the funds can be sent directly to your bank account. This usually takes less than a week after we have asked the funds to be sent to you. When using EFT, all payments will be reported directly to the Internal Revenue Service. You will receive the compensation after each completed assessment. If you withdraw from the study before the end, you will not receive the remaining compensation.

8. Use of research results:

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law. Information about you is protected in the following ways. All information you provide for this study will be identified by a randomly assigned identification number only. A master list matching your personal information with your research number will be kept separate from your personal information. All study records will be kept in locked file cabinets in locked rooms and in password protected computer files that only the research team for this project can access.

All answers that you give will be kept private. The confidentiality of the information you provide to us will be maintained in accordance with the laws of the State of Rhode Island. Under the law, we must report to the state suspected cases of child or elder abuse. If you tell us you're planning to cause serious harm to yourself or others, we will share this information with clinical staff and/or the proper authorities.

Records will be maintained in accordance with the Department of Veteran Affairs Records Control Schedule 10-1. Your research records and the information within them will not be used for any purpose other than that which is described in the study as approved by the IRB.

9. Right of investigator to terminate participation:

You may be terminated from the study if you fail to complete any phone sessions by the 3 month assessment (if chosen for CLASP), you express an unwillingness to complete any future sessions, or you develop problems that would make it impossible for you to complete the program. If Dr. Primack decides that you should withdraw from the study, she will meet with you to discuss alternative treatment options. If you are terminated early, you will continue to be followed for all remaining assessments.

10. Special circumstances:

Significant New Findings
You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

Participant Withdrawal
Your decision whether or not to participate in this study, or a decision to withdraw will not involve any penalty or loss of benefits to which you are entitled. It is possible that your participation may provide no benefits to you directly or may

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result in a worsening of your symptoms. It is your decision whether you choose to continue or discontinue participation. You may choose to stop your participation in this study at any time.

RESEARCH PARTICIPANT'S RIGHTS: I have read or have had read to me all of the above.
Dr. Jennifer Primack or her delegated study staff has/have explained the study to me and answered all of my questions. 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 told that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. The Institutional Review Board at the Providence VA Medical Center or other federal oversight offices may monitor my records for quality assurance purposes. Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the Office for Research Oversight (ORO), the Office of the Inspector General (OIG) and the Government Accounting Office (GAO) may have access to the records as allowed by law. If an FDA-regulated test article is part of this study, the FDA may choose to inspect research records that include research subject's individual medical records. Records will be maintained in accordance with the Department of Veterans Affairs Record Control Schedule 10-1.

If I experience a side effect or adverse (bad or unexpected) reaction as a result of my involvement in this study, I will report these to the study investigator Dr. Jennifer Primack at (401) 273-7100 ext. 6295 who will arrange for any medical treatment that is necessary. If Dr. Primack is immediately unavailable, I will call the Interim Care Clinic at (401) 273-7100 ext. 3400 during regular business hours. After hours, I will call Providence VA Medical Center at (401) 273-7100 ext. 0 and ask for the psychiatrist on call.

In case there are medical problems or questions, I have been told I can call Dr. Jennifer Primack at (401) 273-7100 Ext 6295 or the Interim Care Clinic (401) 273-7100 ext. 3400 during the day and after hours I have been told to call the Providence VA Medical Center (401) 273-7100 ext. 0, and ask for the psychiatrist on call. If any medical problems occur in connection with this study the VA will provide emergency care. I have also been told that I can call the VA National Suicide prevention hotline at 1-800-273-TALK (8255).

The VA has the authority to provide medical treatment to participants (veterans and non-veterans) injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

I can call the IRB Coordinator at (401) 273-7100 ext. 3470, the Research Administrative Officer at (401) 273-7100 ext. 3478 or the Providence VAMC Patient Advocate at (401) 273-7100 ext. 3093 while I am a participant or after my participation is over for the following: 1) concerns, 2) complaints, 3) problems, 4) suggestions, 5) more information, 6) questions about my rights as a research participant or 7) verifying the validity of the study and authorized contacts.

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I voluntarily consent to participate in this study. I confirm that I have read this consent form or it has been read to me, and I agree it explains what this study is about and how and why it is being done. I will receive a signed copy of the consent form document after I sign it.

Participant's Signature	Participant (printed)	Date
Signature of Person Obtaining Consent	Person Obtaining Consent (printed)	Date

Version Date: May 25, 2013; June 20, 2013; April 25, 2014; April 20, 2015