| VA Department of Veterans Affairs | VA RESEARCH CONSENT FORM |
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| **Version Date 4/10/17** | **Page: 1 of 7** |
| **Subject Name:** | **Informed Consent Date:** |
| **Principal Investigator: Marianne Goodman MD** | **VAMC: James J Peters** |

**Title of Study:**

**Suicide Safety Planning Group Treatment: "Project Life Force"**

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

You are being asked to participate in a research study. This pilot study aims to examine a new treatment for suicidal Veterans called "Project Life Force". Participants in this study will be provided a novel weekly group treatment that focuses on constructing an effective and helpful suicide safety plan. Safety Plans are usually developed to help manage suicidal symptoms. The intervention reviews steps of the suicide safety plan and teaches coping, distress tolerance, interpersonal and emotion regulation skills in order to facilitate creation and better use of the safety plan. The treatment lasts for 12 weeks, and will include education, support, use of computer mobile applications and the ability to include family members, if desired. This is an "add-on" treatment to your ongoing care and augments your current clinical Suicide Safety Plan. We will work closely with your current outpatient mental health team and seek their opinions whether this treatment was helpful to you.

As this is a new treatment approach, this study will examine how well the treatment is in effecting change and whether clinicians and Veterans find the treatment helpful. Your participation will last for 6 months, and include 3 months of Project Life Force treatment and one follow up visit 3 months after completing the treatment trial.

You qualify for participation in this study because you are a veteran and have been placed on the James J Peters VAMC high-risk suicide list and/or have had a recent psychiatric inpatient admission for suicidal behavior/ideation or have recently completed a suicide safety plan as an outpatient for worsening suicidality. 50 veterans who meet these criteria will be studied in this project. This research is being funded by the VA Rehabilitation, Research and Development Service (RR&D).

## 2. Description of the Study Including Procedures to be Used:

If you consent to participant in this research study, the Project Life Force treatment will last for 12 weekly sessions lasting 90 minutes each. You will be asked to complete measures of suicidal thinking depression and hopelessness and

a computer task examining your relationship with your community, four times: at baseline, month 1, month 3 and month 6 (e.g. 3 months after the treatment is finished). We estimate these assessments to last approximately 30-40 minutes each. We are interested in testing whether Project Life Force impacted any of your suicidal or depressive symptoms. In addition, we will ask you to complete very brief ratings of the helpfulness and usability after each of the 12 Project Life Force treatment sessions. This will provide us with feedback to determine if any necessary minor modifications of the treatment approach are needed. All clinical activities for this project will occur in the James J. Peters VAMC Mental Health clinic. Patient research participants will not be discontinuing their current therapies.

**Videotaping of Project Life Force Treatment:**

We are requesting permission for videotaping of treatment sessions for individuals receiving the Project Life Force (PLF) Treatment. You and other people in the study who are receiving PLF may be videotaped during skills training sessions. The purpose of this videotaping is to determine whether the therapists are following the treatment manual. The tapes will be reviewed by a senior research staff member, rated for therapist skill and then destroyed. At all times, tapes will be stored in a locked cabinet until review.

3. **Description of any Procedures that may Result in Discomfort or Inconvenience:**

   The Project Life Force treatment is delivered in a group format, which some Veterans may find uncomfortable. Veterans may find the content distressing and may not want to share details of their clinical condition or symptoms with others. Group members are not required to disclose the contents of their safety plans to others and are never required to speak in sessions. Any specific concerns about your reactions may be shared with your psychiatrist and mental health case manager.

   It is also possible that you may still experience suicidal thinking and urges even with participation in this treatment. The research team has developed a safety management plan for the emergence of suicidal thoughts, urges or acts that occur during the treatment. The research team physician (Dr. Goodman) will be available to perform a suicide assessment at any point if you are experiencing a change in your suicidality. They will ask questions regarding

suicidal ideation and suicide plan and arrange for transfer to the psychiatric emergency room and/or inpatient stabilization at the JJPVA should imminent suicidal behavior be expressed.

4. **Expected Risks of Study:**
   You may feel bored when you complete some of the assessments, and in rare cases, may cause some emotional distress or an increase in suicidal thinking or urges. Should you become suicidal during the assessment procedure, one of the study doctors will evaluate you and if you are an outpatient, you may be escorted to the emergency room for a more detailed examination.

5. **Expected Benefits of the Study:**
   The assessment you receive as part of your participation in this study may not be of direct benefit to you, but the knowledge gained will help us design and implement more effective treatments of Veterans with suicidal ideation.

   There are possible benefits by taking part in this study. We do believe that participation in the Project Life Force 12 week treatment will improve the use and effectiveness of your suicide safety plan, which may help you better manage suicidal feelings and thoughts.

6. **Other Treatments Available:**

   It is entirely up to you to participate in this study. If you choose not to participate, you will be assisted in finding clinical treatment if you wish. Your choice not to participate in this study will in no way compromise your access to treatment.

7. **Use of Research Results:**
   Each participant will be assigned a unique study ID and the linking documents will be stored in password protected areas with limited access.

   We will let you and your physician know of any significant new findings s made during this study which may affect your willingness to participate in this study. Suicidal ideation will be reported to your clinician.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

Records will be retained according to National Archives and Records Administration, Records Schedule Number DAA-0015-2015-0004. In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor or sponsors of this study, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and the Office for Human Research Protections (OHRP).

If this study was initiated on or after March 7, 2012, 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 a summary of the results. You can search this web site at any time.

**8. Special Circumstances:**

A copy of this consent form and HIPPA will be placed in your medical record. Data entered into mobile devices as part of the clinical intervention on Suicide Safety Planning mobile applications will not be accessed by the research team and is not the responsibility of the research team.

**9. Compensation and/or Treatment in the Event of Injury:**

The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA medical center.
If you have questions about this medical care, talk to the principal investigator for this study, Marianne Goodman, MD at 718-584-9000 ext 5188.

## 10. Voluntary Participation:

You are not required to take part in this study; your participation is entirely voluntary you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled. This will not interfere with your regular medical treatment, if you are a patient.

Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study. Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately. Also, a signed copy of this consent form will be given to you.

## 11. Termination of Participation:

**Adherence to Protocol**: If you do not follow through with this assessment program and do not regularly keep your appointments you will be discontinued from the study.

## 12. Costs and Reimbursements:

You will not incur any costs for participation in this study nor be required to pay extra for the Project Life Force treatment. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.

You will be offered financial compensation of $50 for each completed assessment battery. Total reimbursement for participation in all three assessments will be $150. It may take up to six weeks for reimbursements to be received.

## 13. Contact Person(s):

To obtain answers to questions about the research, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following

- During the Day: Marianne Goodman, 718-584-9000 ext 5188.
- After Hours: Marianne Goodman MD, beeper # 877-699-6098.

I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints or to offer input.

**RESEARCH SUBJECTS' RIGHTS:** I have read or have had read to me all of the above. Dr. Marianne Goodman or her delegate has 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 understand 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.

This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

| Subject Signature | Date | Time |
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| Person Obtaining Informed Consent (Print Name) | Signature of Person Obtaining Informed Consent | Date |
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