RESEARCH CONSENT FORM

Providence VA Medical Center

IRB # 00001402

Subject Name: **Date:**

Title of Study: Comparative Effectiveness of Two Treatments for Veterans with PTSD

Principal Investigator: M. Tracie Shea, Ph.D.

Study Sponsor (if applicable): Department of Veterans Affairs

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

You are invited to participate in a research study at the Providence VA Medical Center. Please read this consent form carefully and do not hesitate to ask any questions now or at any time during the study. This consent form may contain words you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

This is a study for Veterans who are experiencing problems with PTSD and relationships with others. We are examining the effects of two different interventions in decreasing PTSD severity and improving relationships and quality of life. Being in this study means taking part in research interviews and study sessions over a total of about 9 months. Details about this are listed below. About 88 Veterans will take part in this study.

The Southeast Louisiana Healthcare System in New Orleans, LA will also be performing the same study with a goal of recruiting 88 participants, so 176 participants in total between the two sites. Only de-identified data will be shared between the Providence VA and New Orleans VA.

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

Initial Screening Assessment

- All assessments will take place in Building 32 at the Providence VA Medical Center and all study sessions will take place on the Providence VA Medical Center campus.
- The screening assessment takes about 2 hours and is done by a trained interviewer.
- The interviewer will ask you questions about your stressful life experiences and PTSD symptoms including problems with relationships with others, other types of symptoms such as depression and anxiety level, and current problems with alcohol or drug use.
- The interviewer will also ask you about current mental health treatments you may be receiving, and about any recent changes in medications.
- If you are eligible for the study based on these questions, you will go on to the next step in the study. If you are not eligible, you will be finished with the study.
- If you are eligible for the study, we will ask you to complete additional measures that ask more questions about your experiences with PTSD, how you are functioning in everyday life, your quality of life, and previous mental health treatments that you may have received. These measures take about 2 hours to complete.

Study Conditions (if eligible)

If you are eligible to stay in the study, you will be randomly assigned (like the flip of a coin) to Interpersonal Psychotherapy or Prolonged Exposure treatment. You will continue to get any usual treatment services with the exception of the following: We will ask you to refrain from participating in non-study individual therapy while enrolled in the study therapy with the exception of occasional check-ins with a previous therapist if this is desired. We will also ask you to refrain from group therapy that focuses specifically on trauma processing or relationship problems.

If you are assigned to the Interpersonal Psychotherapy (IPT-PTSD), you will meet with a therapist for 45-50 minutes weekly for 12 sessions. Your sessions will focus on addressing PTSD symptoms and relationship problems and how these can be improved.

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If you are assigned to Prolonged Exposure (PE), you will meet with a therapist for 90 minutes weekly for up to 12 sessions. Your sessions will focus on re-experiencing the traumatic event in a safe and supportive environment to be able to re-engage in activities that may have been avoided due to the trauma. Your PE therapy sessions will also be recorded for you to review at home between sessions. You may use your own recording device (ex. cell phone) or you can elect to use a VA cassette recorder and audiotape during the treatment phase. If you use a VA cassette recorder, you will assume responsibility for the recorder and any information on the audiotapes, and agree to return the cassette recorder to study staff after treatment is completed.

If you are taking any medications, you will continue to meet with your doctor as you normally do throughout the study.

Additional Assessments
• You will be asked to complete a short assessment that has questions like those asked at the initial interview at weeks 4 and 8. These assessments should take 30 to 40 minutes.
• At the end of treatment and again at 3 months and 6 months following the end of treatment, you will be asked to complete additional assessments that have questions like those asked at the initial screening assessment. These assessments last about 2.5 hours.

Study assessments and therapy sessions will be recorded. These recordings will be reviewed only by study research staff and by a psychologist at the Department of Psychiatry at the San Diego VA to see how well those conducting the sessions and the interviews are doing. Recordings will be kept confidential, and only our research team and the psychologist at the San Diego VA will be able to hear them. By signing this consent you agree to these recordings.

During all assessments, including the screening session, you may refuse to answer any questions that you do not feel comfortable answering. You may stop participation at any time. You will not have to tell the study staff your reasons for ending your participation.

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

Some of the questions about your stressful life events and PTSD and other symptoms may cause you to feel uncomfortable.

4. Expected risks of study:

It may be hard for you to talk about yourself and your personal life. Some of the questions in the interviews may make you upset because talking about stressful life experiences can be hard. Some of the therapy sessions may bring up upsetting feelings. You may become aware of problems in your life during participation. If you do feel upset, you can do any of these things:

- You may choose to not answer a question.
- You may take a break and start again later.
- You may choose to stop the interview or take a break from the session.

We will make every effort to minimize discomfort you may feel during the process.

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Another possible risk is loss of privacy. We will minimize this risk by keeping all your information strictly confidential and available to only our research staff. All the forms you fill out, questions you answer, and recordings will be kept secure and identified only by a number. Your VA medical records will note the enrollment in this research study with a copy of the consent form attached. In addition, your attendance at each IPT or PE session will be noted in your medical records. This will include, if applicable, any safety issues (e.g., suicidal or homicidal statements made) and how these were addressed in session. None of the other data from this study will be included in your medical records, except for attendance at each therapy session.

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. Shea will talk to you about your choices (e.g. different types of treatment available, etc.).

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

If you choose electronic funds transfer (EFT) as a method of compensation, there is a risk that your bank account information or social security number could be stolen and misused.

5. Expected benefits of study:

Participation in this study may or may not help you with your PTSD or relationships with others. We hope that you do experience improvement, but we cannot know for sure if this will happen. The anticipated benefits of the study include advancement of knowledge about the effectiveness of IPT-PTSD and PE for different types of outcomes for Veterans with PTSD. By participating in the study, participants may benefit from the intervention that they will receive. Given the level of risk(s) to the participants and the likelihood that some will benefit from the treatment (or from the additional assessment contacts) and the even greater possibility of benefits to the larger population of individuals with PTSD, the risk/benefits ratio seems favorable. More research is necessary in developing treatments for PTSD that address the different types of symptoms and problems that are common among this population. Research comparing different treatment approaches is important to improve understanding about possible differences in benefits of different treatments. It is hoped that information gained from this study will improve treatment for Veterans, even if the Veterans themselves do not experience any improvement during their participation in the study.

6. Other treatment(s) available:

This program is not intended to replace any of your regular care. Your decision about whether to participate in the study will not affect your treatment relationship with the Providence VAMC. If you do not participate in the study, you will continue to get your usual treatment services at the Providence VAMC. Such treatments include individual and group therapy, and medication. 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: You will not be required to pay for the intervention 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.

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Compensation Offered for Participation: You will be compensated for your time spent completing clinical interviews and assessments in the form of either gift cards or electronic fund transfer (EFT) into your banking account based on your preference. 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. For the time spent completing the screening interview, you will receive $50 for the full screening interview. You will receive $35 even if you are found to be not eligible for the study or if you complete only the first part of the screening interview. You will also receive $50 after completing an end of treatment interview, and after completing 3 and 6-month follow-up interviews. You will receive $25 after completing each of the 4-week and the 8-week interviews. Thus, the total maximum compensation for participating in this study is $250.

8. Use of research results:

Information collected from this study will be kept confidential as required by law. The results of this study will be analyzed and published, but your records or identity will not be revealed unless required by law. 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 computed files that only the research team for this study can access. De-identified data will be shared electronically, and only with our research collaborators.

All answers you give will be kept private. The confidentiality of this information that 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 Veterans 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:

It is possible that your treatment provider may urge you to discontinue treatment for clinical reasons (e.g., danger to yourself, danger to others), or if you develop problems that would make it impossible for you to complete the program. It is likely that this will not happen very often since every effort will be made to keep all participants in the study from beginning to end. Even if you do not complete all the therapy sessions you will be invited to participate in 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 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.

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RESEARCH PARTICIPANT'S RIGHTS: I have read or have had read to me all of the above. Dr. Shea or _____ 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 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. Shea at (401) 273-7100 ext. 6248 who will arrange for any medical treatment that is necessary. After hours, I will call the Providence VA Medical Center at (401) 273-7100 and ask for the psychiatrist on call.

In case there are medical problems or questions, I have been told I can call Dr. Shea at (401) 273-7100 ext. 6248 during the day and Providence VA Medical Center at (401) 273-7100 ext. 0, and ask for the psychiatrist on call after hours. If any medical problems occur in connection with this study the VA will provide emergency care.

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, Research Administration at (401) 273-7100 ext. 3066 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: June 15, 2015, July 21, 2015, August 4, 2015, May 17, 2016, April 28, 2017, August 24, 2017

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