Subject's Name: **Date:**

Principal Investigator: Ron Acierno, Ph.D.

Study Title: Improving Function Through Primary Care Treatment of PTSD (IMPACT)

Improving Function Through Primary Care Treatment of PTSD
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Document Date: 05/08/2020

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A. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. The purpose of this study is to evaluate a new PTSD therapy in Primary Care Mental Health Integration (PCMHI) at the Veterans Affairs Medical Center (VAMC). The therapy is a 4 to 6 session Prolonged Exposure for Primary Care (PE-PC) treatment protocol. You are being asked to participate in this study because you indicated an interest in response to our flyers or you were given information about our study by your primary care and/or mental health clinician at the VAMC. The investigator in charge of this study is Dr. Ron Acierno of the Ralph H. Johnson VA Medical Center. This study is being conducted at the Charleston VA Medical Center and surrounding community-based outpatient clinics (CBOCs). It will involve approximately 267 Veterans of all combat eras. This research is funded by the Department of Veterans Affairs.

B. PROCEDURES:

If you agree to be in this study, the following will happen:

1. Your medical or health records may be reviewed, and researchers may need to discuss your health information with your treating physicians, if applicable.
2. You will meet with study staff for a review of the study procedures. You will be asked to complete some questionnaires about your PTSD symptoms in order to determine if you are eligible for the study. Also, researchers will check your medical records to gather information about your medication and other diagnoses. Once eligibility is determined, the baseline assessment (week 0) will be completed. This assessment is made up of questions about your PTSD symptoms, anxiety, depression, and mood. Also, you will be asked to complete self-report questionnaires regarding your mood, anxiety, PTSD symptoms, overall functioning, and prior combat exposure experiences.
3. If you have recently started taking any prescription medication, you will be asked to wait 2 weeks until you start the treatment so that the effects of this medication on you are stable and don't affect our results. If you complete the baseline assessment prior to disclosing that you recently started taking any new prescription medications, or if for any reason there is a

4 week lapse in time between the baseline assessment and first session of treatment, some parts of the assessment may need to be redone before you start therapy. You will also be asked not to change the dose or frequency of any medications you may have been prescribed for your posttraumatic stress symptoms as much as possible so that we can test the effect of the interventions rather than the effect any change in medication. However, if you and your prescriber feel that a change in your medications is needed please let a member of the research team know so that we can record the change in your research file.

4. If you are eligible, you will be randomly assigned to one of two treatments. Randomization means you have a 50/50 chance, like a coin toss, of being in either treatment. Treatment Group A will receive a 4 to 6-session Prolonged Exposure for Primary Care (PE-PC) treatment protocol. Group B will receive treatment as usual (TAU).

   A. If you are in Group A, you will receive Prolonged Exposure for Primary Care (PE-PC) therapy for PTSD, which teaches you to gradually approach trauma-related memories, feelings, and situations that you have been avoiding since your trauma. By confronting these challenges, you may decrease your PTSD symptoms. After your baseline assessment, you will meet with a therapist weekly for the counseling sessions for four to six weeks. This treatment will be in 'individual therapy' format (not group), by a well-trained clinician working under the supervision of project investigators who are clinical psychologists and medical doctors. The therapy will cover PE components including: (a) imaginal exposure (exercises where you will confront feared thoughts and memories by repeatedly describing the traumatic event you experienced), (b) in vivo exposure (confronting situations or objects being avoided due to distress and anxiety), (c) psychoeducation (education offered to you about PTSD and better coping skills), and (d) processing (discussion between you and your therapist about the emotions raised by the imaginal and in vivo exposures). Therapy sessions will last about 30 minutes, and you will receive homework assignments that will involve doing some activities between sessions. These activities may include doing exercises to confront the feared thoughts and memories associated with the traumatic event (imaginal exposure) and approaching situations or places that you have been avoiding since the traumatic event (in vivo exposure).

B. If you are in Group B, you will continue to receive mental health care in PCMHI. This may include referral for specialty care, medication management, or general supportive contact.

5. You will be asked to complete additional assessments at weeks 6, 12 and 24. Assessments will be the same for each group and will include measures of PTSD, anxiety, depression, and overall functioning. We will also ask you to complete a questionnaire during treatment and/or during your follow-up assessments to assess the impact of the COVID-19 pandemic on your research participation and daily life.
6. With your permission (see section N), all clinical interviews and therapy sessions will be audiotaped to ensure that interviews and therapy sessions are being delivered in accordance with the PE manual. In accordance with policies outlined by the Veterans Health Administration (VHA), the audio recordings will be maintained per VA regulations.

C. DURATION:
Participation in the study will last about 4 to 6 weeks, followed by 3 assessments over 18 weeks. Therapy sessions will be about 30 minutes and each assessment will take approximately 2 hours of your time. The homework activities to be completed outside of treatment will last from 20 minutes to 45 minutes each day. However, your participation is voluntary, and you may terminate participation in treatment or assessments at any time without penalty.

D. RISKS/DISCOMFORTS:
Because of the nature of the study you may become upset by questions asking about your mood and/or anxiety level. You may also experience some physical or emotional distress during the interview process as well as the therapy sessions in that you will be asked to think about and discuss things concerning the trauma you experienced. If you do feel significant distress at any time, you may stop the study procedure and you may choose to not answer any questions during the assessment interview that you do not want to answer.

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You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

There are no economic risks.

There are legal risks in that we are required by law to report homicidal intent and suicidal intent.

Your personal identifiers (name) are kept separate from your assessments. All assessments are kept in a locked file cabinet. Thus, it would be very difficult for someone to match personal identifiers with the information you provide during the assessments and during treatment. Every effort will be made to keep your information protected from third parties. Since the therapy sessions are recorded, this could pose a risk to confidentiality; however, all recordings will be kept secure in a locked file cabinet.

E. BENEFITS:
There may be no benefit to you for participation in this study; however, the treatment you receive may prove to be more effective than the other study treatment or than other available treatments at improving your mood and reducing your symptoms of PTSD, although this cannot be guaranteed. The results from the study may also benefit others in the future who are experiencing PTSD.

F. COSTS:
You will not be charged for any assessments (weeks 0, 6, 12 and 24) that are part of this study. If you usually pay copayments for VA care and medications, you may still pay these copayments. The reason you may have copayments is because the treatment you receive through this study is not experimental; thus, it is considered standard care.

G. COMPENSATION:
You will be compensated $50 for the baseline assessment (week 0). If eligible, participants will receive $50 for completing the 6-week assessment, $50 for the 12-week assessment, and $50

for the 24-week assessment for a combined total of $200. The VA will either directly deposit your compensation into your bank account, or if you do not have a bank account you may be able to pick it up from the agent cashier inside the Ralph H. Johnson VAMC. It can take up to 60 days to receive compensation.

H. ALTERNATIVES:

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is individual or group therapy in the form of supportive counseling, or treatment by antidepressant. You may receive this care at the Ralph H. Johnson VAMC or surrounding CBOCs. You also may wish not to seek treatment. In addition, should you like written descriptions of outcome studies of similar, or related treatments, we can provide these you.

I. DISCLOSURE OF RESULTS:

Results of this research will be used for the purpose described in the study. The information may be published, and if so, your information will not be identified and shall be protected within State and Federal laws. We suspect that the information obtained in the study will take about 1 year to analyze. Once this has been done, the reports will be written, and we will make these reports available to individuals who participate in this study upon request, as well as the Veterans Health Administration.

J. NEW INFORMATION:

If there are significant new findings during the course of the study, you will be notified.

K. VOLUNTARY PARTICIPATION/WITHDRAWAL:

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in the study at any time. You should call the investigator, Dr. Ronald Acierno at 843.789.6519, if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

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The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest, if you do not follow the investigator's instructions, or if you fail to keep study visits. This may also occur if there is a protocol violation or early closure of the study.

L. EMPLOYEE PARTICIPATION:

Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this institution.

M. INVITATION TO PARTICIPATE IN FUTURE STUDIES:

From time to time we have other research studies that you may be eligible to participate in. We are inviting you to allow us to contact you by phone, email or mail to see if you would be interested in participating in any future studies. By selecting the "yes" box below, you are indicating that you would like us to contact you by phone, email, or mail if another study becomes available that you might qualify for. To maintain your confidentiality, we will not leave identifiable messages or any identifiable information on letters or envelopes that are mailed to you. By selecting the "no" box below, you are indicating that you do not want study personnel to contact you for any future studies. You may still participate in the current study if you select "no" and you will not suffer any adverse consequences in doing so.

- ☐ Yes, I would like to be re-contacted for future studies. I give permission for study personnel to contact me by phone, email or mail to inform me of other available studies I may be eligible for.
  Please initial here: _____
- ☐ No, I do not wish to be re-contacted for any future studies.
  Please initial here: _____

N. PERMISSION TO AUDIOTAPE INTERVIEWS AND TREATMENT SESSIONS:

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We would like to audiotape the assessments and therapy sessions to ensure adherence to the protocol. This is not required for participation, but it is useful to the study.

- ☐ Yes, I permit audiotaping of my interviews and therapy sessions.
  Please initial here: _____
- ☐ No, I do not permit audiotaping of my interviews and therapy sessions.
  Please initial here. _____

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CONSENT

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by this VA Medical Center. Financial compensation is not available for such things a lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

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VOLUNTEERS STATEMENT

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact Dr. Ronald Acierno (843.789.6519). I may contact the VA Medical Center's Medical Director (843.789.7200) concerning medical treatment.

If I have questions, comments, concerns or wish to voice a complaint, I may contact the VA Research Compliance Officer at (843.789.7399).

If I have any questions about my rights as a research subject in this study I may contact the Medical University of SC Institutional Review Board for Human Research at (843.792.4148).

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Person Obtaining Consent	Date	Signature of Participant	Date