RESEARCH CONSENT FORM

Providence VA Medical Center

IRB # 00001402

Subject Name: **Date:**

Title of Study: Treatment of Trauma-Related Anger in OEF/OIF/OND Veterans

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 were exposed to potentially traumatic events while deployed in Iraq or Afghanistan, and are experiencing problems with anger. We are examining the effect of two different interventions in decreasing anger problems, and improving social and occupational functioning 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 120 Veterans will take part in this study.

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

Initial Screening Assessment

- All assessments and study sessions will take place in Building 32 at the Providence VA Medical Center.
- 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 anger, 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 anger, 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.
- You will receive a gift card or electronic transfer into your banking account in the amount of $40 for partial completion of the initial assessment (i.e., if you found ineligible for the study) or $100 for your time following completion of the full assessment.

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 the Cognitive Behavioral Intervention or the Supportive Intervention. Regardless of which intervention you are assigned to, you will meet with a trained therapist for about 60 minutes each week for 12 weeks. 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 during the 12 weeks of 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 participating in group therapy that focuses on anger management during the 12 weeks of study therapy.

If you are assigned to the Cognitive Behavioral Intervention, your sessions will focus on learning how your thoughts and beliefs may affect your anger, and different ways of managing and coping with anger.

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If you are assigned to the Supportive Intervention, your sessions will focus on current issues and problems that you want to talk about, and how to use problem-solving strategies to help manage your behavior and feelings.

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

Additional Assessments

- 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 ½ hours.
- You will receive $60 in gift cards or electronic transfer into your banking account for each for the end of treatment and 3 and 6 month follow-up assessments.
- You will also be asked to complete assessments about your anger symptoms at weeks four and 8. These assessments take about 45 minutes.
- Your will receive $25 in gift cards or electronic transfer into your banking account for each of the 4 and 8 week assessments.

Recording of research interviews and study sessions

- We will audio record your sessions and research interviews to see how the research staff administering the sessions and interviews are doing. You will always know if you are being recorded. Recording is required for participation in this study.
- Digital recorders will be used to record interviews and study sessions. These recordings will be reviewed only by research staff to see how well those conducting the sessions and the interviews are doing.

Audio recordings of research assessment interviews provide valuable training opportunities for research staff. For this reason, we request your permission to also use recordings of your assessment interviews from the current study to train research staff in other studies conducted by the Principal Investigator. Although recording of research assessments and sessions is required for participation in the current study, allowing your recordings to be used for training purposes in Dr. Shea's other studies is optional, and is not required for participation in the current study.

Please indicate if you give permission for your audio recordings of this current study to be used for training purposes in Dr. Shea's other research studies by checking one of the boxes below:

☐ I give my permission to the Principal Investigator of this study, Dr. Tracie Shea, to use recordings of my assessment interviews for this current study for training purposes on her other research studies.

☐ I do not give my permission to the Principal Investigator of this study, Dr. Tracie Shea, to use recordings of my assessments interviews for this current study for training purposes on her other research studies.

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

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

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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. It may also be upsetting to talk about your experiences with anger. 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.
You may talk with your counselor, another staff member, or a friend or family member about your feelings.
There is a risk that your bank account information or social security number can be stolen and misused.

5. Expected benefits of study:

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Participation in this study may or may not help you with your anger or improve your quality of life. We hope that you do experience improvement, but we cannot know for sure if this will happen. Being in the study and sharing information with us will help us learn more about an intervention that might help improve problems with anger in Veterans. Your participation in this study will contribute to knowledge about ways to help Veterans recover from their anger problems and improve their quality of life.

6. Other treatment(s) available:

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.

7. Costs to participants and compensation:

Costs to Participants: Veterans receiving medical care and services from the VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services. 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. Veterans will be responsible for the additional incurred costs of transportation or time away work while participating in this study. Certain veterans are required to pay co-payments for medical care and services provided by the VA.

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 $100 for the full screening interview . You will receive a $40 gift card 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 $60 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-

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week and the 8-week interviews. Thus, the total maximum compensation for participating in this study is $330 in the form of gift cards or EFT.

8. Use of research results:

Information collected from this study will be analyzed and published. These results will be based on outcomes for the entire group of participants and will not identify you as an individual. The data collected in this study includes information about your experiences with anger and other psychiatric symptoms, your functioning and quality of life, and treatment you have received. The data collected in this study will be used for the purposes described in this consent form.

By signing this consent form you are allowing the research team to access your medical records. We will look in your medical records for information about your age and marital status, about diagnoses you have received, about treatment you have received, and about your current treatment.

If you decide to withdraw from this study, you may revoke your approval for us to get any additional medical information about you. To do this, you only need to tell Dr. Shea or any of the research staff. Data that have already been collected will remain with the research records.

Confidentiality

Every effort will be taken to protect the confidentiality of the participants in this study. All information about you that is gathered during this study will be kept strictly confidential, unless voluntary disclosure is appropriate concerning issues of safety for yourself or others. Documents that contain your name, such as the consent form signed by you, will be securely stored separately from your research data. All research data will be coded in a way that does not identify you by name or initials, and will be kept in a secure place at the Providence VAMC. Only selected study personnel will have access to this information. Your name will not be used in any published report that comes from this study.

Your VA medical record will note your enrollment in a research study with a copy of this consent form included. In addition, your attendance at each therapy session will be noted in your medical record. This will include, if applicable, any safety issues (e.g. suicidal or homicidal statements you made) and how these were addressed in treatment. None of the other data from this study will be included in your medical records, except for attendance at treatment sessions.

Digital recordings of your interviews and sessions will be kept in a locked area at the VAMC. Digital recording files will be password protected and kept on a computer accessed only by the research team.

There may be other times when we will not keep your information private. If we think that you or someone else is in danger, we will tell someone who can help. If we think that a child or adult who cannot care for themselves is being exploited, abused, or neglected, we will tell the proper legal authorities in accordance with VA reporting requirements.

9. Right of investigator to terminate participation:

It is possible that your treatment provider will urge you to discontinue treatment for clinical reasons (for example, if you became a danger to yourself or others and required extended inpatient hospitalization). This will not happen very often since every effort will be made to keep all participants in the study from beginning to end. Possible reasons for termination include the development of symptoms that may require alternative treatment for example suicidal or

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homicidal intent or the onset of symptoms of psychosis, mania or severe alcohol or drug abuse. In the event that this happens, the principle investigator will meet with you to discuss the reasons for your termination and provide a referral for the appropriate treatment.

10. Special circumstances:

Compensation or Treatment for Injury
The VA medical facility shall provide necessary medical treatment to you as a research subject in the unlikely event that you are injured as a result of participation in this study. If you are hurt, sick, or experience psychological distress because of this research study, you can receive medical care free of charge at the VAMC. If you pay out of pocket for medical care elsewhere for injuries directly caused by participation in this study, contact the principal investigator, Dr. Shea, at 401 273-7100 ext. 6248 during normal business hours.

Significant New Findings
We will do our best to tell you about any important new findings during this research study. You can then decide if you still want to be in this study.

Participant Withdrawal
You may choose to stop being in this study at any time. This will not affect your care at the VAMC. If you decide to stop being in the study, you need to tell someone on the research team. This decision will not take away any benefits to which you are entitled.

RESEARCH PARTICIPANT'S RIGHTS: I have read or have had read to me all of the above.
Dr. _____ 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. Tracie Shea at (401) 273 – 7100 ext 6248 who will arrange for any medical treatment that is necessary. After hours, I will call (401) 273 – 7100 and ask for the Emergency Department Physician or Mental Health Professional on call.

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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 401 273-7100 after hours (and ask for the Emergency Department Physician or Mental Health Professional on call). 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, 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.

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

Participation of Significant Other

I voluntarily provide my permission to contact the person named below in order for them to provide an additional perspective on changes they observe in me following treatment. I understand that this is optional, and not a requirement for participation in the study.

_____	_____	_____
Significant Other Name	Phone Number	Relationship
_____	_____	_____
Participant's Signature	Participant (printed)	Date
_____	_____	_____
Signature of Person Obtaining Consent	(Printed)	Date

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