VA RESEARCH CONSENT FORM

Subject Name:_____
First Name MI Last Name

Title of Study: Mindfulness Treatment for Anger in Veterans with PTSD

Principal Investigator: Lorig Kachadourian, Ph.D. VA Connecticut Healthcare System/689

(v.06/7/16)

SECTION I: THE PURPOSE OF THE STUDY AND HOW LONG IT WILL LAST.

You are invited to participate in a research study designed to examine whether Mindfulness Based Stress Reduction (MBSR) helps decrease anger and aggression in Veterans with PTSD. You have been invited because you meet the initial requirements to be eligible to participate in this study. Your participation will last for approximately 5 months.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study which a member of the research team will discuss with you. This discussion will go over all aspects of this research; its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate, if so, you will be asked to sign this form.

SECTION II: DESCRIPTION OF THE STUDY INCLUDING PROCEDURES TO BE USED.

This study will evaluate the effects of MBSR compared to another treatment, the Trauma Recovery Education Course (TREC) on anger and aggression. Your participation will involve 3 in-person sessions at the West Haven VA: a baseline session, a post-treatment session, and a follow-up session (to be held approximately 3 months after the post-treatment session). You also will attend one of two group treatments.

1. Baseline Session: If you decide to participate in this research study, you will be asked to take part in a baseline session lasting approximately 3 hours. At this session, you will take part in a screening assessment to assess the extent to which you were exposed to traumatic life events, and any emotional difficulties you may be experiencing as a result. You also will be asked about any difficulties with anger and aggression you may be experiencing, as well as symptoms of disorders like depression and substance use. This screening will consist of an interview and questionnaires. Once you have completed the initial screening and are found eligible, we will ask you to fill out additional questionnaires. We also will ask you to write about an upsetting traumatic event you experienced. After, an audio recording of the event will be made by the research assistant for play back during the post-treatment session.

2. Group Treatment: At the end of the baseline session, you will be assigned to either the MBSR group or the TREC group. The group you are assigned to will be determined by chance (like a flip of a coin or rolling dice) and you have a 50% chance of being assigned to either group. Each group will consist of 8-weekly sessions lasting 2 hours.

    - The MBSR group will focus on the teaching and practice of mindfulness meditation. During MBSR, you will be taught different mindfulness meditation practices that involve focusing your attention on different areas of the body, your breathing, and different body

sensations during gentle stretching. You also will be taught how to practice mindfulness while engaging in ordinary activities including walking, standing, and eating.

- The TREC group will provide psychoeducation to veterans on PTSD, including common reactions to trauma and the role of avoidance, common problems associated with PTSD, as well as common barriers to care.

- Both the MBSR group and the TREC group will be conducted by trained therapists and will be held in the Mental Health Clinic at the WHVA.

- You will be asked to attend group sessions each week while you are enrolled in this study. If you miss a group session, the group therapist will call you to encourage you to return to the group sessions. If you develop a pattern of missing several group sessions in a row, the therapist will discuss with you how you can problem-solve to attend group more regularly. If you continue to miss group sessions, your participation in the study will end.

- All group sessions for both MBSR and TREC will be audiotaped to evaluate whether therapists are providing treatment correctly. Session recordings will be conducted using a VA-approved audio recorder. Only trained research personnel will have access to these group session audio recordings. Members of the research team at the VA Connecticut Healthcare System will listen to these recordings to ensure that therapists are providing their respective treatment correctly. These recordings are for the research study only. If you do not consent to session recording, you will not be eligible to participate in this study. If you withdraw your consent for session recording during the study, you will not be eligible to continue participating in the group sessions.

- You will be asked to complete questionnaires similar to those completed at the baseline session approximately 3 and 6 weeks after the start of treatment, regardless of which group you are assigned to.

3. Post-Treatment Session. At the conclusion of treatment you will be asked to attend a post-treatment session lasting approximately 2 hours. At this session you will complete similar questionnaires as those completed at the baseline session. We will also ask you to provide a urine sample to test for traceable amounts of psychoactive substances in your urine. These include THC (marijuana), benzodiazepine, amphetamine, opiates, and cocaine. Should we find detectable levels of any of these substances (i.e., should you have a positive toxicological screen), we will ask you to reschedule your appointment for a later date, as these substances could affect your performance on some of the tasks implemented at this session.

   - During this session you will be asked to listen to the audio recording of the traumatic event you described at the baseline session. During this part of the post-treatment session we may also place a few recording electrodes on your hand and forearm to record your body's natural responses (skin conductance response and heart rate) during the task. These electrodes will simply rest on your skin and you will not feel anything from them. The purpose of this task is to examine whether the skills you learned will be helpful when exposed to reminders of the event you experienced.

- After completing the audio recording task, you will then be asked to participate in a task designed to assess whether the skills you learned will help you with your motor performance. The task consists of competing against another research participant, whom you will not meet, in a reaction-time competition. This person will be recruited from a separate study conducted at the West Haven VA and will not be someone that you have interacted with during the treatment group you attended. You will compete in several trials to see who has the faster reaction time. In addition, before each trial, you and the other participant will set a shock for the other person to receive if he or she loses the trial. In other words, the loser on each trial will receive a short shock on two fingers. The shock can range from mild to strong.

  You will compete against this research participant (i.e., your "opponent" on the task). Both of you will be seated in separate laboratories here at the VA. You will interact with each other via computer to compete in a series of reaction time trials. Before the task, two electrodes will be placed on two of your fingertips on your non-dominant hand. Before starting the task, both you and the other participant will complete a threshold procedure to determine what is the lowest level of shock you can detect and at what level the shock becomes uncomfortable and you do not want it to increase anymore. The shocks will be very short (approximately 2 ms) and will start at a very low level, so low that you will probably not feel the first few shocks. We will ask you to indicate the point at which you first feel the shock. Then the shocks will continue to increase in intensity, and we will ask you to indicate when the shock is so unpleasant that you do not want it to increase anymore. At this point we will stop the threshold procedure. During the task, you and your opponent will compete in a series of reaction time trials. This will involve responding to instructions on the computer screen to press and hold down the spacebar, and then to release it as quickly as possible when prompted by the computer. The person who has the faster reaction time will win that trial, and the person with the slower reaction time will lose the trial and receive a shock. The shocks that you and your opponent will receive will be set by each other. In other words, you will determine the level of shock your opponent will receive if they lose the trial and they will determine the level of shock you will receive if you lose the trial. This choice will be made before each of the trials. The shocks can range from mild to strong and will be labeled from 1-10, 0, or 20. The "10" shock will be equal to your and your opponent's respective tolerance thresholds. The "9" shock will be 95% as intense as the "10", the "8" will be 90% as intense, "7" will be 85% as intense, and so on down to the "1" shock. The "0" option will deliver no shock, and the "20" shock will deliver a shock that is twice the intensity of your and your opponent's respective tolerance thresholds. To be clear, this shock will be extremely unpleasant and potentially painful. This level of shock may cause tissue (skin) irritation (i.e., skin sensitivity and warmth, but not burning) that will resolve within a few hours.

4. Follow-Up Session: Three months after the post-treatment session, you will be asked to attend a follow-up session lasting approximately 1 hour. At this session, you will complete the same questionnaires as at the baseline and post-treatment sessions.

SECTION III: DESCRIPTION OF ANY PROCEDURES THAT MAY RESULT IN DISCOMFORT OR INCONVENIENCE.

There may be minimal discomforts from participation in this study associated with screening and evaluation. The history and interview process may be tiring and you will be exposed to the discomfort of being asked personal questions that you may find distressing. If you become overly tired or upset during the interview, it is possible to take a break or complete the evaluation in two visits rather than one. If at any time you wish to stop the interview process you may do so. In addition, you may refuse to answer any questions during the screening process, psychological assessments, or questionnaires without being penalized. You may also experience some anxiety or discomfort when asked to discuss the traumatic events you experienced and listening to an account of the event. You also may experience some anxiety or discomfort related to the competitive task as a result of the electric shocks that are used during the task. As a research participant, you have the right to decline to participate in the study or to stop your participation in the study at any point, with no penalty.

SECTION IV: EXPECTED RISKS OF STUDY:

There are minimal risks associated with writing about the traumatic event you experienced and listening to the account.

There are also minimal risks associated with the electrical shocks used during the competitive task and becoming emotionally upset by the competitive nature of the task. The International Electrotechnical Commission (IEC) has established recommendations for the amount of electrical stimulation that can be used in research (IEC 601-2-10), and the Biopac stimulation system we use was engineered so that the available maximum energy output is considerably less than the maximum set by the IEC. Similar levels of electrical stimulation are being used in other studies at the VA and Yale.

In addition to the referenced risks, there is the possibility that unforeseeable risks occur as a consequence of your participation in this study.

Confidentiality of Information:

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.). The master list linking names to code numbers will be kept separately from the research data. Paper research records will be kept in locked files in locked study offices, and electronic data will be kept on firewalled VA servers. Research records will be maintained according to VA policy. Only approved members of the research team will have access to this information.

Research data and audio-recordings will be uploaded to a secure VA server. All data will then be stored on the VA Connecticut's secure data storage servers and kept for as long as VA regulations require it to be stored.

Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government

Accounting Agency (GAO), or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as VA Connecticut Healthcare System Research Office.

The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for veteran and non-veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

Finally, under certain circumstances you could face negative consequences (legal, personal, or employment) if a positive toxicological result became known by those outside of this research study. To minimize this risk, we will not record or otherwise make any note of the results of your toxicological screen. Your urine sample will be discarded after it is tested (during the session), as will the materials used to test the urine. These materials will not be labeled with any information linking them to your participation (not even a subject number).

We hope that this will prevent any information that could cause you trouble in the future from becoming known to anyone other than the scientists working on this study. While we cannot foresee situations where we would be forced to reveal potentially sensitive information about you, or where people who should not have this information could obtain it, it is possible that presently unforeseen situations may arise where this could happen. Dr. Lorig Kachadourian believes that the risk of this happening to your sample is extremely small.

Minimizing Hazards

If at any time, you wish to stop the interview process you may do so. In addition, you may refuse to answer any questions during the interviews, psychological assessments, or questionnaires and you will be compensated for the time in the study that you completed. If you feel upset when asked about your trauma or listening to the account of your trauma, a psychologist in the Mental Health Clinic will be available to speak with you. In the event that an assessment indicates any acute emotional distress associated with suicidal or homicidal thoughts, a psychiatrist or psychologist will be readily available to evaluate and talk to you. If imminent danger to self or other persists, you may be hospitalized, even if you do not wish to be.

If at any time you wish to stop the competitive task you may do so. In order to minimize the risks associated with the electric shocks, the study will use stimulator equipment that was manufactured to comply with the recommendations of the International Electrotechnical Commission (IEC) on the limits of electrical stimulation to be used in research with human subjects. The stimulator system was designed in such a way as to administer considerably less electrical output than the limit recommended by the IEC.

If you begin to feel upset about the competitive nature of the task and the pressure to avoid the shocks by responding as quickly as you can, you are free to stop the task at any point. In addition, during the competitive task portion of the study, a member of the study team will be monitoring you by video and audio and you will be able to communicate with the study team member by audio if necessary during the entire task. This video and audio will not be recorded.

If the principal investigator decides that you are not appropriate for this study, you could be withdrawn from the study even if you want to continue. This could happen if you do not meet the requirements for the study, if you are not able to do things required by the study (attend assessment session, come to group sessions as scheduled, or consent to recording of group sessions), if it becomes unsafe for you to continue for medical or mental health reasons, or if approval to conduct the study is withdrawn.

SECTION V: EXPECTED BENEFITS OF STUDY.

There is no specific benefit to you for participation in this study. Mental health treatment for anger and aggression is available at VA Connecticut Healthcare System and elsewhere without participation in this project. Your participation in this study may have benefits for future Veterans with anger and aggression. This study is designed to gather preliminary or early information about whether MBSR is feasible, acceptable and potentially useful to Veterans. Without conducting studies like this one, we will not know the answers to these questions.

SECTION VI: ALTERNATIVE THERAPY OR DIAGNOSTIC TEST.

If you decide not to participate in this study, you may participate in similar groups at VA Connecticut Health Care System or you may be referred for similar treatment elsewhere. Participation in this study is voluntary and you are free to withdraw at any time. If you choose to withdraw your consent for session recording, you will stop participating in the MBSR or TREC group sessions. You may be referred to another group at VA Connecticut Health Care System that is not conducting session recording, or you may be referred for similar treatment elsewhere. Whether you choose not to participate or if you withdraw from the study, this will not affect your relationship with the study doctors or with VACHS.

SECTION VII: USE OF RESEARCH RESULTS.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, recognizable photograph, or any other means without your specific consent. Your medical records will be maintained according to VA requirements.

During your study participation, if researchers discover that you are a danger to yourself or someone else, you will be recommended to meet with the principal investigator, a doctor who is covering for him, or emergency room staff for further evaluation. In these cases, a clinician could decide that voluntary (or involuntary) hospitalization is necessary in order to protect your safety or the safety of others.

You will be informed of any important discoveries made during this study, which may affect you, your condition, or your willingness to participate in this study.

SECTION VIII: SPECIAL CIRCUMSTANCES.

If you are accepted into the study you will be paid $100 for participating in the baseline session, $40 for participating in the two assessments conducted during group treatment ($20 for each assessment), $100 for attending the post-treatment session, and $50 for attending the follow-up session to occur approximately 3 months after the post-treatment session. You are free to stop the study at any time, and will be paid for the parts of the study that you participate in. You will not be penalized financially for not participating in the competitive task and you will not be charged for any tests that are part of this research. If you participate in all research evaluations you will receive a possible total of $290.

There will be no charge for care received as part of your participation in this study. However, some Veterans are required to pay a co-payment for medical and other services provided by the VA Connecticut Healthcare System that are not part of the study. These co-pay requirements will continue to apply to medical care and services provided by VA that are not part of this study.

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 information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you are injured as a direct result of your participation in this research study, VA will provide necessary medical treatment at no cost to you. Except in very limited circumstances, this medical treatment will be provided in a VA Medical facility. There are no plans to provide compensation for disability or other losses occurring over the long term or if an injury becomes apparent after your participation in the study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation. If you have any questions about your rights as a subject, you may contact the Chairman of the Human Studies Subcommittee at 203-932-5711, extension 3350. If you have any complaints, concerns or pertinent questions regarding the conduct of this study, or if you have any questions about compensation for injury, you may contact the Human Studies Coordinator in the Research Office at 203-937-3830.

RESEARCH SUBJECTS' RIGHTS

I have read or have had read to me all of the above and I voluntarily consent to participate in this study. The study has been explained to me and my questions have been answered. 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. I will receive a signed copy of this consent form.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems, a research related injury or complaints, concerns, or pertinent questions about the research. I have been told I can call Dr**.** Lorig Kachadourian at 203-932-5711, 5130 during the day and the 24-hour emergency room after hours at 203-932-5711, x4777.

_____ _____

Signature of Subject Date

_____ _____ _____

Signature of Person Obtaining Consent Name of Person Obtaining Consent (Print) Date

_____ _____

Signature of Principal Investigator Date

HSS Approval Stamp