1. Overview of the Research Study:

We are asking you to be in a research study that is being supported by VA Rehabilitation Research & Development service. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to evaluate two interventions for older (age 60 and older) Veterans with PTSD. If you agree, you will be randomly placed into one of two interventions: a psychosocial discussion group or a support group. You will be in the study for 9 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

You might choose to volunteer in the study because of the benefits of joining a discussion group with other Veterans, where you may discuss topics such as anger management, depression, communication, making other positive life changes, and/or receive support from other Veterans. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study because of the potential to experience distress or become uncomfortable being asked questions about your personal experiences. You will find more information about these risks later in this form.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

2. WHAT IS THE PURPOSE OF THIS STUDY?

This research study is evaluating two interventions for older (age 60 and older) Veterans with PTSD. It will be conducted entirely through telehealth appointments (video or phone). The two interventions are a psychosocial discussion group and a support group. The psychosocial discussion group will include talking about topics such as effective communication, anger management, dealing with depression, and making positive life changes. The support group will include discussion of current stressors, coping skills, social support, and general topics of interest to group members. We will conduct several groups of each intervention during this phase of the study, and plan to enroll up to 60 Veterans (up to 10 in each group).

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

In this study, you will be randomly placed into one of the two groups, either the psychosocial discussion group or the support group. You have a 50% chance of being offered each group; it is like a

flip of the coin which intervention you will take part in. Both study interventions consist of 9 group sessions that meet in a telehealth format (either video or phone) for approximately 90 minutes (an hour and a half) once a week. Between one and two months following the final group session, you will be invited to virtually attend one follow-up session. Group sessions will be audio-recorded, and you need to agree to be recorded to participate in this study. For both groups, this study will last about nine months. You will participate in two virtual baseline assessment sessions before attending group sessions. We will also review your VA medical record to document the medications you have been prescribed. For both groups, you will be asked to complete a post-intervention assessment after the last session, and assessments at about one month and six months following the last session. These assessments will be done through the mail. Upon completion of the baseline assessments, and if you are eligible, you will be enrolled in the study.

Baseline Assessments

Part 1: Consent Forms/Surveys

This session will last approximately 30-60 minutes. We will review this consent document as well as the paper and pencil questionnaires. You will have the opportunity to ask questions. After you have signed this consent document, you will be asked to complete the questionnaires. The questionnaires ask about topics such as psychological issues, physical health, and well-being. You do not have to answer any questions you do not feel comfortable answering. You will be asked to mail the completed consent document and the questionnaires to our study staff at the VA.

Part 2: Short Interview

This session will last approximately 30 minutes and will help us assess whether you meet eligibility criteria for the study. You will complete a short interview with a member of study staff about stressful or traumatic events you may or may not have experienced. You do not have to answer any questions that you do not feel comfortable answering. At the end of the session, regardless of whether or not you are eligible to participate further, you will be compensated with $20 that will be sent to you as a check via the VA agent cashier.

Psychosocial Discussion and Support Groups

If you are eligible to participate in the remainder of the study, you will be asked to return for the 9 group sessions (either psychosocial discussion or support group). The study interventions will take place in a telehealth format, either through video or over the phone. All 9 sessions will be approximately 90 minutes long. Each week, you will be asked to complete short questionnaires about your symptoms and experiences with the group and practice assignments. For each of these groups you attend, you will be compensated $10. You will be paid at two time points based on your attendance: after Session 4 (up to $40), and after Session 9 (up to $50). Between one and two months after the final group session, there will be a follow-up telehealth session to check in with

group members, discuss treatment gains and symptoms, and provide referrals and resources as appropriate; you will be compensated $10 for attending this session.

Post-treatment Assessments

You will be asked to complete a post-intervention assessment following the last intervention session. In addition, you will be sent a set of questionnaires at approximately one and six months following the completion of the group. These questionnaires will be very similar to those completed during the baseline assessment. For the post-group and one month follow-up assessments, you will receive $35. Following completion of the six month follow-up assessment, you will be compensated $40. All payments will be in the form of a mailed check.

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

This research involves answering questions about both physical and mental health, which some people feel uncomfortable discussing. In addition, this study asks questions about difficult or traumatic life events, and your symptoms related to these experiences, which may be upsetting. You may also experience some disruption of daily routines due to the scheduling of study treatment sessions and assessments.

Some participants may feel uncomfortable about having the group sessions audio-recorded. The audio recordings will help researchers make sure we are delivering the intervention in the way it was intended, and as feedback to inform future changes to the interventions to make them most effective.

Some people may experience distress or become uncomfortable being asked questions about personal experiences. You do not have to answer any question you do not feel comfortable answering, and you are free to stop your participation at any time. If you feel it would be helpful to talk with a mental health professional after participating in this study, we can arrange a referral. The study treatments may involve risks that are currently unforeseeable.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Participating in this research study is completely voluntary. You do not have to take part in this study, and if you do take part, you may withdraw from the study at any time. If you refuse to take part or

decide to withdraw, you will not suffer any penalty, loss of VA or other benefits that you have a right to receive.

Data already collected for the study prior to withdrawal may be reviewed, but the investigators cannot collect further information, except from public records such as survival data.

7. WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

The only alternative to participating is to choose not to participate. If you do not meet eligibility criteria for the study, if you decide to withdraw from the study, or if you require treatment after completion of the study, we can provide you with a list of treatment providers or make referrals as indicated.

8. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

Dr. Pless Kaiser may terminate any participant who, at her discretion, does not follow the guidelines put forward by the VA Boston code of conduct statement for participants in research studies. Instances in which participation would be terminated include instances of discrimination, disrespect, inappropriate behavior, or where the safety of research staff is in question.

9. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way: Procedures to maintain confidentiality of data and your privacy include: using a code rather than your name and keeping your name separate from your coded data. All information will be password-protected if electronic and only available to research staff. All digital audio recordings also will be coded with an identification number and will not contain any direct identifiers. However, your voice may be identifiable.

All data collected for this study on paper forms will be stored in secure, locked file cabinets in offices that are locked when unoccupied. Study staff at VABHS will have copies of all of your data. Electronic files at VABHS will be kept in a shared drive on a secure server. Only study staff will have access. Additional password protection will be used for any electronic files that include identifying information (e.g., your name, dates of study visits).

Your research records will be kept indefinitely or until the law allows their destruction in accordance with the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed, when allowed, in the following manner:

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved.
- Audio recordings will be transferred from the recorders to the password protected research drive and then deleted from the audio recorder.

Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as **diagnoses, progress notes, medications, labs, radiology findings, demographic information such as name, age, race, e-mail address, audio recordings, and questionnaire or survey responses.**

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Research & Development Committee, Research Compliance Officers, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Dr. Pless Kaiser** and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

To comply with laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to self or others.

10. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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.

11. WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants 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 (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated $20 for the baseline assessment, $10 dollars for each intervention session you attend, $10 for attending the follow-up group session (paid once after 4 weeks and once after 9 weeks), $35 for completing the post-intervention and one month follow-up assessments (each), and $40 for the six month follow-up (final) assessment for your time and effort taking part in this study. You will be compensated up to $230 for full participation in the study. All payments will be sent in the mail as checks.

You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that they may provide compensation to you.

12. WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

14. WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call **Dr. Anica Pless Kaiser at (857) 364-5309** during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. Anica Pless Kaiser at (857) 364-5309** during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Anica Pless Kaiser at (857) 364-5309 and after hours I can call the Medical Center Operator at (617) 323-7700 and ask for the fellow on call for psychiatry.**

I understand that, if at any point during or after this study I have any questions about my rights as a research subject or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

16. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Participant's Signature	**Month Day Year**	**Name (print)**