Participant Name: _____ Date:_____

Title of Study: Multi-site Feasibility of Compassion Meditation for Veterans with PTSD

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Ariel J Lang, PhD, MPH, VA San Diego HCS

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the National Institute for Complementary and Integrative Health. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The aim of this research study is to compare two treatments for PTSD. One is an experimental PTSD treatment called compassion meditation (CM). CM involves learning a meditative practice that focuses on developing compassion for the self and others. The other treatment is called Veteran.Calm (VC). VC involves learning mind-body techniques to calm PTSD symptoms. Your participation will last about 6 months and includes a 10-week class with assessments before and after it.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There may or may not be a direct benefit to you from these procedures, but you may learn a skill that is of interest or notice some improvement in your symptoms. The investigator, however, may learn more about whether these are good treatments to offer for Veterans with PTSD.

For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Your confidentiality will be protected to the extent permitted by law; however, there is always a risk of breach of confidentiality.

For a complete description of risks, refer to the Detailed Information section of this consent.

You may also choose to seek care for your PTSD through the VA or in the community.

For a complete description of alternate treatment/procedures, refer to the Detailed Information section of this consent.

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DO YOU HAVE TO TAKE PART IN THE STUDY?

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.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is {INSERT LOCAL SITE PI (LSI) NAME} oversees study activities in {INSERT SITE NAME}. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: {INSERT LSI NAME AND PHONE NUMBER}

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn whether two different treatment programs, compassion meditation (CM) and Veteran.calm, are a good fit in VA facilities across the country. We also hope to learn more about why these treatments might work and how much impact they have on PTSD symptoms.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years. Your participation will take approximately 2-3 hours each time you complete for an assessment and 90 minutes each time you have a group meeting. You will be expected to come to the hospital or clinic or participate from home, depending on current public health recommendations, 14 times over a 6-8 month period.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you agree to be in the study, the following will happen to you. All procedures are experimental and will be supervised by {INSERT LSI NAME}. All procedures will take place in VA or university facilities or at home and will be documented in your medical record.

1. You will fill out some questionnaires, complete an interview about your symptoms, and complete a thinking test to determine if you are eligible for the study. For this and all other assessments, you are free to skip any questions that you would prefer not to answer. This takes

about an hour and will be conducted by trained study staff. The interview will be recorded for review by a supervisor to make sure that the interview is done correctly. If you are not eligible,

you will be paid $50 and provided with referrals for other types of care. If you are eligible, you will continue to #2.

2. You will fill out additional questionnaires and do additional tasks that typically take 30-60 minutes to complete. Study staff will assist you in completing these. You will be paid $50 when you complete this item.
3. You will have a one-hour personalized goal-setting session to make sure the study is a good fit for you. This meeting will be conducted in person or via telehealth by a VA mental health provider who is employed by the study. If you decide the study is not right for you, you will be provided with referrals for other types of care. If you elect to continue, you will go on to #4.
4. You will be randomly (as if by the toss of a coin) assigned to CM or VC. You will then complete 10 weekly group meetings, each lasting 90 minutes. These meetings are led by a VA mental health provider, who is employed by the study and has received training in the approach(es). Group meetings will be in person or via telehealth and will be video- or audio-recorded for review by a supervisor. During each visit you will also complete questionnaires that take about 5-10 min.
5. You will complete the questionnaires, tasks (45-60 minutes) and interview (45-60 minutes) with study staff again at the end of the group and 12 weeks later. You will be paid $50 each time. You will also receive a bonus of $50 if all three assessments are completed. You may be sent text messages or letters to remind you about completing these assessments. You may opt out of receiving such letters by informing study staff.

With your permission based on scheduling needs, a trained assessor at another VA facility that is participating in the study may remotely conduct some of the interviews or screening thinking test with you, rather than someone at your local VA. In some cases, the group therapist may also be based at another VA facility that is participating in the study. This will provide more flexible group scheduling options. We will let you know whether this is a possibility before your group is finalized.

With your permission, audio-recordings will be made of the interviews and video- or audio-recordings will be made of treatment sessions so that they can be reviewed by supervisors, who will make sure that procedures are the done in the same way at all sites. Recordings of CM group sessions will be shared with Dr. Satya Dev Negi and designated supervisors in his program at Emory University or the VA San Diego, which is overseeing this study, to make sure that the group material is presented correctly. By signing this consent form, you agree to audio- or video- recording of the interviews and treatment sessions. As with all the data you provide, audio- and video- recordings will be kept strictly confidential.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for

future research studies or distributed to another investigator for future research studies without additional informed consent form the subject or the legally authorized representative**.**

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

The following is expected if you take part in this study:

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Complete assessments and practice logs truthfully and follow instructions
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project or begin any new mental health treatments without approval from the investigators. This is to protect you from receiving conflicting information. Taking part in other research studies or care without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

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

Any research study has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur.

1. You may experience discomfort or emotional reactions.
2. The interview questions and/or questionnaires may produce discomfort or anxiety from the discussion of personal or emotional topics. You may choose to skip questions or ask to take a break if you are uncomfortable during assessments. It can also be uncomfortable knowing that another person may listen to the interview later.
3. During treatment, some increased discomfort is common. Learning new skills can be frustrating, and you may be asked to engage in activities that you are avoiding. Typically, if symptoms increase this happens at the beginning of treatment and then the symptoms subside within a few sessions. If you have trouble dealing with any increased symptoms, or if you feel like trying to cope in unhelpful ways (such as drinking alcohol), you should discuss this with your therapist. You should talk to your group leader if any challenges arise during your class.

4. You may experience interruptions or frustration based on the use of technology for data collection and group meetings. Study staff will make themselves available to troubleshoot any problems you experience.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include learning a skill that is of interest to you or reducing your symptoms. The information we get from this study might help others with your conditions.

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

If you choose not to take part in the study, you can seek care through the VA or in the local community. Standard care for PTSD at this facility may include group or individual psychotherapy, medication or their combination. There may be risks associated with standard treatments for your condition. Your health care provider can help you understand these risks.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your confidentiality will be protected to the extent permitted by law; however, there is always a risk of breach of confidentiality. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VA location, or as files behind the secure VA computer firewall. This includes any research records that are created by the assessors and group therapists from this or another participating VA facility. Any presentations or publications from this information will not identify you.

We will include information about your study participation in your medical record. If you are not already a VA patient, a medical record including your name and Social Security number will be entered in the VA Computerized Patient Record System.

We will be collecting your SSN to access your medical record and to issue payments for participation.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections; the General Accounting Office; the VA R&D Committees at participating sites; the VA Central and local Institutional Review Boards at participating sites and Emory University; the National Institute of Complementary and Integrative Health; Westat; and federal compliance officers may look at or copy portions of records that identify you. We also may have to share information about you if you are a danger to yourself or another person or if we reasonably suspect that a child, dependent adult or older person is being abused.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT ARE THE PAYMENTS TO ME IF I TAKE PART IN THIS STUDY?

As described in “What will happen if I take part in this study?”, you will be paid $50 for each assessment you complete and a bonus of $50 if all three assessments are completed. Payments will be made through {INSERT SITE-SPECIFIC PAYMENT MECHANISM}. {INSERT AS NEEDED: Your SSN and banking information will be collected for this purpose.}

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

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you or your insurance unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

In the event of illness or injury that you believe to be related to the study, or have questions about this research, you can call {INSERT LSI NAME AND PHONE NUMBER}. If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact:

{INSERT LOCAL RESEARCH OVERSIGHT CONTACTS}

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable.

If you decide that you no longer wish to participate in this study please call or contact in person {INSERT LSI NAME AND PHONE}. You should come in for a final visit if you decide to stop your participation in this study so that the investigators can ensure your health and well-being.

Data collected prior to your withdrawal may still be used by the investigators, but they cannot collect further information, except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest or if you do not follow the study instructions.

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

If you have any questions, complaints, or concerns about the research or related matters, you may contact the following.

{INSERT LSI NAME AND LOCAL RESEARCH OVERSIGHT CONTACTS}

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may

call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

While you are a participant in this study you will be told if any important new information is found that may affect your wanting to continue.

If the results of this research might influence your medical care after you have completed your participation, the investigators will contact you to let you know these results.

FUTURE USE OF DATA AND RE-CONTACT

Additional Data Repository: With your permission, if you have previously participated in the Post-Deployment Mental Health Data Repository (IRB # 01706), we would also like to add the data we are collecting today to that Repository so that the information can be used for additional and future research studies. The data collected that would be added to the repository includes: questionnaires, clinical interview results, information about your PTSD and your updated contact information. Combining the information you share with other research studies can help us better answer certain research questions. It may also help us understand post-deployment mental health issues from multiple perspectives.

I give permission for the data collected from me during this study to be entered into the Post-Deployment Database within the Post-Deployment Mental Health Data Repository for use in future mental health research studies.

☐ Yes ☐ No Initials: _____ Date: _____

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **07/16/2024**
Per PI Amend 08

LSI Approval Date: **NA**

LSI Verification Date: **NA**

Participant Name: _____ Date:_____

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A note indicating your consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **07/16/2024**
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LSI Approval Date: **NA**

LSI Verification Date: **NA**