Study Title: Feasibility and Acceptability of Mobile Mantram Repetition Program for Veterans with PTSD

Principal Investigator: Ariel J. Lang, PhD, MPH

VA Facility: San Diego

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study about the way that a meditation practice, Mantram Repetition Program (MRP), is taught to Veterans with PTSD. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn the best ways to teach this meditation practice at using technology that can be accessed anywhere.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

You will be asked to complete a complete an interview and brief set of questionnaires to determine whether you are eligible to participate. If you are not eligible, your involvement will end, and you will receive $25. If you are eligible, you will complete some additional questionnaires and will receive $25. Then you will be asked to review a training video and answer some questions about the practice once per week. You will be randomly assigned to complete the trainings on your own or to receive text messages to check on your progress. After 4 weeks of training, you will again complete some questionnaires and receive $50 for completing everything. Your participation in this research will last about one month.

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

You may want to volunteer for this study to help Dr. Lang and her team to develop this new way of teaching meditation. There may or may not be any direct benefit to you from participation. Some Veterans with PTSD have found that MRP reduces PTSD symptoms or improves sleep. You may benefit other Veterans by helping to develop a new tool for treating PTSD.

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

You may not want to take part in the study because of the time and effort involved or because you are not interested in learning meditation in this way. It is possible that you may feel upset or bored by having to answer personal questions or that you may not like the practice or learning method. Participation is voluntary, and the alternative is to not participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Ariel Lang of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: (858) 552-8585 x5359.

Study Title: Feasibility and Acceptability of Mobile Mantram Repetition Program for Veterans with PTSD

Principal Investigator: Ariel J. Lang, PhD, MPH

VA Facility: San Diego

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Ariel J Lang, PhD is asking for your consent to this research. The purpose of the research is to compare different ways of teaching a meditation practice, Mantram Repetition Program (MRP), to Veterans with PTSD. You are being asked to participate because you have been identified as possibly having PTSD. Approximately 40 people will take part in this research at this facility.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take about a month and the whole study will last 1-2 years. You will be expected to attend an initial evaluation (1-2 hours), 4 weekly check-ins (15 minutes) and a final evaluation (30 min – 1 hour). You will be asked to practice using your mantram between sessions for a minimum of a few minutes a day; you may practice more if you would like.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

All study procedures take place by videoconference, online using VA eScreening, or via text. You do not need to come to a VA facility to participate. 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 your questionnaires as instructed, but you can skip any question that makes you uncomfortable and you can stop at any time. Ask questions as you think of them. While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies 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.

Step 1: Eligibility: The first step in the study will be to determine if you are eligible to participate. This will involve answering some interview questions about your mental health and thinking ability (30-60 minutes) and filling out a questionnaire about your individual characteristics. If you are not eligible, your participation will end and you will be paid $25. If you are eligible, you will continue to step 2.

Step 2: Initial evaluation: You will complete a set of questionnaires (15-30 minutes) about your mental health and well-being. You will be paid $25. You will also be randomly assigned (like a coin toss) to learn MRP by yourself or with text-based support.

Step 3: Learning mantram: You will watch one instruction video each week for 4 weeks. Each video lasts approximately 15 minutes. After the video, you will answer questions about your understanding and impressions of the program. After the first week, you will also be asked to track your practice and to answer a short set of

questions about your symptoms (5-15 minutes). If you are in the supported condition, you will receive text messages each day to check on your progress and provide help as needed.

Step 4: Final evaluation: You will complete a short set of questionnaires (5-15 minutes) and be interviewed (15-30 minutes) about your impressions of the program. What you say during the interview will be recorded and transcribed. You should turn off your video and avoid sharing identifying information during the interview. You will be paid $50 for completion.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

All procedures are for research only.

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

Any procedure has possible risks and discomforts. The procedures in this study have all, some, or none of the risks listed; none are serious.

1. Some people become uncomfortable at being asked questions about their mental health. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

2. Mild annoyance is possible if you do not like the intervention or reminder messages.

There is always a chance that any procedure can harm you. 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 reduction of PTSD symptoms or improvement in your sleep. 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 RESEARCH STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as psychotherapy or medication to help manage your PTSD. You may discuss these options with your doctor.

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

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Mx. Gage Chu at (619) 306-9476 or Dr. Lang at (858) 552-8585 x5359.

AFTER HOURS:

Mx. Gage Chu at (619) 306-9476.

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

If you choose to end your participation, please inform study staff. The study team may use data from before you stopped participating but may not collect further information

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigator may end your participation if she feels that it is in your best interest or if you no longer qualify for the study.

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

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Lang.

Your telephone or internet carrier may charge for use of data related to your participation.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will receive $25 for the initial evaluation and $50 for finishing the study. This payment will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

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

If you have any questions, complaints, or concerns about the research or other related matters, you may contact Mx. Gage Chu at (619) 306-9476.

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 the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study related questions or concerns you can contact the research team at (619) 306-9476.

FUTURE USE OF DATA AND RE-CONTACT

You may be re-contacted by telephone in the future about participating in future research. This contact may come from our study team or another VA investigator doing work that might be relevant to you. You are not agreeing to participate in any future studies but only to hear about these opportunities.

☐ **Yes, I may be contacted for future research opportunities as described**. _____ (initial)

☐ **No, I do not wish to be contacted for future research opportunities as described**. _____ (initial)

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. 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.

Your SSN will be collected to issue your payment.

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 protected file behind the VA firewall. Any research records that identify you will be kept only as files behind the secure VASDHS computer firewall.

Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Study Title: Feasibility and Acceptability of Mobile Mantram Repetition Program for Veterans with PTSD

Principal Investigator: Ariel J. Lang, PhD, MPH

VA Facility: San Diego

We will include information about your study participation in your medical record.

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 VASDHS R&D Committee, and the VASDHS Institutional Review Board, and federal compliance officers may look at or copy portions of records that identify you.

While this study is being conducted, you will have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Any presentations or publications from this information will not identify you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

A Research Associate has explained the study to me. 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 given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.

_____ _____

Participant's Signature Date

_____ _____ _____

Signature of Researcher obtaining consent Name (print) Date

A copy of this document will be provided to the research participant.

Study Title: Feasibility and Acceptability of Mobile Mantram Repetition Program for Veterans with PTSD

Principal Investigator: Ariel J. Lang, PhD, MPH

VA Facility: San Diego

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 document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information 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 mental health history and treatment, including drug abuse, alcoholism or alcohol abuse.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. Other VA entities may include the VA Office of Research Oversight (ORO), Institutional Review Board, Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

Your health information disclosed outside the VA as described in 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 may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address: Dr. Ariel Lang, VA San Diego Healthcare System, 3350 La Jolla Village Dr., San Diego, CA 92161.

If you revoke this authorization, Dr. Lang and 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.

While this study is being conducted you will have access to your research-related health records.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study.

AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I

have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records. A copy of this signed document will also be put in my medical record.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.